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Handbook of Research on

Healthcare Standards, Policies, and Reform

Ubaldo Comite

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Handbook of Research on Healthcare Standards, Policies, and Reform

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University "Giustino Fortunato" Benevento, Italy

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A volume in the Advances in Healthcare
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In memory of my father, a distinguished medical doctor.

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Vittorio Lenzo, University for Foreigners "Dante Alighieri" of Reggio Calabria, Italy
Maria C. Quattropani, University of Catania, Italy

In the chapter, the authors will address the delicate role played by caregivers of older adults, discussing the close interaction between caregivers' wellbeing and care recipients' health status. After a brief introduction on the complexity of aging trajectories, the authors will focus on the experiences of assistance to elderly people by formal and informal caregivers, by indicating the main objectives according to the degree and nature of the medical condition. The central topic of the chapter will be the risk of developing a care-related burden by the caregivers, with negative consequences on the caregiver's wellbeing, as well as on the caregiver-patient relationship. In this perspective, the authors will highlight in detail the potential impact on the caregiver burden of peculiar functional and psychological factors exhibited by older care recipients.

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Luca Albino, University of Calabria, Italy

Fundamental rights are born in the form, width, and with the limits that the constitution gives them. Concretely, in single laws and in concrete situations, every right claimed by one person is limited by the other rights and rights of others. In concrete situations, two or more rights cannot be satisfied at the same time; systemic and coherent protection can be given by reasonably balancing interests in the resolution of a specific conflict. As far as health protection is concerned, proportionality assessments are based primarily on the use of the precautionary principle and the determination of the so-called acceptable risk threshold. The aim of the contribution is therefore to illustrate the techniques of balancing interests in the field of health protection with particular focus on the Italian constitutional order.

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Adele Emilia Caterini, University of Camerino, Italy

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In the face of healthcare emergency and the linked problems, the purpose of the work is to identify an economic and organizational tool for the improvement of the person's health condition and, consequently, for the prevention of the spread of future contingent pandemics. Due to the lack of public resources, this system would contemplate private investments balancing social and speculative objectives. It analysed the social impact bond (SIB), the typical form of impact investing that provides for public and private partnership. After examining the structure with its positive and negative aspects, the disintermediation through blockchain technology and smart contracts is prospected. According to the horizontal subsidiarity, stated in the article 118, paragraph 4, Cost., the suggested intervention would represent an operation aimed at realizing the right to health through a negotial tool (the SIB agreement) subject to the control of merit.

Taking into account the current transformation of the healthcare systems in the Western societies, the authors argue that several challenges can be addressed only starting from a relational perspective. In the field of the health practices, psychological vision has been addressed for a long time on single individuals (generally the patients) in order to offer sustain and help to treat their suffering during a disease. In the authors' perspective, being a patient means to take up a positioning within a cultural-normative frame. In this sense, the psychological intervention requires to be directed toward the relational field. The proposal is aimed to present the constitutive elements and tenets of a clinical psychological model of intervention aimed to develop the healthcare relation: the scaffolding for the healthcare relationship. It is based on a clinical, semiotic, and dynamic perspectives of health psychology. By its implementation, the aims of ownership, cum-sensum, sharing decision making, and emotional elaboration are pursued.

In the last decades, attention to corporate social responsibility (CSR) has grown considerably. The new scenario characterized by greater attention to aspects of sustainability poses important challenges for companies operating in the healthcare (HC) industry due to both the high number of stakeholders with which these companies interface and their business model closely related to people's life and health problems. In light of this, companies operating in the HC industry are also called upon to provide an adequate level of non-financial information and in particular environmental, social, and governance (ESG) information to meet the needs of stakeholders. This study aims to examine the financial effects of ESG disclosure in the HC industry. In particular, it analyses the impact on the cost of debt. The results of the econometric analysis, conducted on a sample of 4,271 observations (an unbalanced data panel of 680 international firms for the period 2011-2020), show the existence of a negative association between the amount of ESG information disseminated and the cost of debt.

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Telemedicine services, with the collection and sharing of patient clinical data, have gone from an emergency response during the pandemic to an essential structural investment for the Italian health system. Telemedicine is a part of the main digital transformation process in healthcare and is establishing itself as a key technological tool to increase the efficiency and effectiveness of the system. Indeed, it can make the difference in each phase of healthcare, from prevention to access to care, up to the real patient care, helping to shift the center of gravity of the Italian healthcare system moving from the centralized care in the hospitals to home healthcare. Through a literature review, an overview of the telemedicine in the Italian context is proposed, discussing the factors that facilitate its development, the main barriers to its implementation, and the future prospects of these digital tools that are useful to support the National Healthcare System.

This chapter reviews and discusses findings from studies on healthcare workers facing the COVID-19 outbreak. Previous studies have provided evidence for the role of psychological characteristics in predicting burnout and psychological distress among healthcare workers. Research conducted during the COVID-19 outbreak seems to confirm these relationships. Evidence has also revealed high burnout and psychopathological symptoms among professionals. Several factors were associated with a worse psychological impact of the COVID-19 outbreak, such as assisting infected patients. A growing body of research has pointed out the role of psychological characteristics in mitigating the psychological impact of the COVID-19 outbreak and its related restrictive measures. More research is needed to verify these relationships and to examine the long-term consequences on the healthcare workers heavily involved in the COVID-19 outbreak. Nonetheless, the implication of these studies concerns the implementation of interventions reducing the psychological impact of working during the COVID-19 outbreak.

The recent medical progress ensures high rates of long-term survival even in the face of illness previously with an unfortunate outcome: this is the case of breast cancer, which, to date, ensures more than 80% of long-term survival rates, and that for this reason can be interpreted as a chronic illness. In particular,

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the onset of breast cancer in under-50 women represents a potentially traumatic event that storms in the life of a young woman breaking the narrative sense of continuity, sameness, and integrity. This chapter discusses the role of narrative psychological devices for the understanding and the promotion of sense-making process and psychological adjustment to illness. Within a psychological risk preventive framework, the authors show findings from a longitudinal narrative research on the sense-making processes with breast cancer younger women highlighting narrative indexes of risks and resources during the first year of treatment. Implications for longitudinal support will be discussed.

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Giovanni Tarantino, University of Salento, Italy

The relational dimension of care becomes the foundation of the rights of pupils with SEN when considering the asymmetry that may exist in the relationship between the teacher and the pupil with special educational needs. This asymmetry can, in fact, find the pupil with vulnerability in an inferior position compared to the teacher. This, by analogy, is the same asymmetry that can also be found in the relationship between doctor and patient. From the awareness of this derives the need for an ethical approach to care (of the pupil with SEN, as well as of the patient), which is identified with that moral attitude of the individual who tries to meet the needs of those with a vulnerability. An ethical approach cannot stop, however, in considering only the medical-biological dimension of the subject with vulnerability. It must also address all the dimensions that make up the nature of the human person.

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Federico de Andreis, University "Giustino Fortunato" Benevento, Italy

For the healthcare organization, it becomes more essential implementing organizational measures that change the conduct of operators, through behavior and organizational culture, trying to promote the analysis of adverse events and thus to learn lessons from these events. Good risk management leads to safe care, which is also perceived as service quality. This is where the logic of healthcare marketing comes in, a tool that becomes necessary to communicate the quality and contextual safety of the services offered by healthcare companies. Marketing, which has long been neglected in health systems, plays a key role in this perspective. The user of health services must, in fact, be considered as a corporate client. This analysis aims to investigate how a more marketing-oriented approach in healthcare organizations can be particularly useful in promotion and customer focus strategies.

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Maria Sponziello, Istituto Comprensivo Casarano Polo 2, Italy

The chapter compares the Hippocratic-inspired model of care, based on philanthropia, with the functionalist model, which instead leads to an essentially clinical-therapeutic approach. The reflections are set against the background of the recent school legislation which sanctioned the transition from the school of integration to the school of inclusion, with particular reference to the problems of vulnerable individuals and the solutions proposed in favor of the latter, by the International Classification of Functioning, Disability, and Health. Starting from this, the authors urge the legislator to enhance the dimension of dialogue "with the other" in order to arrive at future legislation leading to the achievement of full protection of the dignity of the human person, considered in all its dimensions.

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The purpose of this study is to describe intensive care nurses' perceptions and experiences of shift working and reveal how to cope with its effects. Data were collected through an individual semi-structured interview guide and transcribed verbatim by using a qualitative descriptive design. Interviews were done with 11 Turkish intensive care unit nurses. As a result of the analyses, four main themes were obtained: 1) the effects of shift working on nurses' lifestyle, 2) the effects of shift-working on nurses' working life, 3) the effects of shift working on nurses' patient care practices, and 4) the strategies used by nurses to cope with the effects of shift-working. The positive and negative consequences of the multifaceted effects of shift-working perceived by nurses should be taken into consideration, and individuals or a group of nurses who have been searching for strategies to cope with and overcome these effects should be supported.

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Emel Aktas, Cranfield University, UK
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This chapter aims to investigate the efficiency of nations in their struggle against the COVID-19 analysing data from June and December 2020 with a novel three-stage methodology. In the first stage, 107 nations were clustered into highly competitive, competitive, and non-competitive countries using their Global Competitiveness Index scores (World Economic Forum) to evaluate comparable countries in the second stage with the Data Envelopment Analysis. In the third stage, the relationship between countries' efficiency and performance in 66 variables published in the United Nations Human Development Report was investigated along with the long-debated aspect of a nation's political governance regime using

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Tobit regression. The worst performing highly competitive nations were USA and UK, competitive nations were Chile and Peru, and non-competitive nations were Brazil and Mozambique. Air pollution, international inbound tourists, urban population significantly reduced while domestic credit and gross national income per capita significantly increased efficiency, but the political regime did not affect it.

The chapter provides the reader with a narrative overview of technological-aided solutions to help individuals with neurodegenerative diseases. Five categories were identified, namely (1) functional and physical activities, (2) communication skills, (3) positive participation, (4) leisure and recreation, and (5) telerehabilitation. Results were fairly satisfactory although few failures occurred. Findings and implications were critically discussed. Some useful insights for future research and practice were highlighted.

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Preface

The scenarios for formulating, implementing, and evaluating public policies are constantly evolving. The reforms of recent years, administrative, organizational, and economic business, are substantially changing the governance structure of the territory and its citizens in favor of new organizational and management forms. Such significant changes are destined to encounter various difficulties and obstacles in the course of their implementation, and this is what is happening above all in the sectors in which the changes concern the system of civil rights, constitutionally guaranteed and protected. Among these sectors, an important role is played by health care which, even more than in other sectors, closely involves the person and the rights linked to human life and its protection. Over the years, the legislator has introduced new organizational models in healthcare with significant changes in the ownership of administrative and political responsibilities. Among the main objectives, alongside the improvement of health services, containment, and reduction of costs, from a spending review perspective. However, the organizational change process could not ignore a precise definition of the care contents that the health system must continue to guarantee. And so, alongside the accountability of governments through greater political involvement of individual territories in the allocation of resources, there is still a strong need to safeguard the principle of equity, which is particularly felt in such a delicate area as healthcare.

Therefore, healthcare has received serious attention and has recently become a major topic of concern for organizations, government institutions, and largely for people interacting with complex systems. As many health, individual and organizational activities continue to grow and are conducted in the general environment, new vulnerabilities have emerged that have led to the need to study the system from different points of view. The nature, source, reasons and complexity of healthcare are not always clearly known or understood, and many times health issues are underestimated. Healthcare has become increasingly important to government, military, corporate, financial, critical infrastructure and medical organizations.

The purpose of this work is to proceed with a “reasoned” reconstruction of health care issues through the problems connected to health standards, policies, and reforms also in light of the recent COVID-19 pandemic emergency.

In Chapter 1, “The Importance of Being Caregivers of Older Adults and the Role of Patients’ Psychological and Functional Health in Contributing to the Care-Related,” Alberto Sardella, Vittorio Lenzo and Maria C. Quattropani will address the delicate role played by caregivers of older adults, discussing the close interaction between caregivers’ wellbeing and care recipients’ health status. Afterward a brief introduction on the complexity of aging trajectories, the Authors will focus on the experiences of assistance to elderly people by formal and informal caregivers, by indicating the main objectives according to the degree and nature of the medical condition. The central topic of the chapter will be the risk of developing a care-related burden by the caregivers, with negative consequences on the caregiver’s

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In Chapter 3, "Worldwide Welfare Society: Healthcare and Social Impact Investments," Adele Emilia Caterini shows how in the face of healthcare emergency and the linked problems, the purpose of the work is to identify an economic and organizational tool for the improvement of the person's health condition and, consequently, for the prevention of the spread of future contingent pandemics. Due to the lack of public resources, this system would contemplate private investments balancing social and speculative objectives. It is analysed the Social Impact Bond (SIB), the typical form of impact investing that provides for public and private partnership. After examining the structure with its positive and negative aspects, it is prospected the disintermediation through blockchain technology and smart contracts. According to the horizontal subsidiarity, stated in the article 118, paragraph 4, Cost., the suggested intervention would represent an operation aimed at realizing the right to health through a negotial tool (the SIB agreement) subject to the control of merit.

In Chapter 4, "The Psychological Model of Scaffolding for the Development of Healthcare Relationship: Addressing a Contemporary Challenge of Healthcare Systems," Maria Francesca Freda, Raffaele De Luca Picione, Maria Luisa Martino, Daniela Lemmo, and Ersilia Auriemma, taking in account the current transformation of the healthcare systems in the Western Societies, argue that several challenges can be addressed only starting from a relational perspective. In the field of the health practices, psychological vision has been addressed for a long time on single individuals (generally the patients) in order to offer sustain and help to treat their suffering during a disease. According to their perspective, being a patient means to take up a positioning within a cultural-normative frame. In this sense, the psychological intervention requires to be directed toward the relational field. Their proposal is aimed to present the constitutive elements and tenets of a clinical psychological model of intervention aimed to develop the healthcare relation: the Scaffolding for the healthcare relationship. It is based on a clinical, semiotic and dynamic perspective of health psychology. By its implementation, the aims of ownership, cum-sensum, sharing decision making, and emotional elaboration are pursued.

In Chapter 5, "The Relationship Between ESG Disclosure and the Cost of Debt in the Healthcare Industry," Antonio Salvi, Felice Petruzzella, Nicola Raimo, and Filippo Vitolla illustrate how in the last decades, attention to corporate social responsibility (CSR) has grown considerably. The new scenario characterized by greater attention to aspects of sustainability poses important challenges for companies operating in the Healthcare (HC) industry due to both the high number of stakeholders with which these companies interface and their business model closely related to people's life and health problems. In light of this, companies operating in the HC industry are also called upon to provide an adequate level of non-financial information and in particular environmental, social and governance (ESG) information

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to meet the needs of stakeholders. Their study aims to examine the financial effects of ESG disclosure in the HC industry. In particular, it analyses the impact on the cost of debt. The results of the econometric analysis, conducted on a sample of 4,271 observations (an unbalanced data panel of 680 international firms for the period 2011-2020), show the existence of a negative association between the amount of ESG information disseminated and the cost of debt.

In Chapter 6, “Telemedicine Services: Opportunities and Developments in Italy,” Alessandra Tafuro and Giuseppe Dammacco argue how telemedicine services, with the collection and sharing of patient clinical data, have gone from an emergency response during the pandemic to an essential structural investment for the Italian health system. Telemedicine is a part of the main digital transformation process in healthcare and is establishing itself as a key technological tool to increase the efficiency and effectiveness of the system. Indeed, it can make the difference in each phase of healthcare: from prevention to access to care, up to the real patient care, helping to shift the center of gravity of the Italian healthcare system moving from the centralized care in the hospitals to home healthcare. Through a literature review, an overview of the telemedicine in the Italian context is proposed, discussing the factors that facilitate its development, the main barriers to its implementation and the future prospects of these digital tools that are useful to support National Healthcare System.

In Chapter 7, “The Psychological Impact of the COVID-19 Outbreaks Among Healthcare Workers and the Crucial Role of Psychological Functioning in Preventing Burnout,” Vittorio Lenzo, Alberto Sardella, and Maria C. Quattropani review and discuss findings from studies on healthcare workers facing the COVID-19 outbreak. Previous studies have provided evidence for the role of psychological characteristics in predicting burnout and psychological distress among healthcare workers. Research conducted during the COVID-19 outbreak seems to confirm these relationships. Evidence has also revealed high burnout and psychopathological symptoms among professionals. Several factors were associated with a worse psychological impact of the COVID-19 outbreak, such as assisting infected patients. A growing body of research has pointed out the role of psychological characteristics in mitigating the psychological impact of the COVID-19 outbreak and its related restrictive measures. More research is needed to verify these relationships and to examine the long-term consequences on the healthcare workers heavily involved in the COVID-19 outbreak. Nonetheless, the implication of these studies concerns the implementation of interventions reducing the psychological impact of working during the COVID-19 outbreak.

In Chapter 8, “The Sense-Making Process in Adjustment to Breast Cancer Experience in Younger Women: A Clinical Healthcare Perspective,” Maria Luisa Martino, Daniela Lemmo, Raffaele De Luca Picione, Ersilia Auriemma, and Maria Francesca Freda deepen the concept according to which the recent medical progress ensures high rates of long-term survival even in the face of illness previously with an unfortunate outcome: this is the case of breast cancer which, to date, ensures more than 80% of long-term survival rates, and that for this reason can be interpreted as a chronic illness. In particular, the onset of breast cancer in under-50 women represents a potentially traumatic event that storms in the life of a young woman breaking the narrative sense of continuity, sameness and integrity. This chapter discuss the role of narrative psychological devices for the understanding and the promotion of sense-making process and psychological adjustment to illness. Within a psychological risk preventive framework, the authors show findings from longitudinal narrative research on the sense-making processes with breast cancer younger women highlighting narrative indexes of risks and resources during the first year of treatment. Implications for longitudinal support will be discussed.

In Chapter 9, “Budget Sustainability and Integrity as Essential but Not Exhaustive Aspects of the Control of the Superior Institutions of Control (ISC) on the Health,” Mauro Orefice explains how the

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health emergency led in 2020 to the definition of numerous measures involving interventions on the health system; measures with a specific financial allocation and aimed at affecting the most problematic aspects of care, which were mainly attributed to the choices made in recent years. This chapter analyses the measures launched to face the crisis. The chapter, moreover, emphasizes how the Italian healthcare system, despite the difficulties encountered, has withstood the impact of the crisis.

In Chapter 10, “The Relational Dimension of Care at the Foundation of the Rights of Pupils With SEN: Between Inclusiveness and Substantive Equality,” Giovanni Tarantino suggests the relational dimension of care becomes the foundation of the rights of pupils with SEN when considering the asymmetry that may exist in the relationship between the teacher and the pupil with special educational needs. This asymmetry can, in fact, find the pupil with vulnerability in an inferior position compared to the teacher. This, by analogy, is the same asymmetry that can also be found in the relationship between doctor and patient. From the awareness of this derives the need for an ethical approach to care (of the pupil with SEN, as well as of the patient), which is identified with that moral attitude of the individual who tries to meet the needs of those with a vulnerability. An ethical approach that cannot stop, however, in considering only the medical-biological dimension of the subject with vulnerability, but which must also address all the dimensions that make up the nature of the human person.

In Chapter 11, “Healthcare Risk Management: A Marketing Approach,” Federico de Andreis shows how for the healthcare organization becomes more essential implementing organizational measures that change the conduct of operators, through behavior and organizational culture, trying to promote the analysis of adverse events and thus to learn lessons from these events. Good risk management leads to safe care, which is also perceived as service quality. This is where the logic of healthcare marketing comes in, a tool that becomes necessary to communicate the quality and contextual safety of the services offered by healthcare companies. Marketing, which has long been neglected in health systems, plays a key role in this perspective. The user of health services must, in fact, be considered as a corporate client. This analysis aims to investigate how a more marketing-oriented approach in healthcare organizations can be particularly useful in promotion and customer focus strategies.

Chapter 12 is “Contemporary Issues on Agriculture and Health: Financial Framework, Reforms, and Competition Policy” by Elena di Paolo, Giustino Lo Conte, Federica Corrente, and Gianclaudio Festa. Rights and restrictions, education and financial resources at both European and national level represent the core points of attention in proposing useful considerations on the effects of the pandemic in the health sector. Looking at health as a single and isolated sector makes it difficult to focus on the specific transversal aspects that are extremely relevant in the context, we live in. Thus, health has to be considered from a multidimensional perspective, which encompasses different aspects ranging from legal to economic and social issues. The chapter develops an analysis that, through a complementary approach, embraces different sectorial dimensions, considering the supranational scenario and the current measures the Italian government has set in place till now. Within this framework, over the years, safe health has been more and more identified as a direct consequence of a safe agricultural environment. Thus, the whole chapter emphasises the important link to be inevitably taken into consideration for the future: the nexus between agriculture and health.

In Chapter 13, “Teledermatology and Telemedicine: Expanding the Reach of Medical Consulting Beyond Physical Barriers,” Pietro Morrone and Luigi Bennardo explain how telemedicine is a new branch of medicine exploiting the new communication devices to expand medical services and consultation beyond physical limits. This new significant chapter in medicine will interest every medical area, taking advantage of digital devices that are becoming more complex, reducing the need for the patient’s

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physical presence only to perform analysis or interventions. Teledermatology is a new expanding area in telemedicine, consisting of the ability to resolve skin-related health problems without the physical presence of the patients. Skin diseases represent a significant source of morbidity and a minor source of mortality worldwide. In this chapter, they will analyze how telemedicine and teledermatology developed, their current use in medicine, and current studies and reviews already present in literature. Also, future possible prospects and developments of these techniques will be analyzed.

In Chapter 14, “Health Protection and Policies in the Pontificate of Francis,” Paolo Palumbo and Antonella Losanno, through a study of the Encyclicals, Apostolic Exhortations, speeches and messages of Pope Francis, as well as some documents of the Roman Curia, highlight how the issue of health protection and policies in support of this human right are central to Francis’ teaching. The protection must not be a mere statement of principle but the concrete realization of the right to health in a broad way, involving not only the physical well-being of the human person but also requires the protection of the environment of which every man is an integral part.

In Chapter 15, “The Condition of Vulnerability in the Educational Context: Ethical Considerations and Legal Perspectives,” Giovanni Tarantino and Maria Sponziello compare the Hippocratic-inspired model of care, based on philanthropia, with the functionalist model, which instead leads to an essentially clinical-therapeutic approach. The reflections are set against the background of the recent school legislation which sanctioned the transition from the school of integration to the school of inclusion, with particular reference to the problems of vulnerable individuals and the solutions proposed in favor of the latter, by the International Classification of Functioning, Disability and Health. Starting from this, the authors urge the legislator to enhance the dimension of dialogue “with the Other”, in order to arrive at future legislation leading to the achievement of full protection of the dignity of the human person, considered in all its dimensions.

In Chapter 16, “How Does 24-Hour Shift-Working Affect Intensive Care Unit Nurses? A Qualitative Descriptive Study,” Eylem Bayrakçı, Mehmet Dinç, Hasan Huseyin Uzunbacak, and Tahsin Akçakanat describe intensive care nurses’ perception and experiences of shift working and reveal how to cope with its effects. Data were collected through an individual semi-structured interview guide and transcribed verbatim by using a qualitative descriptive design. Interviews were done with 11 Turkish intensive care unit nurses. As a result of the analyses, four main themes were obtained: 1) the effects of shift working on nurses’ lifestyle, 2) the effects of shift-working on nurses’ working life, 3) the effects of shift working on nurses’ patient care practices, 4) the strategies used by nurses to cope with the effects of shift-working. The positive and negative consequences of the multifaceted effects of shift-working perceived by nurses should be taken into consideration, and individuals or a group of nurses who have been searching for strategies to cope with and overcome these effects should be supported.

In Chapter 17, “The Efficiency of Nations in the Struggle Against the COVID-19 Pandemic,” Emel Aktas, Füsun Ülengin, Ilker Topcu, and Eda Helin Gundes aim to investigate the efficiency of nations in their struggle against the COVID-19 analysing data from June and December 2020 with a novel three-stage methodology. In the first stage, 107 nations were clustered into highly competitive, competitive, and non-competitive countries using their Global Competitiveness Index scores (World Economic Forum) to evaluate comparable countries in the second stage with the Data Envelopment Analysis. In the third stage, the relationship between countries’ efficiency and performance in 66 variables published in the United Nations Human Development Report was investigated along with the long-debated aspect of a nation’s political governance regime using Tobit regression. The worst performing highly competitive nations: USA and UK, competitive nations: Chile and Peru, of non-competitive nations: Brazil and

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Mozambique. Air pollution, international inbound tourists, urban population significantly reduced while domestic credit and gross national income per capita significantly increased efficiency, but the political regime did not affect it.

In Chapter 18, “Technology-Aided Solutions to Promote Healthcare of Neurodegenerative Diseases: A Narrative Review,” Fabrizio Stasolla and Sara Bottiroli provide the reader with a narrative overview of the nuse of technological-aided solutions to help individuals with neurodegenerative diseases. Five categories were identified, namely (1) Functional and Physical Activities, (2) communication skills, (3) Positive Participation, (4) Leisure and Recreation, and (5) Telerehabilitation. Results were fairly satisfactory although few failures occurred. Findings and implications were critically discussed. Some useful insights for future researdch and practice were highlighted.

Throughout these 18 chapters, the reader of this book is confronted with on Healthcare Standards, Policies, and Reform, the players and the market in healthcare systems, and the global information infrastructure.

It presents the various aspects of both theoretical and empirical approaches in economic, medical and legal of information healthcare, the management of information system, and healthcare business/markets. I’m grateful to all authors for their efforts as the whole process of writing, reviewing, rewriting, editing and proofreading nedd a lot of time.

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Chapter 1

The Importance of Being Caregivers of Older Adults, and the Role of Patients' Psychological and Functional Health in Contributing to Burden

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ABSTRACT

In the chapter, the authors will address the delicate role played by caregivers of older adults, discussing the close interaction between caregivers' wellbeing and care recipients' health status. After a brief introduction on the complexity of aging trajectories, the authors will focus on the experiences of assistance to elderly people by formal and informal caregivers, by indicating the main objectives according to the degree and nature of the medical condition. The central topic of the chapter will be the risk of developing a care-related burden by the caregivers, with negative consequences on the caregiver's wellbeing, as well as on the caregiver-patient relationship. In this perspective, the authors will highlight in detail the potential impact on the caregiver burden of peculiar functional and psychological factors exhibited by older care recipients.

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INTRODUCTION: COMPLEXITY OF AGING TRAJECTORIES

Life expectancy worldwide has increasingly been raised in the last decades, and the percentage of the population aged 65 and over is expected to grow up to 27% by 2050 (WHO, 2012).

As a counterpoint, aging denotes one of the most complex challenge during the lifespan, since it results from the interaction between multiple bio-psycho-social factors (Kim et al., 2021). On the one hand, it appears noticeable that age-related chronic conditions have become dominant sources of health care burden for individuals (Marengoni et al., 2011). In this context, the co-occurrence of multiple chronic conditions (i.e. multimorbidity) denotes a core factor able to shape aging trajectories; in fact, it has been broadly acknowledged as an emerging public health concern (Pefoyo et al., 2015). Besides increased healthcare costs, multimorbidity is associated with several clinical consequences, such as functional decline, worsening of cognitive disturbances and reduced quality of life, which progressively expose older adults to higher risk for negative age-related outcomes, as disability, hospitalization and mortality (Makovski et al., 2019).

On the other hand, a peculiar feature of aging trajectories is represented by the joint decline of both cognitive and physical functioning, which exposes older subjects to increased vulnerability and a consequential loss of independence in performing daily activities. Albeit both the cognitive decline and the physical/motor reduction denote established outcomes associated with older age, they can be able to differently shape the evolution of aging trajectories. Precisely, although following a parallel path, cognitive and motor/physical functions may evolve at different speeds along adulthood, indeed with a different impact on aging. In the last years, several evidence have argued the precocity of the cognitive impairment compared to the motor/physical ones (Bahureska et al., 2017; Taekema et al., 2012), or vice versa (Montero-Odasso et al., 2017; Kim et al., 2019). An alternative scenario has been recently proposed, according to which cognitive and motor/physical functions appear mutually able to accelerate the evolution of each other (McGrath et al., 2020). In line with this bidirectional perspective, the cognitive and motor/physical decline should be considered a common path towards negative age-related outcomes, such as frailty or disability, rather than just merely separate pathways (Basile, Sardella, 2021).

The prevention of negative outcomes represents one of the most complex clinical goals to be achieved in aging. In this context, frailty is nowadays a noteworthy topic in both Geriatrics and Psychology of Aging research, since the co-existence of clinical and psychological determinants (Sardella et al., 2020). The term frailty originally defines a state of increased vulnerability of the individual to stressors, due to reduced homeostatic reserves, and it substantially results from the progressive decline of multiple physiological systems during the life course (Clegg et al., 2013). Different models of definition and instruments of measurement have been proposed for frailty, which have made the nature of this construct often heterogeneous. Despite this heterogeneity, the *frailty phenotype* and the *deficit accumulation* are acknowledged as the two most representative models of frailty. According to the first model, the *frailty phenotype* is defined through a pre-determined set of five criteria, which peculiarly investigate physical domains (i.e. weight loss, fatigue, reduced gait speed, poor handgrip strength and sedentary habits). Therefore, older adults can be classified as robust, pre-frail or frail depending on the number of met physical criteria (Fried et al., 2001). Conversely, the *deficit accumulation* model aims at achieving a multidimensional definition of frailty, which should be the based on the cumulative impact of several health-related deficits accumulated over time by the individual. Consequently, this definition has been operationalized in the so-called Frailty Index, a tool that evaluates frailty as the ratio between the deficits an individual presents and the number of

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age-related health variables considered by the clinician (Rockwood & Mitnitski, 2007). While the *frailty phenotype* checks for general physical signs and symptoms, does not need a preliminary clinical evaluation of the subject, and allows clinicians to immediately identify subjects at risk of negative events, the Frailty Index meets the needs of a multifactorial assessment of the individual. In fact, the distinctive trait of the Frailty Index lies in its continuous nature, which might make it a more useful tool to determine the effectiveness of any intervention and to describe older adults' health status over time (Cesari et al., 2014).

In the last decade, the need to overcome a definition of frailty based on basically physical components or comorbidity has emerged, in line with the World Health Organization's conception of health as "*a state of complete physical, mental, and social wellbeing and not merely the absence of disease or infirmity"*. Consistently, an additional model of frailty has been proposed, which incorporates the assessment of determinants of frailty (i.e. sociodemographic factors and medical history), as well as components of physical (i.e. motor and sensory aspects), psychological (i.e. cognitive and mood disturbances), and social (i.e. social support and relationships) frailty (Gobbens et al., 2010a). According to this approach, frailty is defined as ''*a dynamic state affecting an individual who experiences losses in one or more domains of human functioning (physical, psychological, social), which is caused by the influence of a range of variables and which increases the risk of adverse outcomes*" (Gobbens et al., 2010b). This bio-psycho-social model of frailty could improve the clinical and prognostic evaluation of frailty, by the promotion of a unitary approach to individual care, with the consequential improvement of the quality of care provided to older adults (Gobbens et al., 2010a).

THE CHALLENGING EXPERIENCE OF BEING CAREGIVERS OF OLDER ADULTS

Caregivers play a crucial supportive role for subjects suffering from several chronic medical conditions, whether they are formally or informally involved in the care assistance. In general, the term *formal caregiver* refers to paid professionals, who are frequently provided by public or private healthcare institutions. Consistently, among formal caregivers often are included social workers, professional nurses, physicians, occupational therapists, physiotherapists, as well as paid subjects who, although not carrying out a licensed health profession, are required as figures of support, assistance and supervision in the performance of daily activities (e.g. washing, dressing, eating, housekeeping, or taking medicines). Conversely, *informal caregivers* frequently result from family members, relatives, friends, and/or neighbours. Their principal role fundamentally concerns the assistance of the care recipients in performing basic daily activities, which require physical needs including bathing, toileting, or eating, as well as instrumental daily activities, which include housekeeping, transportation, managing finances and drug administration. In addition, informal caregivers play a delicate emotional support, which significantly improve the dyadic relationship with their relative, family member or friend, with positive benefits on their mutual health status (Li & Song, 2019).

The progressive increase in the older adults' population has led to the necessary and inevitable increase in welfare costs, in order to meet the multiple health needs of such a vulnerable population.

In this context, caring of older adults appears complex precisely due to the different care-related needs older adults may face. As the Authors premised earlier, older adults denote a remarkably vulnerable popu-

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lation due to the progressive decline in their physical and cognitive functions, as well as multimorbidity and the worsening of chronic conditions, which progressively lead to loss of independence in daily life.

Therefore, the role played by caregivers of older subjects is often delicate and highly responsible; however, the other side of the coin highlights the potential risk that caregivers may develop a care-related burden, resulting from the severity of care recipient's health status (Garlo et al., 2010).

The construct of *caregiver burden* denotes one of the topics of major interest in the healthcare research, and it has increased its multidimensional connotation in the last years. Caregiver burden has been originally defined as the all-encompassing challenges felt by caregivers with regard to their physical, emotional and social wellbeing because of caring experience (Pearlin et al., 1990; Zarit et al., 1986). Among the physical consequences of caregiving, physical strain, blood pressure alterations, headaches, coronary heart disease have been considered (Coe & Van Houtven, 2009). The emotional and psychological consequences of caring are principally characterized by mood disturbances (e.g. anxiety and depressive symptoms) and subjective burden. An interesting topic of debate is represented by the distinction between subjective and objective burden, especially in line with the explanation of the negative emotional consequences of caregiving within the Lazarus and Folkman's Transactional Stress process model (Lazarus & Folkman, 1984). Consistent with this model in fact, stress consequences are mainly mediated by the way caregivers tend to perceive, evaluate and cope for their caregiving experience. Therefore, subjective caregiver burden reflects the individual negative reaction to the caregiving experience; thus, caregivers' vulnerability to subjective burden frequently depends on caregivers' physical and psychological health, financial status, social support, as well as on the quality of the dyadic relationship with the care recipient. Conversely, objective burden refers to daily and practical aspects of caring, including intensity and level of care needs, as well as working hours with the consequent restriction of the caregiver's personal (Del-Pino-Casado et al., 2019).

The nature and the severity of burden among caregivers are strongly linked to the nature and the severity of the older adults' medical condition.

Burden Among Caregivers of Older Subjects With Dementia

The assistance of subjects with dementia denotes one of the most acknowledged source of burden for caregivers; in this regard, caregivers of subjects suffering from neurodegenerative diseases may not have to face and compensate only the cognitive impairment of their care recipients, in terms of memory loss and/or executive dysfunctions. In fact, conditions of physical and psychological dependence, as well as the necessity of continuous supervision and care are frequent along the disease's course. Indeed, formal and/or informal caregivers often need to face the progressive reduction in the subject's ability to perform daily activities independently, as well as the occurrence of behavioural disturbances, which negatively impact on patient's functional autonomy and quality of life (Dauphinot et al., 2016; Roland & Chappel, 2019).

Dementia denotes an urgent and crucial public health problem worldwide, which is frequently associated with high economic and social costs, thus considered one of the major epidemics of the 21st century. As stated earlier, the increase in life expectancy and the progressive aging of the population well explain the growing occurrence of those diseases, such as dementia, in which age is a core risk factor. The number of subjects suffering from dementia worldwide has been dramatically increasing in the last years, with an estimation of approximately 47 million of in 2016; however, this number is unfortunately destined to grow, especially due to the increase in the older population aged 80 and over, in which the

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risk of dementia is strongly accentuated. Indeed, it is estimated that a diagnosis of dementia will affect approximately more than 130 million people in 2050 (Prince et al., 2015; Wimo et al., 2013).

A recent systematic review has highlighted that peculiar patients-related factors such as patients' low educational level, type of dementia (with frontotemporal variant of dementia as one of the main contributor of caregiver burden), as well as the eventual presence of neuropsychiatric and behavioural disturbances in the care recipients should be acknowledged as common sources of burden among caregivers. Peculiarly, among behavioral disturbances, aggression, irritability, euphoria, disinhibition and motor hyperactivity denote the principal occurred symptoms, which increase the levels of stress in the caregiver, and negatively affect the quality of life of both caregivers and care recipients, as well the quality of the care provided (Kang et al., 2014; Gimeno et al., 2021).

The severity of burden among caregivers of older subjects with dementia may be additionally worsened by the co-existence of age-related comorbidities, such as diabetes, which is a condition frequently reported by patients with dementia. In fact, individuals aged 65 and over with diabetes are considered at increased risk for developing cognitive impairment and dementia (Talley et al., 2015). Older adults with diabetes have to manage daily drug administration, glycemic control, regular clinic follow-up evaluations, and they need to substantially modify their lifestyle and dietary habits; therefore, the complexity with which diabetes impacts on patients' daily lives makes the assistance of a caregiver extremely necessary. The role of caregivers assumes a considerable relevance especially in assisting those older patients, who present severe complications due to diabetes, such as blindness or limb amputation (Ogunmodede et al., 2019), as well as sleep disturbances, eating disorders (e.g. increased appetite due to insulin resistance), and alcohol abuse (Talley et al., 2015).

On the other hand, the level of caregiver burden, in assisting older adults with dementia, may be additionally exacerbated by several caregiver-related factors, such as older age, socioeconomic status (e.g. low income), low educational level, gender (female appear more vulnerable), quality of the relationship with the care recipient, physical and mental status, depressive symptoms and efficacy of coping strategies (Chiao et al., 2015).

In addition, compared to caregivers of other care recipients, caregivers of subjects with dementia appear at higher risk for cardiovascular problems as hypertension, which may be associated with chronic inflammatory processes. Furthermore, they are frequently exposed to higher prevalence rates of depressive (approximately 30%) and anxiety (approximately 40%) symptoms (Cheng, 2017), and they tend to exhibit higher levels of anger, exhaustion, fatigue, tiredness (Gimeno et al., 2021).

Burden Among Caregivers of Older Subjects With Parkinson's Disease

Parkinson's disease is acknowledged as one of the age-related neurodegenerative diseases, and it frequently involves a complex management due to the co-occurrence of symptoms of different nature. In fact, Parkinson's disease is characterized by the progressive deterioration of motor functioning as well as by the presence of a wide range of non-motor symptomatology (Macchi et al., 2020), with inevitable negative consequences even for caregivers, especially due to the progressive increasing of care demands along the disease's course.

Motor symptoms tend to worsen parallel to the evolution of the neurodegeneration; in this context, motor fluctuations, dyskinesia, gait dysfunctions (e.g. slow gait, freezing), "on-off" switching, postural instability and falls denote relevant sources of amplified burden among caregivers, precisely because they make older subjects increasingly dependent in performing their daily activities, and expose them to

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greater risk of disability. Indeed, one of the negative experiences often reported by caregivers of older subjects with Parkinson's disease is the difficulty in planning outdoor activities, due to the necessary constant surveillance for falls and the strict control for drug administration, which inevitably contribute to reduced social interactions (Mosley et al., 2017).

Since their elevated heterogeneity, non-motor symptoms of Parkinson's disease represent a source of higher burden for caregivers, if compared with motor symptoms (Carter et al., 2008; Shin et al., 2012). As reported by a recent review (Mosley et al., 2017), the burden of caregivers of older subjects with Parkinson's disease is often exacerbated by patients' depressive symptomatology, which may include sadness, pessimism, lack of motivation, fatigue, sense of guilt, up to suicidal thoughts. In addition, apathy and anxiety symptoms can be associated with a worsening of caregiver burden. Apathy could occasionally overlap with depression, and it is frequently accompanied by lack of motivation, presence of negative emotional responses, up to difficulty in performing routine activities such as bathing or dressing without support, with a negative impact on the perceived burden among caregivers. Similarly, caregivers can also suffer from the anxiety-related behaviors exhibited by older patients with Parkinson's disease, such as social phobia, avoidance behaviours, fear of falling, irritability; such behaviors are often accompanied by an excessive dependence of the patients, with a negative effect on the social life of the caregivers (Mercer, 2015).

Caregivers also daily face the negative consequences of Parkinson's-related cognitive impairment, which mainly involves executive dysfunctions, slow processing speed, deficit in attention, language and working memory; these impairments additionally increase the patient's reliance due to their difficulty in planning and performing daily activities independently. The occurrence of neuropsychiatric disturbances (e.g. visual hallucinations, aberrant beliefs), compulsive behaviours (e.g. eating disorders, gambling), sleep disturbances, urinary dysfunctions and sexual disorders (e.g. hyper sexuality) complete the wide range of patients' non-motor symptoms that could generate an elevated burden among caregivers (Hiseman & Fackrell, 2017).

Burden Among Caregivers of Older Subjects With Cancer

The diagnosis of cancer denotes an additional challenge for older adults, with repercussions not only on subjects' life, but also on caregivers' life and care experience. Cancer is unfortunately considered one of those age-related diseases, since the presence of higher incidence and mortality rates among older individuals. The assistance of patients with cancer is usually carried out by a family member, who as a primary caregiver is involved in several disease-related aspects such as treatment decisions, management of treatment-related adverse effects, assistance in daily living activities, as well as emotional support (Ge & Mordiffi, 2017). Furthermore, it is important to highlight that even older adults with cancer could present co-existing comorbidities (Jørgensen et al., 2012; Sardella et al., 2020a), functional decline associated with disability (Mohile et al., 2009), geriatric syndromes as hearing loss, osteoporosis, incontinence (Mohile et al., 2011), and frailty with its syndrome-related outcomes (Handforth et al., 2015). Therefore, these factors might generally denote additional challenges for caregivers of older subjects with cancer, and they might contribute to the worsening of stress and care-related burden. Despite in the last years an established amount of evidence has extensively described the factors associated with caregiver burden among caregivers of subjects with cancer, the peculiar topic regarding caregivers of older cancer individuals has been poorly debated. A recent systematic review (Ge & Mordiffi, 2017) has summarized that younger age, male gender and primary or lower education are those caregivers'

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sociodemographic factors commonly associated with care-related burden. Furthermore, elevated levels of burden can be also associated with the presence of migraine, anxiety, low quality of life, poor dyadic relationship to patient, and low self-efficacy among caregivers. Conversely, peculiar care recipients' characteristics, such as reduced physical functions, presence of an unintentional weight loss, presence of musculoskeletal disorder, psychological distress, progressive limitations in social activities and low self-efficacy, are considered as additional sources of caregiver burden. From a diagnosis perspective, the assistance of older patients with solid tumors appears associated with the perception of higher burden among caregivers. The early identification of factors contributing to burden on caregivers of older adults with cancer still represents an unmet need (at least, a not completely met need), which should be achieved in order to target tailored interventions beneficial for both older care recipients and caregivers.

Burden Among Caregivers of Subjects With Stroke and Dysphagia

In the elderly population, a significant reduction in functional autonomy occurs following stroke, which places older adults at high risk of disability. Previous evidence have reported that approximately 50% of subjects needs assistance in performing daily activities during the first year after stroke (Lo et al., 2008), and approximately 45% remained disabled even after surviving the stroke (Yang et al., 2016). Thus, caregivers of older adults following stroke play a delicate role, which however expose them to high risk of experiencing a care-related burden (Thommessen et al., 2001). Precisely, caregivers assisting older adults with stroke frequently exhibit psychological disturbances, such as anxiety, depression and reduced quality of life, as well as they may be vulnerable to cardiovascular conditions (Danker et al., 2016). Similar to previous discussed medical conditions, several older stroke patients' characteristics are acknowledged as source of burden among caregivers, such as depression, level of autonomy in performing daily activities and gender. Specularly, the amount of time spent on caregiving daily, depressive symptoms and the type of relationship with the older care recipient are suggested as caregiver-related factors able to increase caregiver burden (Rigby et al., 2009; Zhu & Jiang, 2018).

Dysphagia denotes a noteworthy condition affecting older adults in the context of different medical conditions (e.g. severe stage of neurodegenerative diseases, cerebrovascular diseases, and geriatric syndromes), which expose older adults at high risk of negative outcomes, such as malnutrition, pulmonary diseases and mortality (Christmas & Rogus-Pulia, 2019; Takizawa et al., 2016). The already delicate role of caregivers assisting patients with dysphagia becomes more complicated when the patient is an older adult, who can often exhibit several comorbidities, as well as an increased difficulty in performing daily activity due to cognitive or functional impairments (Quattropani et al., 2021). In the context of older adults with dysphagia, the potential occurrence of feeding-related behaviors (e.g. continuous tongue or mouth movements, accepting food but failing to swallow, presence of coughs or chokes, closing mouth firmly, clenching teeth or lips) is acknowledged as source of burden among caregivers. The inevitable necessity of using feeding tubes, which could be used as a proxy for severe swallowing difficulties, is considered an additional source of severe burden, with a significant emotional impact especially on family caregivers (Namasivayam-MacDonald et al., 2018). Caring for older patients with dysphagia can have further negative impact on the wellbeing and the quality of life of caregivers when dysphagia is a consequent symptom of co-existing conditions such as Parkinson's disease (Perry et al., 2021) and stroke (Davis et al., 2021). Similarly, caregivers of older adults with dysphagia due to neurological conditions can report increased anxiety levels, compared with caregivers of individuals without dysphagia (Serel Arslan et al., 2017).

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The burden among caregivers of older adults with dysphagia represents a relevant public health concern, and it has been gaining interest in the last years; the actual challenge is to effectively evaluate the levels of burden and to identify concrete methods of reducing it, in order to consequently improve older patients' care (Shune et al., 2020).

FRAILTY AND DISPOSITIONAL OPTIMISM IN OLDER ADULTS AS CONTRIBUTORS OF BURDEN AMONG CAREGIVERS

Hitherto, in the present chapter, the association between caregiver burden and clinical and psychological characteristics of older adults has been discussed, with regard to several medical conditions. Ultimately, an additional mission of the chapter was to highlight in detail the potential impact on the caregiver burden of peculiar functional and psychological factors exhibited by older care recipients, namely frailty status and dispositional optimism. Both frailty and optimism have acquired increasing prominence in the Psychology of Aging research, yet they are little explored as determinants of caregiver burden.

In the last years, the impact of older adults' frailty status on the caregiving experience has reached an increasing interest, suggesting frailty as a further source of burden for the caregivers. A link between the degree of care recipients' frailty and the level of caregiver burden has recently emerged, indicating the presence of greater burden (associated with low quality of life, occurrence of physical problems mood disturbances) among those caregivers of older adults that exhibit a worse frailty status. Interesting evidence have additionally suggested that the frail care recipients' psychological wellbeing might play an important role in contributing to burden among caregivers; consistently, those caregivers of older adults who exhibit an adequate (or even improved) psychological wellbeing can maintain higher care-related quality of life over time (Oldenkamp et al., 2017).

Most of the studies investigating caregiver burden in the context of frail older subjects predominantly focused on a substantially physical frailty, expressed in terms of weight loss, fatigue, gait speed, handgrip strength, and sedentary habits, which have been suggested as sources of greater care-related burden, depression and anxiety among caregivers (Lan et al., 2021; Ringer et al., 2017).

However, the evaluation of the burden experienced by the caregivers might appear reductive if solely referred to physical aspects of care recipients' health. Thus far, few studies exploring the construct of caregiver burden have attempted a comprehensive assessment of care recipients' frailty, by though using tools that partially capture the complexity of elderly subjects. Consistently, these studies evaluated frailty through composite scores including cognition, general health status, functional independence, social support, medication usage, nutrition, mood, continence and functional performance (Abreu et al., 2020; Lopez Hartmann et al., 2019; Sugimoto et al., 2018).

A recent attempt to overcome this issue has been advanced, by investigating the link between caregiver burden and a multidimensional index of frailty (i.e. the Frailty Index), in accordance with the deficit accumulation approach (i.e. the presence of different age-related deficits accumulated over time) (Rockwood & Mitnitski, 2007). This study has suggested that the burden of caregivers might be exacerbated by the complex frailty status of their care recipients, with a negative impact on a wide range of burden-related aspects, such as the caregiver's restriction of personal time, feeling of failure, physical stress, perception of role conflicts, and feeling of embarrassment (Sardella et al., 2021b).

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The implementation of interventions in the context of frail older adults appears an increasingly important goal, which can be beneficial for the improvement of wellbeing and health status in both older adults (Apóstolo et al., 2018) and caregivers (Chan et al., 2018).

As premised earlier, in the present chapter the Authors further aimed at discussing the potential impact on the caregiver burden of peculiar psychological factors exhibited by older care recipients.

Yet again, elderly people with dementia characterize the most explored clinical population; the majority of studies has predominantly discussed the psychological factors of patients within the broad construct of behavioral and psychological symptoms in dementia (BPSD), highlighting the negative effect of patients' depressive behaviors, apathy, or euphoria on the caregiver's health (Yang et al., 2019; Feast et al., 2016).

In recent years, there has been debate on the hypothesis that some psychological factors capable of promoting resilience in the elderly could also have a positive effect on the caregivers. In this perspective, dispositional optimism has been increasingly acknowledged as a psychological factor contributing to a better adaptation to aging in older adults, by promoting the adoption of healthy behaviors and a consequent improvement of health-related quality of life (Dos Santos et al., 2018; Sardella et al., 2021c; Sardella et al., 2021d; Serlachius et al., 2015; Schiavon et al., 2017). According to the original model proposed (Scheier & Carver, 1985), dispositional optimism is a stable dispositional factor, which reflect the individual's positive expectations for the future; consistently, this optimistic attitude translates into daily life in the motivated adoption of health-oriented behaviors, with benefits in terms of both general wellbeing and physical health, especially in the presence of adversity to overcome.

With regard to the positive effect of optimism on the caregiving experience, previous evidence has highlighted that caregivers' higher levels of optimism might improve their mental wellbeing and reduce distress (Butow et al., 2014; O'Dwyer et al., 2013); similarly, health workers with a more optimistic disposition tend to exhibit lower levels of emotion exhaustion (Malagón-Aguilera et al., 2020). The other side of the coin indicates that the link between the care recipients' optimism and the burden expressed by the caregivers has been poorly investigated, even though it may represent an interesting point of debate. In line with this perspective, a recent study has showed that lower levels of optimism among older care recipients significantly contributed to higher levels of overall burden, as well as to peculiar higher levels of burden due to the restriction of personal time, among family caregivers (Sardella et al., 2021b). A stimulating hypothesis to verify through further studies could be that caregivers might benefit from the adoption of health-oriented behaviors by optimistic older care recipients, which in turn would relieve their care-related burden (Tan et al., 2015).

Sealing the close connection between older care recipients and caregivers represents an actual challenge, and the approach according to which patients-related functional and psychological factors might be beneficial also for their caregivers should be encouraged in future researches. Similarly, it is increasingly necessary for the caregivers to be able to recognize the different alarm bells in their care recipients' functional and psychological health, in order to improve the quality of care.

Social and professional support should necessarily be provided to caregivers, in order to better manage the heterogeneous complexity of older adults' care-needs and reduce the levels of caregiver burden. In this perspective, it is necessary to create the conditions for a holistic approach to the health of older adults, in which the caregiver should cope for the care needs of the care recipients within a multidisciplinary team (Holroyd-Leduc et al., 2016). Furthermore, in order to increasingly improve the quality of care in such a vulnerable population, appears essential to encourage an active participation of caregivers, especially if they are family members, in making health care decisions together with their care recipients. Consis-

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tently, caregivers should be routinely included in educational health-oriented programs and strategies, jointly with patients and additional care professionals, with the purpose of improving their knowledge and care skills (Kojima et al., 2019). Ultimately, caregivers of older adults may benefit from several tailored interventions aimed at reducing the negative consequences of care, such as psychoeducational program, psychotherapy, problem solving and communication skills workshops, and mindfulness sessions; furthermore, the use of mobile apps providing useful information on older adults' health appears promising (Sala-González et al., 2021).

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Chapter 2

Health Protection and Resonable Balancing of Interests

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ABSTRACT

Fundamental rights are born in the form, width, and with the limits that the constitution gives them. Concretely, in single laws and in concrete situations, every right claimed by one person is limited by the other rights and rights of others. In concrete situations, two or more rights cannot be satisfied at the same time; systemic and coherent protection can be given by reasonably balancing interests in the resolution of a specific conflict. As far as health protection is concerned, proportionality assessments are based primarily on the use of the precautionary principle and the determination of the so-called acceptable risk threshold. The aim of the contribution is therefore to illustrate the techniques of balancing interests in the field of health protection with particular focus on the Italian constitutional order.

CONFLICTS BETWEEN RIGHTS AND BALANCING

As stated by the Italian Constitutional Court in its first judgment, n.1 of 1956, in a general way, the rule which confers a right does not exclude the regulation of the exercise of it. A regulation of the methods of exercising a right, so that the activity of a person aimed at the pursuit of his own objectives is compatible with the pursuit of the objectives of other persons, would not be considered in itself a violation or denial of the right. And even if someone would think that from the discipline of exercise can also indirectly derive a certain limit to the right itself, it should be remembered that the concept of limit is inherent in the concept of right and that in the context of the legal system the various juridical ‘spheres’ must necessarily limit each other, so that they can coexist in the orderly civil coexistence. Thus, rights are born in form and scope and with the limits that the Constitution gives them;

The limits of a right can be classified as follows:

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- ‘Internal’ limits and other general counter-interest
- ‘External’ limits i.e. the other rights and rights of other persons

However, the protection of rights must always be systemic and not divided into a series of uncoordinated rules that are potentially in conflict with each other. If this were not the case, there would be the unlimited expansion of one of the rights, which would become a “tyrant” in relation to the other constitutionally recognized and protected juridical situations, which constitute, as a whole, an expression of the dignity of the person.

The implementation of the system of rights in the legal system and especially in the Constitution follows a very precise logic:

1. Identification in the Constitution of the typical hypothesis of the object of protection, (‘head’ of law).
2. Identification in the Constitution of the typical hypothesis of counter-interest, (‘internal’ limit).
3. Development of discipline in other sources and, in particular, in ordinary legislation (‘body’ of law) and balance with other rights or interests (so-call ‘external’ limits).

As for health protection, it can be said that the ‘head’ and the typical counter-interest are indicated in the text of art. 32 Cost, while the ‘body’ is found e.g. in l. 132/1968 (so-called hospital law), in law 833/1978 (establishment of the National Health Service), in law 119/2017 (mandatory vaccinations).

The right to health, pursuant to Article 32 of the Constitution, in fact, it has at least 4 dimensions (Bartole-Bin 2008)

1. Negative claim that public authorities or individuals refrain from conducts that could affect their physical integrity.
2. Positive demand for the public authorities to provide facilities, therapeutic means and free treatment for the most deprived.
3. Negative claim not to be forced to undergo certain health treatments beyond those of a mandatory nature.
4. Collective claim that each individual has care of his health in order not to cause damage to the psycho-physical integrity of other members of the community.

In the abstract, rights do not conflict. The Constitution sets out in absolute terms the rights and interests it recognises and protects and does not offer an unambiguous solution to the problems of reconciliation between them. It sets the “tolerance limits” with which the various legislative choices have to deal. (Onida 1988)

However, rights do not live in isolation, but they are in a situation of potentially continuous conflictual interaction. In such situations, two or more rights cannot be met at the same time, and traditional antinomies resolution criteria (chronology, hierarchy, specialty) cannot be used. The purpose of balancing is to reach a solution to a specific conflict between rights and/or interests that has manifested itself in a concrete case. (Pino 2010, 187)

Traditionally, conflict hypotheses are classified as follows:

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1. Conflict between individuals in the enjoyment of the same right (e.g. conflict between the right to a welfare benefit and the limited financial resources of the State)
2. Conflict between individuals in the enjoyment of two non-homogeneous rights (e.g. conflict between economic freedoms and the right to health
3. Conflict between individual interests and the interests of the community (e.g. conflict between the individual dimension and the collective dimension of the right to health).

It must be remembered that balancing is not a 'conciliation'. It does not consist in 'agreeing' the two conflicting interests or in finding a point of 'balance' between them, or in the equal partial sacrifice of both (Guastini 2006). The balancing of interests involves the prevalence of one of the interests and the compression of another interest, which must, however, be protected in its essential content.

Balancing also presupposes a division of institutional roles. The legislator has the task of fixing the balance, of finding the balance between the different interests. The political discretion of the legislator cannot exceed the limits set by the Constitution for each right and it cannot compress constitutional rights and interests below the essential content. (Pino, 2017, 145)

The judges verify the balance drawn in the abstract by the legislator, interpreting the law to resolve the concrete case, If they consider that a legislative provision has violated the "tolerance limits" they can turn to the Constitutional Court, raising - with the question of constitutional legitimacy - a series of objections either on the balance set by the legislator or on the insufficiency of the balance established because it is faced with new or unexpected situations, making the request to "add" the new rule (which seems consistent with the Constitution) to the law that does not provide for it.

The Constitutional Court assesses the reasonableness of the legislator's balance in the perspective of the objections raised by the judge.

The scheme of the balancing judgment, or test, followed by the Constitutional Court, consists of a series of phases: mapping of the interests at stake (so called topography of the conflict), reconstruction of the ratio legis and evaluation of the legitimacy of the aim, evaluation of the means-aims congruity, judgment of proportionality, identification of the essential content of the right subjected to compression (Bin 1992, 62)

Negative results in the individual phases of the test no longer identify a reasonable limitation or regulation of the right or interest but a violation of it.

With regard to the right to health and the balancing of interests, the question of constitutional legitimacy decided by the Court with judgment no. 5 of 2018 appears of great interest and topicality. It was a 'ricorso in via principale' of the Veneto Region against various articles of l.117 of 2017 which extended the number of mandatory vaccinations for minors up to 16 years of age.

1. Preliminary operation: mapping the interests at stake

The interests at stake must be of a constitutional level. If the interest of which the compression is complained of is not recognized as a constitutionally protected right, a judgement of illegittimacy (infondatezza) is issued. In that judgment, the Court stated that the jurisprudence of this Court on vaccinations is firm in stating that art. 32 Cost. postulates the necessary balancing of the individual's right to health (also in its content of freedom of care) with the coexistent and reciprocal right of others and with the interest of the community, as well as, in the case of compulsory vaccinations, with the interest of the child, which also requires protection against parents who do not fulfill their care tasks.

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2. Identification of the *ratio legis* and the legitimacy of the aim. (What purpose is pursued by law? Is this aim worthy of protection, i.e. legitimate?)

In the case in question, the law that forces to a health treatment is aimed not only at improving or preserving the state of health of those who are subject to it, but also to preserve the state of health of others and these purposes are not incompatible with art. 32 Cost.

3. Suitability and adequacy of the legislative instrument (means) with respect to the aim. (Does the law have the capacity to serve the protection of the interest that the legislator intended to protect ?)

According to the Constitutional Court judgement, the legislative instrument in question has a rational connection with the purposes that are proposed if it is expected that it does not adversely affect the state of health of the one who is obliged, except for those only consequences that appear normal and, therefore, tolerable; and if, in the event of further damage, the payment of a fair indemnity in favor of the injured individuals is provided for and this is regardless of the parallel compensatory protection.

4. Criterion of necessity-proportionality. To achieve its objective, has the legislator used the instrument deemed suitable that involves the least sacrifice of interest or competing right (so-called least restrictive means)?

The Court, again in judgment no. 5 of 2018, stated that the balancing of these multiple principles leaves spaces for the discretion of the legislator in the choice of the methods through which to ensure effective prevention from infectious diseases, since he can sometimes select the technique of the recommendation, sometimes that of the obligation, as well as, in the second case, calibrate the measures variously, including sanctions, aimed at ensuring the effectiveness of the obligation. This discretion must be exercised according to the different sanitary and epidemiological conditions, ascertained by the authorities, and of the ever-evolving acquisitions of medical research, which must guide the legislator in the exercise of his choices in this field.

There is also a variety of approaches in comparative law. Given a general legal favor for the policies of dissemination of vaccination practices - based on the statistical and experimental evidence of the competent authorities and especially of the WHO, which consider vaccination an indispensable measure to guarantee individual and public health - there are several tools chosen by the various systems to achieve the common objectives.

5. Criterion of adequacy or proportionality in the strict sense and identification of the essential content. (Analyzing costs and effects, is the sacrifice, imposed on the right or competing interest, total or does it still allow a sufficient exercise of that right?

It should be remembered that the measure of the constitutionally permissible sacrifice required of a right or interest can never be such as to nullify its essential content. According to that judgement of the Constitutional Court, the choice of the legislator cannot be censured on the level of reasonableness. This legislative choice has not unduly and disproportionately sacrificed individual self-determination to protect the other constitutional assets involved. Undoubtedly, the legal constraint has become more

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stringent: what was previously recommended has now become mandatory. But in assessing the intensity of this change for the purposes of judging the reasonableness of the balance made by the legislator, two factors must be theld in consideration. In the medical field, recommending and prescribing are actions perceived as equally necessary in view of a given objective, so much so that in terms of the right to compensation, recommended and mandatory vaccinations are not affected by differences. The legislator has established an adequate space for a relationship between medical authorities and citizens based on information, comparison, persuasion and conscious adherence. The Court therefore concluded that in the present context, therefore, the legislator considered necessary to strengthen the cogency of the tools of vaccination prophylaxis, configuring an intervention that is not unreasonable in the current state of epidemiological conditions and scientific knowledge.

In this perspective of enhancing the evolutionary dynamics of the medical-scientific knowledge that must support the regulatory choices in the field of health protection, the legislator has appropriately introduced a periodic monitoring system that in the perspective of the data emerged in the scientific community can result in the cessation of the mandatory nature of some vaccines.

According to the Constitutional Court, which had already addressed the issue in other judgements, the essential content of the right to health - that is, the minimum level of protection that cannot be further compressible by balancing operations - can be found in the concept of human dignity. The limitation of this assumption lies in the fact that the concept of human dignity cannot be declined in a legally univocal way. Its definition depends on context variables (historical, social, economic, cultural), but also on the subjective conception that each individual has of himself. This implies, from the point of view of legal life, an inevitable widening of the constitutional court's margin of appreciation in assessing the reasonableness of the balances made by the legislator.

The questions of constitutional legitimacy raised by the Veneto Region with regard to l.119 of 2017 were thus declared partly inadmissible and partly unfounded.

A similar pattern is followed by administrative judges to verify compliance with the principles of proportionality and adequacy by the Public Administration. In this case the test consists of three phases:

1. Test of suitability and congruity of the legislative instrument (means) with respect to the aim.
2. Test of necessity-proportionality.
3. Test of adequacy or proportionality in the strict sense

According to the administrative judges (e.g., T.A.R. Lazio 08.07.2020 n. 2049) any restrictive power must be exercised in the active administration and in court or judicial proceedings, in compliance with the principles of proportionality and adequacy which constitute, at the same time, internal limits to the correct exercise of public action. The positive passing of each phase of the test is the prerequisite for the verification of the next one, so that, only the measure that positively exceeds all three phases of verification can be attributed the predicate of definitive legitimacy.

While balancing is a necessary and inevitable activity to resolve conflicts between constitutional rights and interests, it is not, however, free from critical issues and risks. The danger is transferring essentially decision-making powers from the so called political decision-making circuit to the so-called guarantees circuit. This is because balancing has in itself discretionary aspects that risk invading the field of political assessments due to the legislator. The Constitutional Court thus risks transforming itself from a "negative legislator" (repeal of laws contrary to constitution) into a "positive legislator" or co-legislator with the related margins of uncertainty and unpredictability of judicial decisions.

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PROPORTIONALITY TEST, PRECAUTIONARY PRINCIPLE, RISK THRESHOLDS

The Constitutional Court in sentence no. 85 of 2013 affirmed that the Italian Constitution, like the other contemporary democratic and pluralist Constitutions, requires a continuous and mutual balance between principles and fundamental rights, without claims of absoluteness for any of them. The right to health also lives in a constant balance with other rights and interests. Consequently, the Court cannot agree with the assumption that the adjective 'fundamental' contained in art. 32 Cost., would reveal a "pre-eminent character" of the right to health over all the rights of the person. The Court goes on to point out that the Court's definition of the environment and health as 'primary values' does not imply a "rigid" hierarchy of fundamental rights. The qualification as "primary" of the values of the environment and health therefore means that they cannot be totally sacrificed to other interests, even if constitutionally protected, not even if they are placed at the top of an absolute hierarchical order. The point of balance, precisely because it is dynamic and not fixed in advance, must be assessed – by the legislator in the making of the rules and by the judge of the laws during the control – according to criteria of proportionality and reasonableness - such as not to allow a sacrifice of their essential core.

In the context of the evaluations that govern the establishment of the balance by the legislator in the field of the right to health, in particular for the proportionality test of instruments that compress one of the interests, the precautionary principle is used.

This principle is used and modulated according to the level of risk of injury to the right to health to which the individual is subjected in those areas for which it detects the scientific uncertainty about the possibility of damage.

The principle was born and established in relation to the protection of the environment, but it has been extended in its application to other interests such as the protection of human health. It is present and protected in the international legal order, in the national legal systems of several States, in the legal order of the European Union (Article 191(2) TFEU).

It can therefore be said that the precautionary principle is an explication of the more general principle of proportionality. In order to understand how this principle works and to understand its impact on national law, it is appropriate to start from the EU legal system.

The art. 5(4) TEU states: Under the principle of proportionality, the content and form of Union action shall not exceed what is necessary to achieve the objectives of the Treaties'.

The EU Court of Justice, in its judgment of 1.10.2019 (Mathiew Blaise et others., C-616/17) had the opportunity to state that, 'although Article 191(2) TFEU provides that environmental policy is based, in particular, on the precautionary principle, that principle is also applicable in the context of other Union policies, in particular public health protection policy and when the European Union institutions adopt, within the framework of the common agricultural policy or the internal market policy, measures to protect human health'.

However, the European Commission (Communication COM/2000/0001) has already pointed out that the precautionary principle can be invoked when a phenomenon, a product or a process can have potentially dangerous effects, identified through a scientific and objective assessment, if this assessment does not allow to determine the risk with sufficient certainty.

The precautionary principle can only be invoked in the event of a potential risk, and that principle cannot, under any circumstances, justify an arbitrary decision.

Recourse to the principle is therefore part of the general framework of risk analysis and, more particularly, of decision-making and management.

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The principles of risk management can be listed as follows:

- Proportionality between the adopted measures and the level of protection sought;
- Non-discrimination in the application of measures;
- The coherence of measures with those already taken in similar situations or using similar approaches;
- Examination of the benefits and burdens resulting from action or lack of action
- The review of the measures in the light of scientific developments.

In the field of the right to health, the case of medicines, for example, is particularly appropriate.

The precautionary principle for those products, operates in the form of prior authorisation (positive list) before being selled. This is already a way of applying the precautionary principle by shifting responsibility for the production of scientific evidence. This is because some substances are considered, in advance, dangerous or can be potentially dangerous at a certain level of absorption. In this case, the legislator, as a precaution, has provided for the reversal of the burden of proof, establishing that these substances are considered to be dangerous until proven otherwise. It is therefore up to the companies to carry out the scientific work necessary for risk assessment. Until the level of risk to health and the environment can be assessed with sufficient certainty, the legislator cannot legitimately authorise the use of the substance, except in exceptional cases to carry out tests.

Due to the principle of integration between EU and national sources, with the prevalence of the EU law over national law, the precautionary principle has entered the Italian legal system. It was codified in art. 1,1 of law 15 of 2005 reform of the administrative procedure and in d.lgs. April 3, 2006, n. 152 (Code of the environment), which after having recalled it to art. 3-ter among the principles that must inform the environmental action, regulates it in art. 301.

With specific reference to the right to health and in particular to the issue of vaccinations, we can mention the opinion given by the Consiglio di Stato (Special Commission of 20 September 2017, n. 226) on the request made by the Veneto region on law n.119 of 2017 – extension of mandatory vaccinations, of which we had the opportunity to talk previously.

The Consiglio di Stato stated that in the adoption of administrative measures the precautionary principle must be used. That principle requires the public decision-maker (legislator or administrator) in specific contexts to prefer, among the multiple hypotheses that can be suspected, the solution that makes it possible to balance between the minimization of risks and the maximization of benefits, through the identification, on the basis of a proportionality test, an acceptable hazard threshold (so-call adequacy and proportionality assessment).

In cases where the act issued, as a result of the emergency state, should not be responsive to the context to an extent "neither adequate nor proportionate" could be the subject of attention by the administrative justice or, in particular cases of the ordinary jurisdiction and, incidentally, of the Constitutional court itself.

In certain legal arguments directed against the vaccination obligation, the invocation of the mentioned precautionary principle often occurs. However, an interpretation is offered of it according to which, in summary, the State should refrain from imposing the vaccination obligation since vaccinations would imply an inevitable risk of adverse reactions or more serious prejudices of the physical integrity of the vaccinated subjects; in other words, a condition of so-called "zero risk" would be absent.

Well, given that no human conduct is accompanied by a "zero risk", it is clear that the reported conception of the precautionary principle would fundamentally prevent any development of medical-

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surgical sciences (and any other science). Furthermore, the theses, which have just been mentioned, tend to misrepresent the meaning and finalism of the precautionary principle, the application of which, far from being based on an anti-scientific prejudice, postulates a solid scientific basis more than any other principle of law.

The precautionary principle does not live, in fact, in a predominantly axiological dimension (that is, it does not presuppose a precise choice of aims-values) nor does it operate in a single direction (in particular, in that of the ban on "risky" public decisions). On the contrary, the precautionary principle applies essentially methodologically and is bidirectional.

It has been argued in doctrine that the precautionary principle does not offer "rules for deciding", but only "rules to proceed", since it allows to identify the path of proceeding of the decisions of public authorities in situations of uncertainty, allowing a collective management of risk.

In other words, the precautionary principle does not in any way oblige the choice of "zero risk". It requires to the public decision-maker (legislator or administrator), in specific contexts, to prefer the solution that makes it possible to balance between the minimization of risks and the maximization of benefits, through identification, on the basis of a proportionality test, an acceptable danger threshold; the selection of this threshold, however, can only be made on the basis of complete knowledge and, above all, accredited by the best available science.

Thus, the precautionary principle may, at times, lead public authorities not to act or, in other cases, may encourage them to take action, adopting measures proportionate to the level of protection chosen (i.e. adequate in relation to the acceptable danger threshold).

In the protection of the right to health, therefore, there are risk and safety assessments necessarily.

In this sense it should be remembered that safety/risk as such is a concept of a technical nature offered arithmetically in the form of numbers by science and statistics; while the safety/risk threshold is a juridical concept.

The threshold of acceptable safety /risk is assessed with criteria that go beyond the mere technical, based on comparison and balance with other interests at stake that relate to the case. The legal acceptability of the risk is a datum decided by the legislator, on the basis of scientific data, with the affixing of a legal limit that varies with the changing context.

In order to be able to carry out such assessments, the central issue is that of the reliability of the scientific data in the risk assessment. As Popper (1970) said, "the empirical basis of the objective sciences has nothing 'absolute' in itself. Science does not lay on a solid layer of rock. The daring structure of his theories rises, so to speak, above a swamp. It's like a building built on stilts. The pile dwellings are driven from above, down into the swamp: but not in a natural or "date" base; and the fact that we desist from our attempts to stick pile dwellings deeper does not mean that we have found solid ground. Simply, we stop when we are satisfied and we believe that at least for the moment the supports are stable enough to support the structure".

One case that deserves to be mentioned is the one that saw the application of the principle of proportionality and balancing techniques in a conflict that has arisen between the right to health and economic freedoms. This is the case that involved the ILVA steel plant in Taranto and its workers. The harmfulness to human health and the environment of the emissions of this plant led in 2012 to its seizure and opened a complex judicial case that involved the Italian administrative and penal courts, but also the Court of Justice of the European Union for Italy's non-compliance with the EU legislation on polluting emissions and the European Court of Human Rights for neoplasic diseases, cardiovascular and respira-

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tory that affected the workers and several inhabitants of Taranto in relation to cause and effect with the emissions of the Ilva steel plant.

That case came to the attention of the Italian Constitutional Court. In a first decision (sentence n. 85 of 2013) the Court stated that the compression of a fundamental right such as that to health – generally not tolerated, in an ordinary condition – becomes reasonable if temporary (that is, subject to the gradual rehabilitation of the plant and the surrounding territory) and if functional to prevent another emergency: the loss of employment of thousands of people. The judgment invited also the legislator to provide with the regulatory instrument to put his hand to a rehabilitation of the plant to better balance the right to health and the right to work. The choice of legislator was scrutinized by the Court five years later.

With the sentence n. 58 of 2018 the Court decided how the legislator had not respected the need to balance in a reasonable and proportionate way, all the relevant constitutional interests, incurring a defect of constitutional illegitimacy for not having taken into adequate consideration the protection of health and life itself (articles 2 and 32 of the Constitution), to which the right to work in a safe and non-dangerous environment must be considered inseparably connected (articles 4 and 35 of the Constitution), giving excessive priority to the interest in the continuation of production activity. The freedom to conduct a business (art. 41 of the Constitution) is expressly limited when it endangers the safety, freedom and human dignity of workers. The constitutional provisions referred to in articles. 32 and 41 Cost. require employers to pay the utmost attention to the protection of the health and physical integrity of workers.

In cases like these one is evident the dramatic nature of the balance and its being a necessary but imperfect solution like all things of law. In fact, the choice for everyone was to protect the workplace, in an inevitably harmful environment, or to defend own health, but with the probable loss of the job

HEALTH EMERGENCY AND REASONABLE BALANCING OF INTERESTS

Health protection, moreover, and especially in this period of pandemic health emergency, conflicts with other rights protected by the Constitution: the right to education; right to work, economic freedoms, civil liberties.

The Italian Constitution does not lay down specific rules to regulate the so-called states of emergency. The will of the constituent appeared well determined in wanting to regulate only the state of war (art. 79 Cost.) and the cases of extraordinary necessity and urgency that legitimize the adoption, by the Government, of the Decreto Legge (art. 77 Cost.). The state of war does not seem to be applicable to the current situation, nor does the reference to the idea of necessity as a source of law seem to be consistent with our constitutional framework. The reference to necessity seems, in fact, dangerous for the potential absence of limits that it contains and that could ultimately even lead to a substantial 'setting aside' of our Constitution (Cardone A, 338). The situation of necessity has instead allowed the activation of a series of mechanisms provided for in our Constitution to protect various interests and which can be traced, in the last instance, to the personalist and solidarist principle (art 2 Cost.), to the principle of unity and indivisibility of the Republic ex art. 5 Cost and the so-called supreme principles (referred to in the judgment n.1146 of 1988 of the Constitutional Court) (Luciani, 4; De Siervo, 301).

The basic fact that must never be forgotten is that the pandemic health emergency has not manifested itself and is not manifesting itself as a punctual event that took place at a precise moment and whose consequences were addressed in the following time (Pinelli 2020, 4264). The most significant factors are the problems related to the identification of the variables that affect the methods of transmission of

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the virus, the variable trend of infections over time and in the different areas of the country, the variations of the virus, the discovery of pharmacological and vaccination therapies to combat the epidemic, the economic and social repercussions.

The pandemic is, therefore, a process that varies over time in a diversified and, in some and even unpredictable way. This has led to the need for differentiated regulatory and administrative interventions, with different time modulations. Unfortunately, the normative, administrative and jurisdictional determinations, in many cases, have shown a lack of ability to anticipate the negative consequences of events, limiting themselves to chasing individual emergency situations with a framework of disorganized interventions, which have often appeared dictated by the attempt to give some partial responses to subjects with differentiated and conflictual interests, with logic sometimes short-lived and somewhat incoherent. Therefore, the research and reconstruction of the coherence and completeness of the legal order has not given definitive and satisfactory results. A series of issues and problems have been solved, but other critical issues have remained, the result, as mentioned at the beginning, of structural criticalities of the system that the health emergency has brought to light in an impetuous way.

With regard to the temporal articulation of the interventions, it should be noted that in the first months of 2020 there was a production of regulatory acts whose balancing of the interests at stake with a clear prevalence of health protection and a strong compression of other rights (economic freedoms, right to work, civil liberties, social rights). Since the autumn of 2020, however, we have seen the heavy weight given to other constitutional interests. The balancing of the interests at stake has no longer seen a clear prevalence of the right to health and the precautionary principle, but measures differentiated by territory and by duration that vary the proportionality and reasonableness of the same. The in force so-called system of colors differentiated by territorial areas (Regions-Municipalities) has been introduced, susceptible to verification and modification over time.

It must be said, however, that the right to health, beyond the statements of façade and measures, sometimes inconsistent with each other, sometimes of doubtful effectiveness, has seemed in some circumstances to be compressed and reduced to the minimum essential content, especially with regard to the weak subjects of the legal system (for example minors, old people). Faced with the needs, even legitimate, of an economic and working nature that have not been able to be met in a different way, the greatest risk of losing health has been considered – by the legislator and by the jurisprudence that has endorsed these choices – an acceptable risk.

Just for example, we can highlight some typical hypotheses of conflict of interest related to the right to health that have occurred more frequently in this period of health emergency.

With regard to the conflict between different subjects in the fruition of the right to health as a positive claim to be taken care of by the sanitary structures, it must be said that in general this contrast finds its foundation in the limited financial, organizational and human resources that can prevent the full provision of the necessary services. In particular, in recent months, we have seen a series of limitations in the sanitary services provided to subjects, carrying other pathologies than COVID patients. But also - and in some cases even dramatically - to the benefits provided in favor of one COVID patient rather than another.

With regard to the hypotheses of conflict between individual interests and the interests of the community, concerning the conflict between the right to health as a negative claim of the individual not to be forced to certain non-mandatory health treatments (vaccinations) and the right to health as a positive claim that each individual has care of his health in order not to cause damage to the physical integrity of other individuals. This case is perhaps the most topical at the time of writing, referring to the application and use methods of the so-called Green Pass.

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Finally, with regard to the hypotheses of contrast between different subjects in the enjoyment of two non-homogeneous rights, it can be said that the cases are really multiple and very differentiated. Among the main hypotheses of conflict can be highlighted, first of all, those relating to the right to health as a negative claim not to be subjected to situations and risks prejudicial to one's integrity (for example the obligation / right of education of the children that may conflict with the right / duty of parents to work).

Secondly, it must be mentioned the conflicts between the right to health as a community interest in conflict with the freedom of private economic initiative. (for example, the closure of a variable series of commercial activities, in various periods, depending on the level of risk of territorial contagion). But the right to health as an interest of the community can conflict with the right to work and to receive a payment (this is the case of employees who find it impossible to work due to the closure of the company).

It can also be recalled how the right to health as a negative claim not to be subjected to situations and risks that could harm to one's integrity, can conflict with the obligation to guarantee work performance (for activities that must / can remain open and cannot be carried out in smart working in distance).

These examples should not, of course, be understood as abstract contrasts, but should then be declined in the cases identified by the legislator in the legislative provisions and brought to the attention of the judges in litigation and possibly to the Constitutional Court with a range of possible resolutions as wide and diversified as possible.

THE ALLOCATION AND BALANCE OF LEGISLATIVE COMPETENCES BETWEEN THE STATE AND THE REGIONS IN THE MATTER OF HEALTH PROTECTION

In the Italian legal system, regulatory power in areas affecting health is shared between the State and the Regional legislators. Consequently, in addition to the assessments on the reasonable balance of interests in the material areas related to health, just analyze, it must be added to those of compliance with the spaces of regulatory competence attributed to the different legislators.

In this contribution, the analysis will be limited to the regulatory interventions of primary legislative level put in place by the State and the Regions and to the assessments on the balance of interests carried out by the Constitutional Court.

With regard to the allocation of legislative competences between the State and the Regions, in the material areas directly or indirectly affected by the health emergency, it can be recalled that the State has exclusive competence in the field of international prophylaxis (Article 117, paragraph 2, letter q, Cost), State security (Article 117, paragraph 2, letter d, Cost.), general rules on education (Article 117, paragraph 2, letter n, Cost), public order and security (Article 117, paragraph 2, letter h, Cost.). But above all, the 'transversal' competence in the matter of determining the essential levels of services concerning economic and social civil rights should not be forgotten (Article 117, paragraph 2, letter .m, Const.). The Regions, on the other hand, have concurrent legislative competence in health and health protection matters (Article 117, paragraph 3, Cost.), which, however, essentially relates to organizational and management profiles.

Primary-legislative power is linked to secondary-regulatory power. In this sense it should be remembered, pursuant to Article 116 paragraph 6 of the Constitution, that in matters of exclusive competence the regulatory power belongs to the State, while in the competing or residual ones it belongs to the Regions.

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With regard to the regulatory powers of ordinance, l. n.833 of 1978, art. 32 Cost. and the Civil Protection Code attribute them to the Regions in emergency situations that relate to health protection profiles.

In this period of health emergency, the decisions of the State and of the Regions have not always moved in a harmonious way. We have often been faced with conflicting interests for which balancing operations have been necessary.

The main conflicts of interest have concerned and concern, first of all, the dimension of the emergency that makes it necessary, on the one hand, a unitary intervention by the central State in the matters of exclusive competence involved and, on the other hand, the territorial modulation of the interventions because of the differentiation of the contagion and the intervention capacity of the individual administrative and health structures. Secondly, the time factor. The need of normative interventions, often quickly, on the part of the State has found a counterweight in the regional competences in the field of health protection. As the result, the legal order sets some concerted mechanisms with the Regions inspired by respect for the principle of loyal collaboration that require longer times for the decisions.

The principle of loyal collaboration is therefore fundamental to evaluate the reasonableness of the allocation of normative determinations.

The fundamental coordinates of this principle can be schematized as follows:

1. The seats of loyal collaboration are the system of Conferences and in particular the State-Regions Conference for measures that concern all regional autonomy and meetings with individual regions for measures that concern only that territory.
2. The failure to establish a ‘Chamber of Regions’ has led to the exclusive ownership of the conference system of coordination functions between the different levels of government.
3. Even with the textual introduction to article 120, 2 Cost (substitute powers) the principle of loyal collaboration remains attributable to the principle of unity and autonomy ex. article 5 Cost. and must preside over all the relations that exist between the State and the Regions.
4. The conference system has undoubtedly acquired a central and strategic role in the political-institutional link between the State and territorial autonomies. However, this has not prevented causes at the Constitutional Court so far, which have highlighted limitations in the system’s ability to ensure the necessary composition of political interests on certain occasions.

The weaknesses of the Italian system (Caretti, 298) of loyal collaboration can be found as follows:

1. A multi-level system of government does not operate correctly if precise guarantees are not placed on the legislation.
2. The absence of main guarantee instrument: the Chamber of Regions.
3. Loyal cooperation in Italy establishes guarantees at the administrative level but is practically non-existent at the legislative level; I.e. an agreement reached between the State and the Regions on the contents of a draft law can be unilaterally disregarded by the State without legal consequences.

However the functioning of the system cannot be correctly understood if you do not consider:

1. The substitutive power of the Government (Article 120 of the Constitution) according to which the Government may replace bodies of the Regions, Metropolitan Cities, Provinces and Municipalities in the event of non-compliance with international rules and treaties or EU legislation or of serious

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danger to public safety and security, or when the protection of the legal unit or economic unit and in particular the protection of the essential levels of services concerning rights civil and social, regardless of the territorial boundaries of local governments .

2. Attraction/call in subsidiarity (introduced by the Constitutional Court in judgment 303 of 2003). According to this mechanism, the assignment of an administrative function by the State (Art. 118 Cost.) it also 'attracts' the corresponding legislative function. This undoubtedly means a compression of regional competences. However, the attraction in subsidiarity of a legislative competence on the part of the State requires to respect regional autonomy in the procedure. In other words, the removal of legislative competence is compensated for by involvement in the decision. The choice by the State to attract a legislative competence to subsidiarity requires, in fact, the agreement with the Regions at the State-Regions Conference under penalty of unconstitutionality, in the forms of additive pronunciation (... in the part in which it does not provide for the agreement ...). The agreement between the State and the Region makes it possible, in a certain sense, to overcome the problem of the constitutional distribution of competences. The agreement also makes it possible to deal with the related financial issues related to the exercise of competences. It should be remembered that, in the current constitutional framework, the State can no longer invoke the national interest as it was in the previous system, but can recall unitary instances in order to justify the attraction in subsidiarity

By this regulatory framework, it is clear, first of all, that we are faced with a situation of allocation of competences in which there are inevitable areas of overlap. In cases such as these that relate to emergency situations, the Constitutional Court has recently reiterated - in sentence no. 246 of 2019 (relating to the so-called 'Decreto Genova' and the seismic events that hit the Marche and Umbria) - that in the event of a large-scale disaster, recognized with the declaration of the state of emergency of national importance, it is possible to call administrative functions into subsidiarity through their allocation at state level.

In that cases, it is possible to call into subsidiarity administrative functions by allocating them at the state level. In matters of shared competence, administrative functions may be assigned at central level in order to identify rules of a technical nature requiring uniform choices throughout the national territory. However, in emergency situations the Region is not excluded in any case, "since, within the polycentric organization of civil protection, it is necessary that it itself provides the agreement for the deliberation of the Government and, therefore, cooperates in loyal and solidarity collaboration.

Therefore, it must be ruled out that regional laws may intervene in these areas, derogating from or suspending the state legislation in force. It is, as always in these cases, a problem of balancing interests. In general, the Constitutional Court, when (as in the well-known judgment n. 307 of 2003 on electromagnetic emissions) deals with assessing the reasonableness of the balance between the right to health and other constitutional interests operated by the regional legislator who had issued more restrictive derogatories than those provided by the national legislator, proceeds by articulating its test in the following way.

1. Definition of the problem: The Court assesses whether the determination of parameters (threshold values, exposure limits, attention values, quality objectives defined as field values), the setting of which is left to the State, can be modified by the Region, setting lower threshold values, or stricter rules or shorter times for their adoption.
2. Reconstruction of the *ratio* of the legislation and the setting of the parameters. If this *ratio* consisted exclusively in the protection of health, it could be legitimate to consider admissible an intervention

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> of the Regions that would dictate a more restrictive discipline than the State one. For example, if a Region wanted / could guarantee higher standards of health protection, the intervention could not be censored. If, on the other hand, the setting of parameters, as often happens, responds to a more complex and articulated *ratio*, such as the one that provides for a balance between the interest in health protection, on the one hand, and other interests (economic freedoms, right to education, freedom of movement, etc. just to mention the cases most recallable in this period of health emergency), on the other, then the setting of parameters at national level, cannot be derogated from by the Regions even in a more restrictive sense. According to the Court, this solution represents the point of balance between the opposing needs, especially in the material areas of a concurred competence, in which the regulatory intervention of the Region is bound by the fundamental principles established by the laws of the State.

On the other hand, the possibility for the Regions to regulate material aspects of a local or territorial type in compliance with national parameters would remain unaffected and provided that they are not such as to prevent or unjustifiably hinder the operation of national rules.

Similarly, it can be said of the so-called derogations in melius dictated by regional rules that weaken the parameters dictated by the State.

Therefore, summarizing, there is a prevailing need for uniformity in the protection of constitutionally guaranteed rights, a uniformity that would be compromised by an institutional division of competences and that requires taking into account all the interests and rights at stake, necessarily on a national scale.

In this context, the recent judgment no. 37 of 2021 of the Constitutional Court should be mentioned. In this decision, the Court addressed the issue of the allocation of competences between the State and the Regions in matters relating to the pandemic health emergency by ruling on the constitutional illegitimacy of a series of articles of l.no. 11 / 2020 of the Valle d'Aosta Region.

These rules on the management of the pandemic emergency were contrary to the provisions of national legislation. The regional legislation provided for the possibility of operating a series of economic activities in compliance with safety protocols always dictated at regional level, which instead at national level were prohibited (so-called derogations in melius).

The Constitutional Court held that the material scope of the health emergency falls within the exclusive competence of the State in the field of international prophylaxis (Article 117, 2 letter q) Cost.) as the Covid 19 disease must be considered a pandemic disease and, as such, international, due to the diffusivity that characterizes it. This material framework includes any measure designed to combat or prevent the pandemic. It concerns rules which also guarantee uniformity in the implementation, at national level, of programmes drawn up at international and supranational level. In this sense, "logical reasons, rather than legal ones" justify a unitary national discipline. In this way, the equality of persons in the exercise of the fundamental right to health is preserved and the interest of the community is protected. The differentiation between regions or sub-regional areas can be provided for by national legislation (so-called system of colors) not by regional legislation without prejudice to the regulatory spaces reserved for the power of ordinance.

The Court then recalls that the law establishing the National Health Service (Articles 6, 7 of l.833/1978) provides that international prophylaxis and prophylaxis of infectious and diffusive diseases, for which compulsory vaccination or quarantine measures are imposed, are entrusted to the competence of the State (although the latter type of measures can be delegated to the Regions). Consequently, however

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fundamental is the contribution of the regional health organization, through which the State itself can pursue its own goals, the state legislature is entitled to foreshadow all the necessary measures.

In particular, according to the Constitutional Court, the state legislature, in the face of the pandemic, has chosen to introduce new regulatory and regulatory responses calibrated on the latter and, consequently, versatile tools have become necessary, suitable to adapt to the changeability of the situation and the Regions, even with special autonomy, cannot interfere legislatively with the discipline established by the competent state legislator, nor use their legislative power in order to make a state law inapplicable in their territory, which it considers constitutionally illegitimate.

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KEY TERMS AND DEFINITIONS

Balancing: Technique to reach a solution to a specific conflict between rights and/or interests that has manifested itself in a concrete case.

Legislative Competences: In the Italian constitutional order, legislative competence is divided between the State and the Regions according to the matters. Article 117 of the Constitution establishes three types of legislative competences. 1) Exclusive competence of the State: only the State can enact laws in those matters; 2) Competitors: The laws of the State establish the fundamental principles of the matter, the regional laws establish the detailed rules; 3) Residual of the Regions: it is up to the Regions in all matters not expressly reserved to the legislation of the State.

Loyal Collaboration: Requires that the different levels of government that are part of a legal system (e.g., State and Regions, Member States, and EU) must cooperate with each other in view of the interweaving of competences.

Precautionary Principle: The precautionary principle can be invoked when a phenomenon, a product or a process can have potentially dangerous effects, identified through a scientific and objective evaluation, if this evaluation does not allow to determine the risk with sufficient certainty.

Principle of Proportionality: The principle of proportionality prescribes the adequacy between means and aims in the exercise of normative powers.

Principle of Reasonabless: The principle of reasonabless requires that the legislative provisions are adequate or congruent with the Objectives pursued by the legislator.

Right to Health: In the Italian Constitution (art. 32) the right to health establishes that the Republic safeguards health as a fundamental right of the individual and as a collective interest, and guarantees free medical care to the indigent. No one may be obliged to undergo any health treatment except under the provisions of the law. The law may not under any circumstances violate the limits imposed by respect for the human person.

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Chapter 3

Worldwide Welfare Society:
Healthcare and Social Impact Investments

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ABSTRACT

In the face of healthcare emergency and the linked problems, the purpose of the work is to identify an economic and organizational tool for the improvement of the person's health condition and, consequently, for the prevention of the spread of future contingent pandemics. Due to the lack of public resources, this system would contemplate private investments balancing social and speculative objectives. It analysed the social impact bond (SIB), the typical form of impact investing that provides for public and private partnership. After examining the structure with its positive and negative aspects, the disintermediation through blockchain technology and smart contracts is prospected. According to the horizontal subsidiarity, stated in the article 118, paragraph 4, Cost., the suggested intervention would represent an operation aimed at realizing the right to health through a negotial tool (the SIB agreement) subject to the control of merit.

Globalization facilitates the rapid expansion of infectious diseases around the world. This spread hinders the effectiveness of interventions limiting the contagion at the national level and exacerbates the situation of developing countries. The latter, in fact, do not have an organizational and economic structure suitable for dealing with the risks. For this purpose, international institutions have set up financial systems such as the Contingency Fund for Emergencies (CFE), established in 2015 by the WHO to respond immediately to a disease outbreak, and the Pandemic Emergency Financing Facility (PEF), developed by the World Bank in 2016 to make pay-outs through insurance and cash windows. However, the aforementioned tools present some critical issues that prevent the fulfillment of an immediate and decisive response. The CFE does not constitute a flexible and adaptable system to every viral pathology due to the mainly constrained and voluntary nature of the budget. Regarding the PEF, the beneficiaries are exclusively low-income countries with weaker health systems that are members of the International Development Association (IDA). A further limitation concerning the insurance window is represented by the circumscription to a predetermined group of diseases. The cash window, on the other hand, also covers new or unknown

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pathogens but the economic availability is very limited. For the activation of this financing mechanism, excessively stringent criteria must be met, just like pathogen type, outbreak size (number of cases or deaths), spread (number of countries affected), and growth (over a period of time). The inadequacy of these tools emerged with the advent of COVID-19. Having, in fact, spread primarily across high- and middle-income countries, the funding occurred only on April 27, 2020, almost four months into the pandemic. For these reasons, the World Bank Group established a new Health Emergency Preparedness and Response Multi-Donor Fund (HEPRF), with the intention of incentivize low-income countries to increase investments in health preparedness and support the immediate COVID-19 response. In consideration of the economic and organizational shortcomings in the health sector, both nationally and internationally, it is therefore necessary a transnational intervention suitable for facing possible future pandemics through adequate investment in developing innovative vaccines, broad-spectrum antivirals, appropriate non pharmaceutical interventions and surgical device. Such preventive measures would ensure not only a prompt and effective reaction to the onset of an infectious disease but also a saving in public spending. As agreed with the GPMB's annual report 2020 the costs of COVID-19 are over US $ 11 trillion with a future loss of US $ 10 trillion in earnings, while investments in preparedness are measured in US $ 5 per person annually. In conformity with the report «it would take 500 years to spend as much on investing in preparedness as the world is losing due to COVID-19» (Global Preparedness Monitoring Board, 2020, p. 6).

The experience of the current health emergency and the inadequacy of the remedies adopted have led to a new international dialogue about the solutions that can be adopted to counter the spread of future and new pathogens.

On the occasion of the 74th World Health Assembly of 31 May 2021, the opportunity of an international treaty on pandemics that guarantees cooperation between States and establishes adequate collective action for the identification, alarm and response to future pandemics was discussed. The stipulation of this treaty would pursue the objectives of prevention and early detection of future pandemics, improvement of the response to them through a coordinated worldwide approach to research activity and equal and universal access to medical formulas as well as through a "One Health" which relates the health of human beings, animals and the planet.

The lack of economic availability, accompanied by the rigid budgetary constraints introduced with the Stability and Growth Pact, currently suspended until 2023 due to the health emergency, and by the austerity policies, has caused the State to lose the role of exclusive guarantor of social rights. Therefore, problems have arisen regarding the reconciliation between these financial constraints and the satisfaction of social rights. According to an approach adopted by the Constitutional Court, the right to health care is configured as "financially conditioned", as full and absolute implementation cannot be ensured due to limited financial resources (Constitutional Court, 2011). According to a different orientation, the implementation of the protection of a constitutionally relevant asset, such as health, can take place gradually, through a reasonable balance with other interests or assets of equal constitutional protection and with «the real and objective possibility of disposing of the necessary resources [...]» (Constitutional Court,1990). However, if the requirements relating to the balance of public finance «in the balancing of constitutional values operated by the legislator, had an absolutely preponderant weight, such as to compress the essential core of the right to health connected to the inviolable dignity of the human person, we would be faced with a macroscopically unreasonable exercise of legislative discretion.» (Constitutional Court,1994). It follows that reasonableness acts as a parameter for the exercise of the discretion of the legislator who, in the reconciliation between financial constraints and the implementation of social

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rights, meets the limit of the incompressible core of minimum guarantees «that affects the budget, and not the balance of this that affects its due payment.» (Constitutional Court, 2016). An «unequal balance» would be configured, or more correctly it would not be «a real balance (which is always between equals)» since «the end (the satisfaction of the rights of the person) should not be on the same level as the medium (economic efficiency)» (Luciani, 1995, p. 126). It follows that the legitimacy of discretionary choices made by the legislator can be questioned only in the presence of discriminatory measures or which affect the incompressible core of the rights (Mignone, 2020, p. 12). The need of a full and effective implementation of social rights, first of all the health one, supported by traditional orientations their nature of claim against the State, is compromised by the lack of sufficient public resources. To this are added the crisis of the redistributive policies of wealth and the deconcentration of competences both at the regional level through constitutional reforms and at the supranational level in consideration of the economic and monetary union of the European Union, where welfare systems presuppose a centralization of national power (Perfetti, 2020, p. 87 ff.).

These shortcomings, therefore, require the involvement of the private sector through a constitutional reading of the central institutions of private law. In confirmation, the European Social Charter in article 11 guarantees the effective exercise of the right to protection of health, providing that «the Parties undertake, either directly or in cooperation with public or private organizations, to take appropriate measures designed inter alia: […] to prevent as far as possible epidemic, endemic and other diseases, as well as accidents.».

The difficulty of public-private integration lies in reconciling the pursuit of social objectives, such as health, with the profit-making intent of investors. According to a doctrinal orientation, it is possible to find the constitutional basis of forms of capital investment in activities of social relevance, combining the objectives of profit and of general interest (Bugli, 2016, p. 39 ff.). First of all, the principle of economic and social solidarity is relevant as mandatory duties pursuant to art. 2 of the Constitution as well as the principle of substantial equality pursuant to art. 3, paragraph 2, of the Constitution which requires the Republic to remove economic and social obstacles as they constitute impediments to the full development of the person and the effective participation of workers in the economic and social organization of the country. Furthermore, art. 45 of the Constitution recognizes the social function of cooperation as an economic activity with a mutualistic purpose and without intentions of private speculation. The article, however, provides for this action to be performed with the most suitable means, guaranteeing its character and purpose by carrying out appropriate checks. Adhering, therefore, to a teleological interpretation of the provision in question, the latter would favor the pursuit of the cooperation function also through speculative investment activities, as long as they are adequate for the social purpose.

The third sector code (Legislative Decree 3 July 2017, n. 117, as last amended by the d.l. 22 March 2021, n. 41) also establishes that the entities referred to in art. 3 of the code, including social enterprises, may carry out activities other than those of general interest, as long as they are secondary and instrumental to them (art. 6). The social enterprise, in fact, as a private organization that carries out one or more business activities of general interest on a permanent and main basis for the pursuit of civic, solidarity and social utility purposes, allocates its profits primarily to the achievement of the object social. However, forms of remuneration of the share capital are mandated, subject to conditions and within the maximum limits identified for cooperatives with prevalent mutuality (Article 6, paragraph 1, letter d, l. June 6, 2016, n.106). Although the pursuit of a subjective profit-making purpose is prohibited, the social enterprise may allocate a share of less than 50% of the annual profits and of the operating surpluses to a free increase in the share capital subscribed and paid in by the shareholders or to the distribution

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of dividends, also through the issue of financial instruments. However, the law provides for contained returns limited, in the first case, to changes in the general annual national index of consumer prices for blue-collar and white-collar families, calculated by ISTAT for the period corresponding to that of the financial year in which the profits and operating surpluses were produced and, in the second case, to the maximum interest of the interest-bearing postal bonds, increased by two and a half points compared to the capital actually paid (Article 3, paragraph 3, letter a), Legislative Decree 112/2017).

In this perspective, art. 41 of the Constitution provides for the freedom of private economic initiative as it is instrumental to the realization of the person and the development of his personality. The same article, however, establishes, with a view to economic and social solidarity, that economic activity is directed and oriented towards social purposes, providing for appropriate controls and programs.

By means of a systematic and axiological reading of the analyzed provisions, it is therefore possible to infer the admissibility of forms of investment in which profit-making and social purposes coexist. Among these, Social Responsible Investments (SRI) aim to avoid or reduce negative impacts by adopting the so-called ESG criteria for the assessment of an investment. They, in addition to the economic one, constitute parameters for the analysis of an investment that has an environmental, social or governance impact. These forms of investment are also supported internationally. The 2030 Agenda for Sustainable Development, in fact, adopted by all United Nations Member States in 2015, identifies the 17 Sustainable Development Goals (SDGs), among them good health and well-being, that guide the ESG and impact investing's choises. In implementation of the Agenda, the action plan on sustainable finance, adopted by the European Commission on 8 March 2018, intends to promote sustainable development from an economic, social and environmental point of view in order to direct financial investments towards more sustainable activities.

Differently, Impact Investing represents a proactive method characterized by the intention to generate, in addition to a financial return, a measurable social impact on the environment or society (Falkowski & Wisniewski, 2013, p. 79). This expression, coined in 2007 during a meeting organized by the Rockefeller Foundation, describes, according to the Global Impact Investing Network (GIIN), a set of «investments made with the intention to generate positive, measurable social and environmental impact alongside a financial return.». In similar terms, the Social Impact Investment Task Force (SIIT), established in 2013 as part of the G8, qualifies social impact finance as «that finance that supports investments linked to measurable social objectives capable, at the same time, of generating a economic return for investors» (Social Impact Investment Task Force, 2014, p. 24).

For the purposes of applying this method of financing for the preparation of a preventive system aimed at dealing with possible pandemics, it is necessary to identify an adequate organizational and economic scheme. Given the lack of an exhaustive discipline on the subject, it is necessary to refer to the negotiation tools adopted in practice in which economic interests and social purposes coexist. In fact, «social impact finance is a phenomenon that arises from below» (Mignone, 2017, p. 119). In this way, the act of private autonomy takes on the function of regulating economic activities that are instrumental to the fulfillment of the primary needs of third parties (Mignone, 2017, p. 118). Therefore, the rigid distinction between negotiation autonomy for the realization of individual interests and subsidiary intervention for the performance of activities of general interest is overcome, pursuant to art. 118 of the Constitution (Perlingieri, 2016, p. 688). In this context, a central role is played by the control of the merit of the structure of interests adopted in practice, not identifiable with that of lawfulness as the absence of conflict with the hierarchy of constitutional principles but qualifiable as that concerning the suitability of the regulation for the positive implementation of the same (Mignone, 2017, p. 118). Similarly to the

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limits, set out above, of the legislative power affecting fundamental rights, also the negotiation measures for the welfare of private individuals and public administrations, they must be reasonable, adequate and proportional.

The symbolic instrument of social impact finance is represented by the social impact bond (SIB). It was first pioneered by the UK Minister of Justice in 2010 with the aim of reducing the recidivism rate of 3,000 short-term inmates at Peterborough Prison and, consequently, the daily public expenditure incurred for each prisoner.

The SIB is qualified as a form of public-private partnership through which capital is raised from private lenders for the implementation of social policy programs of a preventive nature. The subjects of the transaction are: the public administration which determines the social result to be pursued and, subject to agreement with the service provider, the program to be implemented with consequent provision of the investment return in the event of a positive outcome; private investors who provide the necessary financing, generally through payments made upon the achievement of interim results; the specialized intermediary acting directly or through a vehicle company (special purpose vehicle set up to manage this contract specifically); the service provider, usually a third sector organization, who undertakes to render the service, being also responsible for the quality of the service, whose remuneration, in compensation for the costs incurred, is made by the intermediary with the capital of the investors, generally regardless of the achievement of the objectives; the neutral evaluator, a third and independent body whose task is to measure the results obtained with the relative social impact and to determine the remuneration of investors.

Furthermore, additional figures may intervene such as the advisor as technical support to public figures; the guarantors of the investment, parties to a surety agreement with the intermediary and the investors who ensure to the latter the return of at least part of the amount; the managers of the guarantee instruments who reduce the risk borne by investors by encouraging forms of coverage of part or all of the capital (Napolitano, 2020, p. 356 ff.).

It turns out, therefore, to be a flexible instrument whose core is represented by the agreement between the public administration and an intermediary or vehicle company. With this contract, the p.a. undertakes to pay the amount set for the achievement of the corporate purpose in terms of public spending savings.

The model-scheme provides for a minimum content that includes the identification of the social problem to be solved; the determination of the reference population and, within it, the group of beneficiaries (so-called target group); the impact variable to be measured and the related indicators; the outcomes on which the remuneration and the specification of the amounts that the p.a. undertakes to transfer to the lead contractor, in case of achievement of the same, depend (Mignone, 2017, pp. 120-121).

The peculiarity of this so-called "outcomes based-contract" lies in the fact that the reimbursement of the invested sum and the payment of the related interests, (Investments could target a range of returns from below market to market rate, depending on investors' strategic goals. In the first case, investors primarily aim to generate social or environmental good, and are often willing to give up some financial return if they have to (cc.dd. impact first investors). In the second, however, they are typically commercial investors who seek out subsectors that offer market-rate returns while achieving some social or environmental good: "financial first investors" (Freireich & Fulton, 2009, p. 33), is conditioned by the pursuit of the pre-established social results, measurable ex post through indicators and, therefore, to a saving of public expenditure. In fact, the term bond does not express the nature of the security but the correlation between profitability and social results (Del Giudice, 2015, p. 45). SIBs, in fact, rather than debt securities that attribute to the holder a fixed interest (coupon) accrued within a certain period of

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time and the repayment of the loaned capital, are attributable to equity securities as the financial return depends on the achievement of specific social results (Bolton & Saville, 2010, pp. 247-257).

The overall dividend that the investor aims to obtain has been defined as "mixed", i.e. consisting «in identifying those social benefits that a prevention activity is able to generate, quantifying the economic aspect in terms of future spending savings and using a rate of this savings to remunerate the investor who has "bet" on the success of a project» (Del Giudice, 2015, p. 12). It is therefore essential to identify a method that measures the social impact produced. The evaluation of the same is defined pursuant to art. 7, paragraph 3, l. 6 June 2016, n. 106, such as «the qualitative and quantitative assessment, in the short, medium and long term, of the effects of the activities carried out on the reference community with respect to the identified objective.». Although this formula was considered excessively «generic» (Caselli & Rucco, 2018, p. 57), it has the merit of having combined quantitative and qualitative impact measurement indicators. The quantitative ones, in fact, guarantee investors objective parameters for assessing risk and profitability but are not sufficient (European Economic and Social Committee,2013). Therefore, it is necessary to use qualitative criteria for the purpose of adequately ascertaining the resolution of the social problem and the effects produced.

The most common impact assessment is the Social Return On Investment (SROI) consisting of the measurement in monetary terms of the costs, benefits and any negative consequences of an activity, in addition to a report of the effects deriving from the program (Barone, 2020, p. 427).

It is therefore a high-risk operation that falls entirely on the investors. The payment depends, in fact, on a variable, the social impact, connected to factors beyond the control of any actor in the operation and in part influenced by the adequacy, quantitative and qualitative, of the service provider's performance. For these reasons, in the Rikers Island model adopted in 2012 in New York to reduce the recidivism rate of young prisoners, a guarantee fund was set up by Bloomberg Philanthropies, with the function of limiting the risk of loss of the capital invested in the event of failure to achieve the social objective.

Added to this, it is quite difficult for the investor to assess *ex ante* the probability of verification of the social impact and he has no power to control the disbursement activity (Mignone, 2017, p. 123).

With the spread of this social impact financial model, opposing doctrinal orientations have arisen in this regard. Some have pointed out the positive effects such as the finding of additional resources and of greater breadth than those deriving from traditional channels (bank credit, public financing and private donations) in order to improve the quality of services and ensure preventive interventions with medium- long-term objectives more effective and less expensive than those of a subsequent and restorative nature. According to a critical view, impact finance constitutes an exploitation of personal services for profit-making purposes (Mchugh et al., 2013, p. 247 ff.). This would lead to the choice of programs aimed at obtaining easily measurable objectives and with a reasonable probability of return for investors, as well as the tendency of the service provider to maximize the numerical objectives set out in the agreement, with potential degradation of the underlying public interest (Mignone 2020, pp. 34-35). This could cause a selection of the target group in a discriminatory way. This is the danger of the so-called "cherry-picking" consisting of the exclusion of individuals with personal qualities such as to reduce the probability of success of the program. Discrimination is considered prohibited only if it consists of a disproportionate measure compared to the prejudice suffered by the discriminated and the possibility of finding valid alternatives, as well as constituting an inadequate method for the adoption of other solutions with less sacrifice of the users' interest. In this case it would affect the lawfulness and merit of the cause of the contract with consequent illegality of the administrative discretionary activity and of the power of autonomy (Mignone, 2020, p. 42 ff.).

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Further negative consequences would be represented by the exclusion of small non-profit sector organizations from participating in a SIB due to the lack of sufficient resources to bear the resulting risks (Del Giudice, 2015, p. 101) and the alteration or circumvention of the classic selection, monitoring and control procedures (Mchugh et al., 2013, p. 254). Furthermore, due to the still embryonic diffusion of this instrument, there are few highly qualified and specialized intermediaries in this sector with consequent high costs for the operation.

There are those who believe, however, that the use of these tools in the Italian system encounters legal obstacles.

The first problem concerns the compliance of this atypical legal transaction with the public accounting rules of the public administration. In fact, in the SIB, a sub-type of payment-by-result contractual schemes, the remuneration for investors is uncertain in the *an*, as it is conditioned on the achievement of a specific social result. The amount of the payment of the p.a. also depends on the savings in public spending resulting from a certain level of social impact. If the latter was positive, it must be established whether the investor's remuneration should be fixed and, therefore, uncertain only in the *an*, or proportional to the level of social impact, in this case also uncertain in the *quantum*. The latter hypothesis is incompatible with the certainty - or predictability - that characterizes the formation of the financial statements of public bodies. On the p.a., in fact, there is the obligation to draw up multi-year financial statements which must show that the spending commitments for the obligations assumed bind a certain amount in the *an* and in the *quantum*.

In order to overcome the conflict, with the stipulation of the SIB the p.a. should register in the current year the amount corresponding to the remuneration of investors in the event of a positive social impact, posting an amount equal to the maximum amount. Based on whether the transaction was successful or not, the p.a. will have to pay an amount equal to, or less than, the item posted in the financial statements or record an extraordinary income that can be reinvested in other public or social policies (Napolitano, 2020, p. 362 ff.).

Another aspect concerns the legal classification of this model in one of the figures contemplated in the code of public contracts. Among these, the public contracts defined by art. 3, paragraph 1, lett. ii), Legislative Decree 18 April 2016, n. 50. As can be deduced from the ANAC determination of 2015, n. 10 (ANAC, 2015) what differentiates this contract from that of the concession of both works and services, "is the sharing of the risk between the administration and the concessionaire. In the absence of risk related to management, regardless of the *nomen iuris* used, not the concession but the contract is configured [...]» (p. 6). Therefore, it does not seem that the SIB is attributable to this scheme as on the p.a. there is no market risk for the services provided (Napolitano, 2020, p. 372).

The concession of services, on the other hand, is regulated in the Article 3, paragraph 1, letter vv of the Legislative Decree 18 April 2016, n. 50. The characteristic therefore lies in the transfer of the management risk to the economic operator whose remuneration derives from the provision of the service to third-party users. According to a feasibility study (Human Foundation, 2016-2017, p. 83 ff.), it is recognized the concessionary nature of the SIB, understood as a contract between the Administration and the "implementing body" made up of private investors, the service provider and the specialized intermediary. This is based on the fact that the financial risk of the operation weighs on private investors and not on the public side. In this case, the service provider would be remunerated by a third party (the investors). According to the jurisprudential orientation, however, the onerousness of the contract would be maintained, in a substantial or weak sense, «whenever from the execution of the contractual service the contractor may appear to derive a legitimate and autonomous economic benefit, even if not

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paid to him as contractual exchange by the contracting authority» (Cons. St., 2017). Criticisms have been raised (Napolitano, 2020, p. 372 ff.): by virtue of the flexibility of the model, the agreement is not always stipulated with subjects all linked by the "aggregative bond", as *uti singuli* relationships may have been established. Furthermore, in the absence of a risk to the service provider, the contract would no longer be framed in the concession but in the contract. It has been specified that the risk of the private-investor in the SIB does not correspond to the entrepreneurial one in the strict sense as it derives from the uncertainty of the realization of the expected social impact and, consequently, the remuneration by the Administration is uncertain in the *an* and in the *quantum*.

A different doctrinal orientation qualifies the SIB as an "atypical random contract of public-private partnership" (Blasini, 2015). The latter, as can be deduced from Articles 3, paragraph 1, lett. eee) and 180, Legislative Decree n. 50/2016, represents a versatile negotiating tool subject to public procedures due to the public interest pursued. The distinctive character of this scheme is the «transfer of risk to the economic operator, under the triple profile of construction risk, availability risk and demand risk for the services rendered» (Lombardy Regional Administrative Court, 2018). The three types of risk are defined respectively by art. 3, paragraph 1, lett. aaa), bbb) and ccc) of the Legislative Decree n. 50/2016. It has been authoritatively argued that risks, such as construction risks, do not exist or present different traits in the SIB (Napolitano, 2020, p. 385 ff.). The risk of availability is different from that typical of the SIB characterized by conditional reimbursement: the service provider must not generate revenues for himself but provide a service with a positive social impact such as to determine cost savings. The demand risk, on the other hand, does not exist as the beneficiaries of the services are predetermined and do not have the freedom of choice on the provision of the same. Another essential element is the economic-financial balance intended as a hedge of management and investment costs with the revenues (Opinion Cons. St., 2017). It requires, pursuant to art. 3, paragraph 1, lett. fff), Legislative Decree no. 50/2016, two conditions: economic convenience and financial sustainability. In relation to the SIB, this negotiation scheme is by nature uncertain and, in the event of failure to achieve the social result, the Administration must not use public resources to equalize the losses as investors bear the risk of capital loss (Napolitano, 2020, p. 387).

The last identifying element consists in the monitoring by the contracting authority on the activity of the economic operator, in particular on the permanence of the risk borne by the same operator (Article 181, paragraph 4, Legislative Decree no. 50/2016). Differently, in the SIB the supervisory activity is entrusted to a third and impartial party and concerns the quality standards of the service.

The Social Impact Bond was also linked to project financing (Pasi, 2015, p. 213). The first tool, however, unlike the second one, does not finance a specific subject but a complex project and is subject to conditional remuneration (Napolitano, 2020, pp. 359-360).

The activation of a public evidence procedure also results in the selection by tender of the private contractor. It was considered that this choice can be made through competitive dialogue (Clarich, 2009, p. 292). The latter constitutes a flexible procedure that guarantees a continuous comparison between the participating economic operators and the contracting authority and allows the public interest pursued to be satisfied in the best possible way. Although governed by the new code of public contracts as an ordinary procedure, it is necessary the existence of one of the conditions set out in art. 59, paragraph 2, legislative decree 18 April 2016, n. 50 including the innovative nature of the solutions or the presence of particular circumstances in relation to the nature, complexity or financial and legal setting of the object or because of the risks associated with it (Article 59, paragraph 2, letter a), nn. 2 and 3 of Legislative Decree 18 April 2016, n. 50). These ones seem, in fact, to be included in the structure of the SIB.

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Furthermore, it is advanced the adoption of the restricted procedure pursuant to art. 61, legislative decree n. 50 of 2016 (Napolitano, 2020, pp. 366-367).

Beyond the limits of legal compatibility, the adoption of a model such as that of the SIB derives from the principle of horizontal subsidiarity pursuant to art. 118, paragraph 4, of the Constitution which encourages “bottom-up” interventions for the pursuit of social goals through negotiation schemes. Private initiative is, therefore, to be included in the legal system as a whole «as part now implementing, now conforming, now creative and constitutive» (Perlingieri, 2016, p. 687). In any case, there is a unitary «functional foundation, which finds its due anchoring in the hierarchy of constitutional principles, whatever the concrete source of regulation and source of financial supply» (Mignone, 2020, pp. 47-48).

With a view to the successful implementation of the social principles and merit of the transaction, however, it is primarily necessary to fill the information gap of investors who, assuming a high risk through the financing of a social program, must receive clear, complete and understandable information. For the purposes of adequate protection of investors and, therefore, of the development of impact investing, it is therefore necessary to regulate the disclosure requirements that are not merely limited to the profitability of the securities and the material factors from which it derives but also including the social objectives and related measurement procedures, as well as reasonable projections and information regarding past outcomes achieved in the sector (Mignone, 2016, p. 924 ff.). This awareness must also exist not only at the time of signing the agreement but also during the execution of the program through a control, although indirect, of the service provider’s activity. Hence there is the need for monitoring by the third party not only in the final phase concerning the qualitative assessment of the service provided but during the operation.

Furthermore, since it is a win to win model from which all parties involved in the operation benefit, the risk of program failure should be shared, albeit in different terms, also by the other actors, in particular by the service provider as responsible of the service. In fact, the achievement of the social purpose and the economic return for investors deriving from savings in public spending depend on the latter.

The Epiqus Occupational Wellness I represents an innovative SIB model created in Finland in 2015 for the resolution of the social problem of low productivity and high absences from work due to illness and high stress of public employees. In fact, it provides for an allocation of the risk of failure of the initiative through the subordination of the liquidation of the margins of 20% of the service providers and the management fee of the intermediary to the total return to the backers of the invested capital and through the distribution of profits resulting from the success of the program in the amount of 70% for the investors and 30% for the suppliers and the manager of the SIB. Another peculiar element is the absence of the public contracting authority and, in replacement, the establishment of a fund that collects and manages the revenues of customers, that is, public employers.

Disintermediation, with a consequent reduction in management costs, could be carried out through the use of the Blockchain.

It, attributable to the Distributed Ledger Technology category, is defined as «a shared and synchronized digital database that is maintained by a consensus algorithm and stored on multiple nodes (computers that store a local version of the database). Blockchains are designed to achieve resilience through replication, meaning that there are often many parties involved in the maintenance of these databases. Each node stores an integral copy of the database and can independently update the database. In such systems, data is collected, stored and processed in a decentralized manner.» (European Parliamentary Research Service, 2019, p. 1).

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The digital register therefore has the structure of a chain of blocks containing the transactions validated by the nodes of the network by means of the consensus mechanism established by the protocol. A distinction is made between permissionless blockchains, accessible to anyone, and permissioned blockchains whose subjects operating on the network are limited and selected by central entities. Its adoption determines greater security of transactions which, once registered, cannot be easily modified or subject to cyber attacks by virtue of the concatenation mechanism achieved through hashing processes. Modifying a block, in fact, that includes the hash of the transactions contained in the block and the hash of the previous one, would invalidate the subsequent ones.

Another positive factor is the transparency of the operations as the information added to the blockchain is immediately visible and distributed to the network participants and updates are shared with them without having to rely on a third party. The last feature is the anonymity of the participants whose identity is used through a system of asymmetric cryptographic keys: a public key or address on the blockchain and a private one for carrying out transactions on the network.

This tool therefore constitutes a functional mechanism for finding economic resources by investors from different countries quickly and economically through the use of the web.

The adoption of this technology in the financial field took place with the so-called tokenisation, «a method that converts rights to an asset into a digital token» (European Securities and Markets Authority, 2019). It represents ownership of assets on DLT. The relative offer, so-called Initial Coin Offering (ICO), is aimed at raising capital for the financing of a project in exchange for traditional or virtual currencies. It is characterized by the use of blockchain technology; from the advertising and promotion of offers via the web and from the publication of a so-called whitepaper instead of the prospectus provided for the so-called Initial Public Offerings (IPOs). In cases of qualification as finantial instruments under the Directive 2014/65 / EU of 15 May 2014 (MIFID II), more precisely as transferable security that means «those classes of securities which are negotiable on the capital market, with the exception of instruments of payment, such as: (a) shares in companies and other securities equivalent to shares in companies, partnerships or other entities, and depositary receipts in respect of shares; (b) bonds or other forms of securitized debt, including depositary receipts in respect of such securities; (c) any other securities giving the right to acquire or sell any such transferable securities or giving rise to a cash settlement determined by reference to transferable securities, currencies, interest rates or yields, commodities or other indices or measures» (art. 4 (1) (44) of MIFID II), the rules provided for financial instruments are applied. To this end, the SEC in the 2017 DAO Report applied the Howey Test, developed by the US Supreme Court in SEC v. W.J. Howey Co., 1946, that qualifies an investment contract for the purposes of the Securities Act as a contract, transaction, or scheme entailing: (a) an investment of money (b) in a common enterprise (c) with a reasonable expectation of profits (d) deriving from the efforts of the promoter or of a third party (Securities and Exchange Commission, 2017).

In Europe, according to ESMA «the actual classification of a crypto-asset as a financial instrument is the responsibility of an individual NCA [National Competent Authority] and will depend on the specific national implementation of EU law and the information and evidence provided to that NCA. […] The existence of attached profit rights, without having necessarily ownership or governance rights attached […], was considered sufficient for a majority of NCAs to qualify crypto-assets as transferable securities (where such crypto-assets also meet the other conditions to qualify as transferable securities)» (European Securities and Markets Authority, 2019). CONSOB, as the Italian national competent authority, in fact, established that the tokens, in compliance with the category of financial products ex art. 1, paragraph 1, lett. u) including both the typed figures of "financial instruments" and "any other form of investment

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of a financial nature", were attributable to the latter notion. In fact, this form of investment implies the coexistence of the three elements: a) an use of capital; b) a return expectation of a financial nature; c) the assumption of a risk associated with the use of capital (CONSOB, 2019).

Smart contracts, qualified as «agreement [s] in a digital form that [are] self-executing and self-enforcing» (Werbach & Cornell, 2017), represent an implementation of the blockchain. In fact, they are identifiable in computer protocols or scripts that automate the execution of the services, with consequent registration on the blockchain and, therefore, irreversibility of the same, upon the occurrence of certain conditions. The latter may concern parameters within the network or real-world events whose data are transferred to smart contracts using software (Sarzana & Nicotra, 2018, p. 102).

The use of the technology in question is encouraged in Europe where the potential of blockchain applications, also through the facilitation of smart contracts, in the financial sector (European Parliament, 2017) and the benefits deriving from their use are highlighted (European Parliament, 2018).

These issues have also drawn attention of the Italian legislator who has provided for the development of some important definitions. Art. 8-ter of the decree law 14 December 2018, n. 135, converted with amendments by law 11 February 2019, n. 12, configures "technologies based on distributed ledgers" as «Technologies and computer protocols that use a shared, distributed, replicable, simultaneously accessible, architecturally decentralized on cryptographic basis, such as to allow registration, validation, updating and the storage of data both in clear text and further protected by cryptography verifiable by each participant, which cannot be altered and cannot be modified.». In the doctrinal sphere, however, criticisms have been made. In fact, the fulfillment of an identification between DLT and Blockchain has been disputed, whereas the latter, on the other hand, would constitute a *species* of the former as it is characterized by additional elements such as the use of cryptographic tools and hashing processes (Aiello, n.d., pp. 18-19). It was also noted that the "non-alterability" and "non-modifiability" would be compromised by the risks of a "fork", that is, the possibility of a modified or updated version of existing software (Aiello, n.d., p. 13), and a "51% attack". It «could occur if a party or colluding group controlled at least 51 percent of the computing power of the network, allowing them to determine what is recorded to the network's records, and potentially to revise the existing record. For a variety of reasons, many consider the risk of a successful 51 percent attack to be essentially zero, but others see it as more uncertain» (Walch, 2017). Lastly, it was noted that the provision does not contemplate the mechanisms of consent and the forms of remuneration of the block validation activity (Manente, 2019, p. 10).

The second paragraph of the same article, on the other hand, qualifies the "smart contract" as «a computer program that operates on technologies based on distributed ledgers and whose execution automatically binds two or more parties on the basis of predefined effects.». The regulatory provision identifies a general notion of smart contracts without making any distinction between those that automate existing contracts and those constituting a mandatory relationship between the parties. With reference to the former, the subordination of the onset of the bond between the parties to the execution of the contract would be in contrast with the consensual principle ex art. 1376 of the Civil Code. An alternative interpretation, therefore, means the reference to the execution as that of the computer program whose constraint would concern the immutability of the data, once recorded on the blockchain (Aiello, n. d., p. 25). With regard to the latter, on the other hand, an intermediate orientation has developed with respect to that which denies the possibility of a smart contract as a source of obligations (Parola et al., 2018, p. 685) and that which admits its contractual nature (Panisi, n.d.). It adopts the theory of the so-called "Split contracting model" which involves the use of technology to link a contract generally in written form and including the requirements of the law to the smart contract code, with the function of executing the

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agreement. Therefore, these are "hybrid contracts" which, similarly to the so-called "Ricardian contracts" are both readable by individuals and can be analyzed and managed by software (Aiello, n.d., pp. 26-27).

Faced with the automatism that characterizes smart contracts, although an assessment cannot be made before fulfillment, an *ex post* corrective judicial intervention inspired by the principles of good faith, fairness, reasonableness and proportionality is possible (Bellomia, n.d., pp. 18-19).

With reference to smart contracts, it is also noticed the protection of the digital consumer who, in addition to acting for purposes unrelated to any entrepreneurial, commercial, craft or professional activity carried out (Article 3, paragraph 1 letter a), Legislative Decree lgs. 6 September 2005, n. 206), remotely and with a digital tool, uses a new contractual tool, thus increasing the position of weakness (Bellomia, n.d., p. 19). Therefore, the rules provided for consumer contracts will apply. In particular, in cases of distance marketing of financial services to consumers, such as social impact bonds, the legislation contained in Section IV-bis of Legislative Decree 6 September 2005, n. 206 is implemented. It provides for the fulfillment of information obligations before the conclusion of the contract regarding the supplier, the financial service, the distance contract and the appeal (Article 67-quater, paragraph 1, Legislative Decree no. 206/2005) whose violation determines the nullity of the contract if it has significantly altered the representation of the characteristics of the same (Article 67-septiesdecies, paragraph 4, Legislative Decree No. 206/2005). It is also contemplated, pursuant to art. 67-undecies, paragraph 1, legislative decree n. 206/2005, the communication of the contractual conditions and the aforementioned information on paper or other durable medium, available and accessible to the consumer before the conclusion of the distance contract, except for the hypothesis referred to in paragraph 2 of the same article. It follows that both the contractual conditions and the preliminary information must be contained in the contract, corresponding to the computer one, drawn up in the traditional form.

The second sentence of the analyzed paragraph also recognizes the requirement of the written form, subject to computer identification of the interested parties, through a process identified by the Agency for digital Italy with guidelines that should have been adopted within ninety days of entry into force of the law but which have not been published yet. It evokes the provisions of the legislative decree 7 March 2005, n. 82 regarding the evidential effectiveness of computer documents. In accordance with the definitions of computer document and electronic document, it was argued, in fact, that the notion of smart contract could have been recalled in the discipline contemplated for computer documents (Aiello, n.d., p. 28).

The third paragraph recognizes the legal effects of electronic time stamping pursuant to art. 41 of regulation (EU) n. 910/2014, 23 July 2014, so-called eIDAS. This validation, or timestamping, operates through the connection of data in electronic form at a particular time and date in order to prove their existence at that moment (Article 3, paragraph 1 n. 33, EU Reg. No. 910 / 2014, 23 July 2014). It is also defined as "qualified" if it meets the requirements of art. 42 of the eIDAS regulation (Article 3, par. 1 n. 34, EU Reg. n. 910/2014, 23 July 2014). Art. 41, par. 2, of the regulation provides for a presumption of accuracy of the date and time indicated and the integrity of the data associated with them only with regard to qualified electronic time stamping. It follows that, in the case of unqualified validation, the accuracy assessment must be carried out by the judge. The problem therefore consists in identifying which type of validation the discipline referred to in art. 8-ter, paragraph 3, d.l. 14 December 2018, n. 135. It has been argued that the discipline in question refers to both categories of validation (Bomprezzi, 2019).

The last paragraph establishes that the Agency for Digital Italy identifies the technical standards that the technologies must possess for the production of the effects provided for in the previous paragraph.

The critical raised issues regarding the use of blockchains, especially the permissionless ones, pertain to compatibility with the regulation relating to the protection of personal data contained in the

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EU regulation 2016/679, of 27 April 2016. The first one consists in the fact that «the GDPR is based on the underlying assumption that in relation to each personal data point there is at least one natural or legal person - the data controller - that data subjects can address to enforce their rights under EU data protection law. Blockchains, however, often seek to achieve decentralization in replacing a unitary actor with many different players. This makes the allocation of responsibility and accountability burdensome, particularly in light of the uncertain contours of the notion of (joint) -controllership under the Regulation. A further complicating factor in this respect is that in light of recent developments in the case law, defining which entities qualify as (joint-) controllers can be fraught with uncertainty.» (European Parliamentary Research Service, 2019, p.1). The regulation, in fact, governs the figures of the controller and of the data processor. It is problematic to identify these subjects in permissionless blockchains. Some argue that «[n] odes are indeed not subject to external instructions, autonomously decide whether to join the chain, and pursue their own objectives. As a consequence, it appears that the Regulation's legal obligations would rest on each node, meaning that data subjects can invoke claims vis-à-vis each node independently» (Finck, n.d., pp. 26-27). Others distinguish between the hypotheses in which users actively operate on the blockchain and those in which they use third-party applications within the blockchain (Ibáñez et al., 2018, p. 5). In the first case, the ownership of the treatment would belong to the participants themselves; in the second one to the application managers.

Another issue concerns the immutability of the data recorded and inserted in the chain of blocks where Articles 16 and 17 of the GDPR provide for the modifiability and deletion of personal data for the purpose of conforming to the legal requirements. While believing that the registration of personal data referred to in art. 4, paragraph 1 n. 1, GDPR could occur on chain, the data used in the transactions are "converted" into cryptographic tools. Recital 26 of the GDPR itself states that «The data protection principles should therefore not apply to anonymous information, i.e. information that does not refer to an identified or identifiable natural person or to personal data made sufficiently anonymous to prevent or not to allow plus the identification of the data subject. This Regulation therefore does not apply to the processing of such anonymous information, including for statistical or research purposes.». Pseudonymised data, on the other hand, which, again on the basis of the same recital, «could be attributed to a natural person through the use of additional information, should be considered information on an identifiable natural person.». The hashing processes and the use of asymmetric keys should also be included among the pseudonymisation techniques. The same resolution of the European Parliament of 3 October 2018 considers that «the DLT promotes the pseudonymization of users, but not their anonymization». «It has, however, also been stressed that the compatibility of these instruments with the Regulation can only ever be assessed on a case-by-case basis.» (European Parliamentary Research Service, 2019, p. 101).

Another critical aspect concerns the identification of the applicable law and jurisdiction for transactions carried out on chain, especially for those registered on public blockchains, whose nodes can be located in any place. There is also the risk that behind these operations, being characterized by "semi-anonymity", there are hidden illegal activities such as money laundering or terrorist financing.

Given the transnational nature of the technology, uniform regulation at the European level that clearly defines the concepts of blockchain and smart contract would be desirable. It would also be necessary to identify the applicable law and the responsible party in the event of the onset of disputes, by virtue of the pseudonymisation generally adopted in this context. Considering the embryonic nature of the blockchain, however, an intervention, that is not definitive, is considered necessary in order to monitor and acknowledge possible developments (European Union Blockchain Observatory and Forum, n.d., p. 33 ff.).

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In the light of the examination of the organizational and financial structure of the Social Impact Bond and the related changes that can be made by virtue of its flexibility, it is therefore possible to identify a comprehensive model of preventive health services, suitable for improving the living and health conditions of the person. It would have an impact, albeit indirect, on the possible emergence and spread of pathogens of infectious diseases, limiting their impact. Strengthening the state of health and the immune defenses would in fact reduce both the risk of contagion and that of serious symptoms with consequent repercussions on vital organs. It would therefore be a question of the provision by the service provider of those services defined as "essential levels of assistance" (LEA) that should be guaranteed to all citizens by the National Health Service. They are identified by the d.P.C.M., 12 January 2017 in three macro-areas corresponding to collective prevention and public health; district assistance; hospital care.

In line with the SIB structure, it is also necessary to determine the group of beneficiaries to whom these treatments, health and non-medical, and on whose outcome the success of the operation depends. In accordance with the intent of the program, the choice should fall on the most fragile and vulnerable subjects to be identified on the basis of medical studies such as the elderly belonging to a certain age group or people suffering from serious diseases.

To this is added the selection of the body for monitoring activities and measuring the social impact which, given the sectorial nature of the social problem, must be composed of competent people in the reference area as well as third and impartial parties to guarantee a neutral and correct evaluation. The control activity, in fact, is also functional to the communication of complete and truthful information to investors during the course of the program.

For the purposes of the implementation of social rights achieved through the positive outcome of the project and the encouragement of these forms of impact investing, it is necessary, as previously stated, to limit the risk of failure which, according to the general scheme, falls entirely on private investors who lack control and management powers. A reasonable sharing of the same with the subjects assigned to the provision of social services is therefore a suitable solution to make them responsible and, consequently, to ensure the effectiveness of the model.

Furthermore, the registration of financial instruments issued on the blockchain and the use of the smart contract tool could be established to automate the return of the invested capital and any remuneration to investors in the event of the production of a positive social impact. These technologies, in fact, if properly regulated, would constitute valid disintermediation mechanisms such as to ensure a reduction in costs as well as greater safety, transparency and efficiency of the program.

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Chapter 4

The Psychological Model of Scaffolding for the Development of the Healthcare Relationship:

Addressing a Contemporary Challenge of Healthcare Systems

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ABSTRACT

Taking into account the current transformation of the healthcare systems in the Western societies, the authors argue that several challenges can be addressed only starting from a relational perspective. In the field of the health practices, psychological vision has been addressed for a long time on single individuals (generally the patients) in order to offer sustain and help to treat their suffering during a disease. In the authors' perspective, being a patient means to take up a positioning within a cultural-normative frame. In this sense, the psychological intervention requires to be directed toward the relational field. The proposal is aimed to present the constitutive elements and tenets of a clinical psychological model of intervention aimed to develop the healthcare relation: the scaffolding for the healthcare relationship. It is based on a clinical, semiotic, and dynamic perspectives of health psychology. By its implementation, the aims of ownership, cum-sensum, sharing decision making, and emotional elaboration are pursued.

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INTRODUCTION. THE TRANSFORMATIONS OF THE CURRENT SCENARIOS OF HEALTHCARE CONTEXTS

Currently, the scenarios of the processes of care and healthcare are undergoing multiple transformations. They involve various dimensions, from medical and scientific to social, cultural, economic and political ones. The breadth and variety of these transformations within westernized societies are such as to assume a systemic scope. Therefore, an approach based solely on understanding the conditions and disease experiences of individual patients is incomprehensible or inadequate for the complexity of contemporary scenarios.

In our perspective, we trace these systemic transformations to two macro-domains: on the one hand, the changes are generated within the same medicine; and on the other hand, they are about the strategic political lines in their effort to offer directives and forms of regulation of what is happening in health systems.

In the first macro-domain, we observe that medicine offers itself as a continuously evolving system supported by scientific research and the development of new diagnostic and treatment devices. The impact of its progress is shown widely and in various areas. There are many and shareable cues of these progresses. Take in account the reduction of mortality compared to diseases considered fatal until a few decades ago (just think, for example, of the life predictions of heart attacks or cancer patients). The same condition of chronicity, for which a person can be considered not curable tout-court, in many cases it can be seen as the effect of medical progress through the implementation of new care and assistance protocols.

Medical conditions that until a few years ago were considered an unfortunate sentence, can now be considered as health conditions within a chronic process. In addition, think also of the increased predictive capacity of contemporary medicine, through which it is able to increase the possibilities of diagnostic tools to predict the future onset of a disease. It is made possible by the new frontiers of medicine - for example genetics - and by the ability to produce diagnoses, often of a probabilistic nature, well in advance of the possible manifestations and onset of diseases. This capacity is made possible both through the precision and deepening of examinations and tests on the individual, and through the increasingly extensive knowledge coming from the extension of epidemiological studies and longitudinal studies on large sectors of the population.

In the other macro-domain, we observe the effort to identify strategic lines aimed at defining in terms of principles, priorities and regulation of social relations within the health system. Here, also, there are typically systemic dimensions that characterize the contemporary scenario. The increased demand for health services, the repeated processes of spending review on health expenditure, the decrease in professional resources despite the increase in demand, the search for forms of supply efficiency and the identification / reduction of waste, etc., all these can be read as phenomena that declare the inappropriateness of old management styles in the face of the changes that have taken place. In fact, health management models in terms of “total care of the patient” seem to show their pachydermal impracticability.

We observe the request for revision of the service delivery model based on the classic paternalistic model based on an asymmetrical arrangement between the physician who possesses strong power and the patient who in a dependent manner entrusts his health to him. Cultural and social adherence to this approach ensures that the doctor carries out his / her activity according to the objective and general knowledge available, without being disturbed by the patient’s idiosyncratic and subjective aspects. This asymmetry is also based on the action of relying on a person at a particularly critical moment in their life (the onset of a disease) towards those who are recognized as competent to deal with such circumstances.

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This relational structure is based on a dichotomous approach between health and disease and the hope of a practice of medicine aimed at *restitutio ad integrum (i.e., return to wholeness).* For several decades, this model has shown its criticalities and difficulties of implementation. To this end, it seems interesting to us to consider the idea of the "*sick role*" in the 1950s. According to the sociologist Parsons, there were four presuppositions that concurred to define a sick person:

1. The sick person is not to blame for his being sick;
2. The sick person is excluded from responsibilities and daily tasks to the extent required by his illness;
3. The sick person has the duty to get back to health as quickly as possible;
4. The sick person must seek professional help.

These criteria can be considered as the collusive basis of an idea of welfare state that assumes the full care burden of the patient during the limited period of illness (in consideration of the fact that the patient has no responsibility towards her condition of illness and she fully relies on the doctor to allow him to carry out medicine mandate).

If we consider the current strategic lines of the political, economic and social agenda, we can observe how the crisis of the paternalistic model of healthcare provision is recognized along a whole series of guidelines and decisions increasingly centered on: prevention, health promotion, healthy lifestyles, empowerment of citizens, increasing of their autonomy in taking charge of their health conditions.

We think of recent documents from the WHO and the Italian Ministry of Health (National Prevention Plan 2014-2018) which centralize the importance in terms of culture and practice of the prevention of the various situations that can favor the onset of diseases and more and no longer the idea of cure and treatment when it has already arisen. Therefore, the notion of promotion and education towards "healthy lifestyles" becomes central (National Health Plan, 2006-2008), as a responsible adoption of attitudes, habits and behaviors considered as preventive and protective (some of the increasingly crucial themes are nutrition, obesity, alcohol abuse, physical activity, the transmission of diseases, etc.).

Consistent with the importance of these aspects, the notion of *territorialization* of health services becomes central, in the idea of a distributed network of health facilities at different levels throughout the territory capable of offering forms of primary care in terms of continuity of care, integration between services and places of life. Within this direction, the political decision-maker and the legislator define the importance of a transition from a '*paradigm of waiting for services*' (for example, waiting for the provision of services in the hospital logic) to a '*paradigm of the initiative*', where people are subject considered active and responsible for their health conditions.

In this way, health promotion is pursued through the structuring of new strategies, such as for example the diagnostic-therapeutic assistance paths, which provide complex interventions characterized by the organization of the care process for specific groups of patients, through coordination and the implementation of standardized consequential activities by a multidisciplinary team.

In this institutional-economic scenario, the concepts of autonomy, empowerment, resilience, empowerment, engagement as relational and psychological processes at the basis of any possible promotion and development of health processes take on more and more importance. The recognition and dissemination of these notions enters not only into the needs of the political and economic agenda but also into the same cultural systems that guide choices, beliefs, attitudes and behaviors.

In summary, on the one hand the developments in the medical discipline, its successes, its progress, and on the other hand the difficulty of supporting old models of healthcare provision, mark a very im-

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portant and crucial moment of transition in the negotiation with demand-offer of care. It is precisely in the intersection and interconnection of these two macro-domains of phenomena that a systemic and complex crisis occurs, which takes the form of a real anthropological break.

In this sense, the proposal to model a psychological intervention in the healthcare context is not specifically aimed at an intervention for an individual subject, first of all, the patient; rather, it is addressed on the relational field in which each participating agent assumes one's own contingent positioning (i.e., patient, general practitioner, specialist doctor, various health workers, nurses, etc.) within the institutional, contextual and cultural trajectories. These general premises lead us to believe that psychological intervention in the health relationship must start from the fundamental observation that the intersubjective relationship in the health sector is built in the dialogue of a relationship already codified and permeated by systems of meaning that have a generalized extension, shared and collusive.

THE MEDICAL RELATIONSHIP: IDENTIFICATION OF SOME RELATIONAL CONSTANTS

In the well-known painting depicting a pipe (*Ceci n'est pas une pipe*, 1928-29), René Magritte places a writing under the image of a pipe, stating that "Ceci n'est pas une pipe" (i.e. " *This is not a pipe* "), showing the divergence between representation and reality (Fig. 1a). The drawing is not reality, the pipe is not real, and the caption - we could argue - works precisely in the exercise of its warning function of not confusing the plane of our representations with something ontologically given or assumed.

The message of this painting offers us considerable opportunities for psychological reflection on a semiotic level, grasping some forms of process in the construction of the meaning of the experience of illness. The disease, in fact, does not exactly correspond to the label that gives it a name, although this fulfills the important and central function of being able to share a meaning, an experience, a system of beliefs (in short, a knowable and therefore shareable and treatable condition).

However, it happens more and more often that through therapeutic advances and successes, the relationship between "disease and name" is intertwined in a very particular way with unprecedented implications. Predictive medicine, for example, can warn a patient and their family of a disease not yet manifested that could show its effects in the near future or in the next 10/20/30 years. On the other hand, think of the spread of chronic conditions in which a patient can experience for many years of her life. How can it be considered? Sick or Healthy? Half sick and / or half healthy?

This condition could be traced back to Fig. 1b in which the pipe (i.e. the object of our representation) is not represented (the dotted line indicates its non-existence) however the caption "*This is a pipe*" invites us to trace and find the object in the background or to look for it despite not showing itself to the vision.

In some way, this is the condition of those who receive a diagnosis (through a genetic test as well) of a disease that has not yet shown any signs and symptoms. The patient will have to build her representation of the disease starting from something that is not there but that she knows (she knows she has, she was told, communicated) starting from the diagnosis. This example is interesting to us for the implications that it allows us to discuss in terms of the ability of the medical relationship to mean the experience of illness and the entire therapeutic path.

The patient, the sick person, the user of a health service, they all are such by virtue of their positioning within a discursive field and meanings that guide the actions, choices and strategies used. The same is true for all health professionals: they perform functions that are regulated by the legislative and

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Figure 1. Magritte's pipe and its semiotic transformations

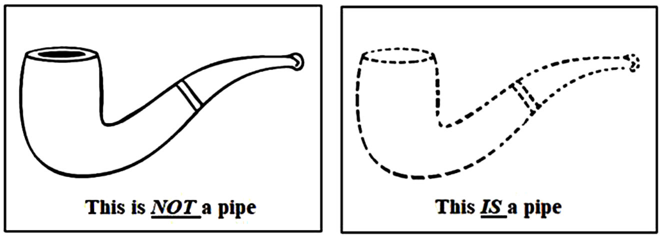

Fig. 1a

Fig. 1b

consensual dimension through which their existence is made possible. It is in this meaning that we place our perspective on the development of principles for psychological intervention in the health sector.

The very forms of pain, suffering, and discomfort are historically determined expressions. This occurs not only through the determination of a norm and a regularity set to measure diversity and deviance, but through the complex organization of a field of meanings that orient the observation, evaluations, cognition and the very feeling of subjects that participate in it, albeit according to their different positions.

The patient role is constructed through a relational discursive domain that defines it; the disease takes shape within a diagnostic system that certifies it.

Therefore, it becomes essential to define the characteristics of the health relationship (which field of meanings) within which the intervention is articulated.

Medicine is a practice that is established starting from the relational asymmetry of the subjects involved. The doctor and the patient are constituted precisely by virtue of their difference. The one who "*does not feel well*" demands for a doctor as the holder of a double knowledge, the "*know what*" and the "*know how*".

Relational asymmetry is linked precisely to the doctor's ability to functionally articulate theory and practice, guided by a specific, time-limited objective: diagnosis, prognosis and treatment. Without this specific relational dimension, medicine as a cultural and social practice cannot establish itself and be realized. In fact, it is this that leads to turn to the doctor and to assume the intersubjective positioning of the patient, whose condition is first of all that of trust, given that one's own resources are not considered sufficient to overcome this phase of life.

The term trust indicates a pact, an act of faith "of unconditional adhesion", implying an emotional dimension of absolute devotion and prostration even in the absence of tangible signs (Gleijeses, Freda, 2009a). The patient then through the medical consultation seeks reassurance (that is, that he will be able to do it) and sufficient causes (when not necessary) to explain her condition as a patient. We have on the one hand the doctor with the duty to manage the treatment, on the other the patient with the right to be treated in the best possible way.

The specificity of the medical relationship and its emotional and symbolic intensity are experienced and shared by all the subjects. An aspect seems important to underline: medical relationship and its practices involves the patient's body (during diagnosis and treatment). This element seems particularly significant to us because in our culture and in the symbolic system that regulates relationships between people, the permission and legitimacy to have to do directly, very intimately and deeply with the body of another person is granted to only three relationship systems:

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1. The care relationship between the caregiver and the infant;
2. Consensual sexual relation;
3. Medical practices by those who are recognized legitimized and authorized as competent in this area.

The medical intervention, precisely because of its specific competence of "action on / in the body", brings with it from the beginning, the difficult management of a fleeting border between the meanings of care and violence, care and bullying, development of self-determination of person and threatens her autonomy (with the imposition of obedient behavior). The affective dynamics in the health relationship is strongly characterized by the relationship of trust, benevolence, hope and therefore, conversely, also of mistrust, fear, anxiety, uncertainty and feelings of being abandoned.

The intense affective value of the medical relationship, although always experienced as a subjective emotional experience, unique and in the first person, is primarily a function of the relational structure itself. It often shows itself as an affective polarization, generating one-dimensional evaluations and considerations, the establishment of relationships that suddenly pass from the need for reassurance to the need to defend oneself and avoid the experience of painful (both for the doctor and for the patient). The intense affective activation (for example of fear, anxiety, uncertainty, disturbance, restlessness, disgust, etc.) generates an affective disintegration in which the different emotional connotations are all experienced moment by moment as intolerable, and violently invalidating the very possibility of generating alternative and possible interpretations. The emotions that run through the health relationship are built from the same object of the relationship

The "difficulty in thinking" is always inherent in a medical relationship supported by precise rules and by the continuous sense of urgency that requires action (Clerici & Veneroni, 2014). It happens that the meanings are directly "acted out", that is, the medical relationship (the vision of the world that it conveys and the relational-contextual proposals that organize it) is translated into immediate actions, due to the emotional joint pressure that doctor and patient exert in this direction. The health relationship often translates into the immediate coding of diagnostic labels and therapeutic responses to cope with the anxiety generated by uncertainty. The waiting and lack of knowledge in the health sector take on the guise of fallacy and guilt.

In our opinion, this intolerance to the condition of uncertainty cannot be interpreted by reason of an implicit violence of the medical power on the fragile subjectivity of the patient: rather, it is the result of a dialogic dynamic in which the patient first of all participates with her need to delegate the problem, her urgency feeling of reduce anxieties. The emotions - we are talking about - are not, therefore, those that belong to the individual components of the relationship, the emotions of the doctor, the patient, the child and / or the parent in pediatrics. We are talking about the emotions that go through the relationship. Containing and elaborating this emotionality is not the task of one of the interlocutors; it is the task of the whole relationship itself.

THE FORMS OF COEXISTENCE OF PSYCHOLOGY AND MEDICINE IN THE HEALTH RELATIONSHIP

The social mandate of the medical discipline (Carli & Paniccia, 2003; Salvatore, 2016; Salvatore et al, 2017; Freda & De Luca Picione, 2017) has a strong and stable character, and it does not require to be

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legitimized from time to time for every single occurrence. Medical scientific research itself and the efficiency of care systems are considered indicators of a society's well-being and development.

The history of medicine (Canguilhem, 1963; Cosmacini, 2011, 2008; Federspil, Giaretta & Moriggi, 2008; Foucault, 1988; Gmerk, 1995-99; Laplantine, 1987; Shorter, 1985) - from the Enlightenment onwards - preserves and reiterates the faith in progress, in the development of knowledge and in the implementation and invention of new therapeutic techniques and discovers.

Although in the last centuries different scientific paradigms have followed one another - from mechanistic, anatomical, surgical, physiological, microbiotic, pharmaceutical (and now we are in the age of genetics) - medicine discipline is not questioned in its function of social utility. Indeed, it has shown itself as a discipline capable of renewing itself, strengthening itself and achieving new successes starting from the breakdown of certain convictions and the establishment of new scientific visions and paradigms (Kuhn, 1969).

In the social representations of Western culture, the patient goes to the doctor to be treated, and this must be done in the shortest possible time, with the lowest possible cost and with maximum efficiency. On the other hand, the patient is in some way not totally assimilable to the highly specialized medical discourse and that there are spaces of his experience of illness that, even if exceeding the discourse of medicine, can be welcomed with profitability and increased well-being.

Therefore, we simultaneously have two different directions of meaning that start from the same point: on the one hand, there is the desire for an efficient medicine without too many frills - fast, practical, decisive-. On the other hand, the observation that the patient is no longer only a body, but a unique human being who must and wants to be listened to and understood in her life experiences. The question that departs from this polarization of perspectives is now considered as a classic *vexata quaestio*.

On the one side, we have the reference to the need for humanities in the medical field (with reference to the emotions and subjective experiences that the patient experiences). On the other side, it seems difficult to dialogue with an evidence-based medicine approach based on evidence of efficacy in which the evaluation and systematic use of contemporary research results are the basis for clinical decisions (Sackett et al, 1996; Timmermans & Mauck, 2005; Greenhalgh, 2010).

How is it possible to relocate these two trajectories in dialogue? How can psychology offer intervention models to support a dialogue in which neither the medical operation nor the subjective component is lost?

We believe that an approach capable of reading the field phenomena from a systemic perspective may be able to provide intervention proposals based on relational, cultural and semiotic units of analysis and intervention.

From a system perspective, attention turns to grasping the symbolic forms and the different and various representations shared by the participants of a system. From a system perspective, meanings are not ontological, pre-assumed and defined entities to which people conform, rather they are devices of cognitive, affective, relational and agentive regulation that act in contextual terms (Salvatore, 2016; Valsiner, 2014, 2021; Salvatore et al, 2021a, 2021b; De Luca Picione, 2015, 2020a, 2021a, 2021b).

The same so-called emotional factors cease to be considered as innate and natural expressions of the human being. People are seen as interacting subjects within cultural symbolic frames. The same forms of pain and discomfort manifest themselves starting from the encounter of subjective experiences with culturally, historically, socially and anthropologically mediated forms. Pain, suffering, but also hope are not purely individual and solipsistic data but are the same forms that the patient's subjectivity takes within the system of meaning available in the health field itself.

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In the absence of a systemic and cultural framework for the observation of intersubjective dynamics, our gaze falls on more restricted circumstances than human phenomena, with the significant effect of producing psychological models of intervention characterized solely in individual terms. We define these operational models as '*algebraic models of intervention*', since the relationship between the medical and psychological disciplines is based on the addition and / or subtraction of different areas of the disease experience to be treated. That is, the experience of the disease is fragmented, divided by defining specific skills for the treatment of each part.

That is to say, for the physical disease **M** we administer the drug **F**, and for the suffering **S** that arises from this procedure **(M-F)** we administer the psychological intervention **Z.**

Note that (**M-F**) is to be read as: "Physical disease minus the drug", that is to say "the difference that advances from the treatment of physical disease after the administration of the drug.

If this reasoning has its own plausibility, the psychological intervention **Z**, then, it is the response offered to the single individual to the difference, to the gap generated by the same medical model that fails to respond totally to the disease**: Z→ S (M / F).** The psychological intervention **Z** is used to treat the individual suffering of the soul **S**, which remains unresolved when the Physical Disease **M** is treated with the means of medicine **F**.

Consider, for example, the interventions aimed at supporting the patient's self-efficacy, her motivation, the expression of emotional experiences and the elaboration of the mournful experience of the disease. Without reducing the importance of these objectives, however, they are often realized, in a generalized way due to the mere presence of the disease condition, in the frame of an individualistic approach, in which the individual patient is considered as the exclusive recipient, her inner world, her specific cognitive capacity, her resources to cope with the critical event.

It is worthy to note that the psychological intervention in the healthcare relationship always occurs within a context of already given and organized meanings, and thus within this context it is constituted. If we do not consider psychological intervention through a critical and reflective perspective, we observe that it often risks of being engulfed by the cultural discursive logic that requires it and invokes it. These considerations lead us to re-consider psychological intervention according to a procedural and system perspective, addressed to the way in which the processes of sensemaking that orient relational and choice systems are organized at the same time. We are not saying that the psychological interventions described above are useless or harmful, since in some phases of the diagnostic and curative process they prove to be functional and capable of supporting and helping the patient. Yet, they must not be considered as absolute, a-contextual and exclusive solutions, based on the reductionist logic of the individual recipient.

If the perspective is a-contextual and individualistic one, it can happen collusively - for example in psychology interventions in collaboration with medical teams - that psychology is involved only as a *residual function,* i.e. aimed at the release, treatment, temporary management of those areas of the person that are considered problematic. At best, psychology is summoned to support and develop specific areas of a context or to lubricate some jammed relational mechanisms (without it being able to intervene on what already "works well"), while at worst psychology is called to distinguish what is good and what is bad in order to eradicate any dangerous or obstacle mechanism.

Thinking about psychology in a healthcare context raises the question of how a psychological intervention can be organized that is not the simple provision of a service of assistance to an individual, but directly interacts with the discursive and meaningful field in which it is involved.

Medicine and psychology are two disciplines that in the performance of their function operate through different models. In fact, medicine responds in a normative, technical and procedural way (Carli &

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Paniccia, 2003) based on the mutual reinforcement between social mandate and common sense. While psychology (in its role as a discipline aimed at developing the ability to signify one's own experiences and relationships in which one is involved) operates through the understanding and discussion of what is happening within the relational contexts and the perspective position that people assume within them.

Within a medical perspective, the intervention is not questioned from its origin (except for technical evaluations within the intervention itself, in terms of usefulness, feasibility, time of action). The psychological perspective - in its semiotic guise aimed at the dynamic processes of sensemaking (Salvatore, 2015, 2016; Freda, 2008; De Luca Picione, 2015, 2020a, 2020b) - carries out its intervention starting from the reflection and discussion on the construction of the interpersonal relationship, on what it is happening in it. In doing that, Psychology trying to contemplate all those aspects considered useless, residual or obstacles because they are not directly connected to the carrying out of the health task.

This diversity of vision implies a not immediate and easy solution in proposing a psychological intervention that does not distort the meaning of medicine and psychology. The end of the psychological intervention is the *integration of the task of the health relationship with the multiple meanings* activated and acted upon through it. Integration is clearly something different from a summative operation. Integration becomes the result of an effort to understand and signify what is happening in the healthcare relationship and not the initial assumption of a rigid redistribution of tasks and duties (the body to medicine and the mind to psychology).

TASKS OF DEVELOPMENT OF THE HEALTHCARE RELATIONSHIP IN A SYSTEM PERSPECTIVE

In light of the various systemic transformations of healthcare scenarios and the importance of interventions that are not aimed exclusively at the individual, it becomes important to trace conceptual as a guide for the strategic actions to be implemented. These organizers must offer guidance for the definition of psychological intervention consistent with a vision of the healthcare relationship as an intersubjective, systemic and culturally characterized organization, which is expressed in procedural terms within a local dynamic.

We define four specific development tasks, the pursuit of which fulfills the function of orientation for the intervention within the complexity of the current healthcare scenarios: *ownership, cum-sensum, autonomy and elaboration* (Fig. 2).

In general terms, psychological intervention in the context of the healthcae relationship is aimed at the implementation of these tasks through the development of expansive semiotic processes of construction and translation of the meanings that it itself instances.

We deal with the four tasks one at a time:

1. The *construction of the ownership* of the healthcare relationship is aimed at moving from a position of mere use of the service to the development of subjectivity within a relationship. Ownership is understood as the recognition of a situated point of view, in relation to the disease event and the actions necessary to cope with it. The construction of ownership considers that the protocol dimension of the medical relationship does not have a repressive-suppressive character with respect to the needs (values, life contexts, preferences) of the person, rather it is a moment of singular construction and of taking one's own point of view within the intersubjective context of belonging.

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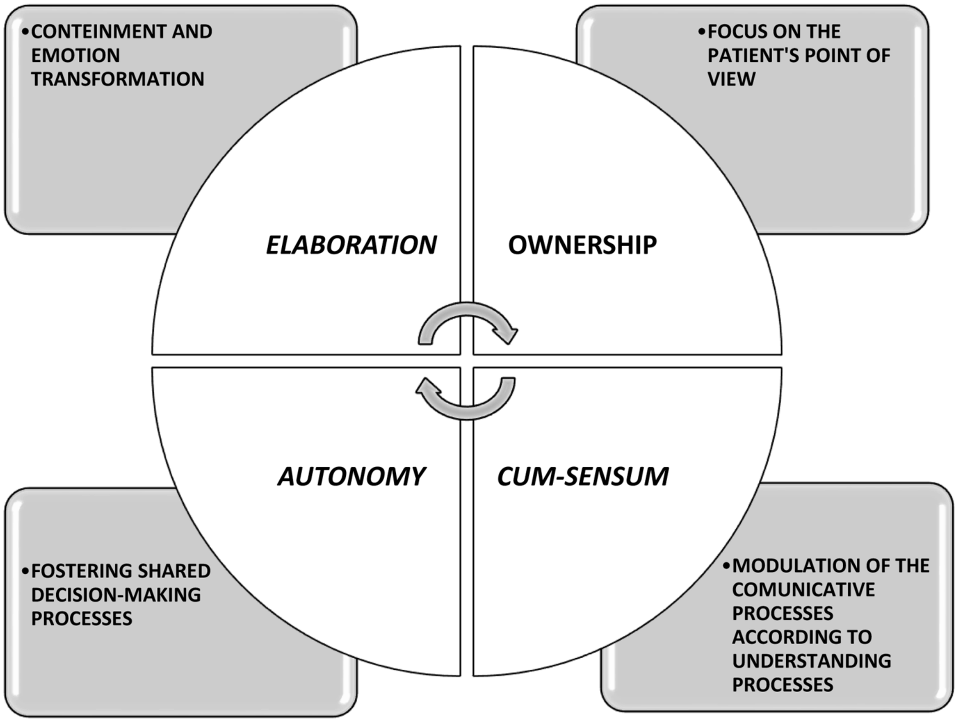
Figure 2. Tasks of psychological intervention in order to foster the development of the healthcare relationship



2. With the *cum-sensum* we mean a movement aimed at transforming the informed consent (as a disclaimer by the doctor for taking in vision the health treatment) into the development of meaningful resources. This process is aimed at transforming the information and contents of the healthcare relationship into meaningful resources that are understandable and usable by the various protagonists of the relationship according to their different purposes. Informed consent is not a moment of mere passive passing of information (which ends in the acknowledgment and affixing of one's signature) but a progressive expansion of the meaning of one's own experience of the disease and of the diagnostic-therapeutic process. We move from an ingenuous-naturalistic vision of dialogue (as a natural condition that is established between people who exchange information) to a study of the dynamics and semiotic foundations of dialogue (as a way of constructing interpretative models and agentive models of one's experience starting from the relationship with other points of view).
3. The development of autonomy is an active process that gradually shifts from the assumption of therapeutic adherence and compliance towards shared decision-making and concordance in the treatment processes. It aims to:
   a. Identification of useful strategies to treat and elaborate the cognitive delegation usually assumed by the doctor in the health report.
   b. Elaboration of the user's dependency condition.

It is a matter not only of taking a perspective, rather of participating in concrete choices and of entering in the circuit of distribution and assumption of responsibilities. Decisions are not only made on a

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super partes algebraic criterion of costs and benefits, or of epidemiological probabilities of success and risk. This task is reached through the inclusion in the decision-making process of what a certain choice means and implies for the patient, her life, her family and relational context.

4. The *elaboration of experiences* related to the illness becomes a task whose realization is always contextualized within intersubjective and cultural frames. This task has a double direction. On the one hand it recognizes the importance of containing and welcoming affects, as embodied matrices of psychic life (Salvatore et al, 2021a, 2021b; Salvatore & Freda, 2011). On the other hand it intends to offer a symbolic frame to the experience of loss and trauma that a disease always implies. It is central to recognize the value of the elaboration of affects, since this reflective task translates into an increase in the dimensionality of the experience, otherwise all aspirated into a dynamic of acting out and in fixed forms of evaluation of the experience. The elaboration of affects allows you to restore relational, dialogical and decision-making flexibility of all the participants in the relationship.

Within such an orientation, the psychological intervention cannot therefore aim at clarifying the contents of the healthcare relationship through the "cure" of communication processes (such as passage, transfer of information from the doctor to the patient for therapeutic purposes, and from the patient to the doctor for diagnostic purposes). The communication process is always the outcome of a semiotic process that helps to re-configure and shape the same relationship. Arranging a psychological intervention in the healthcare context means first of all grasping the transformative and dialogic dynamics of the medical relationship, rather than constructing a static representation of the same as constituted by well-defined rules and behaviors to strive for or to enforce.

SCAFFOLDING AS A PROCESS OF SEMIOTIC REGULATION OF A RELATIONSHIP

In light of the above, we define the guidelines for the preparation of a psychological intervention in a healthcare context:

1. Analyzing each healthcare relation according to its task (which is the condition that establishes it and which cannot be neglected at any time);
2. Exploring the configuration that the field assumes due to the multiple systems of signification that emerge;
3. Identifying the areas of perturbation generated by the confrontation / clash of sensemaking processes that outline areas of uncertainty within which behaviors and choices can be oriented in different directions.
4. Promoting the integration of the different and multiple sensemaking processes in the management of uncertainty;
5. Supporting and fostering the development of new sensemaking systems for guiding practice.

We define *scaffolding* in the healthcare domain as a dynamic intervention model aimed at organizing support and building an integration between the medical system, the patient's subjectivity, her family

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system, the social and cultural context. The support, built through psychological intervention, is centered on the integration of the different systems of meaning that are produced and transformed in the healthcare relationship. In this sense, the scaffolding process is a semiotic translation process (Lotman, 2005) which favors the comparison between different cultural and discursive codes (specialized medical speech, common sense medical speech, patient's subjective affective speech, family speech, etc.).

By focusing on the multiple systems of signification that cross the healthcare relationship, the scaffolding intervention is aimed at promoting the integration of psychological functions and tasks within the healthcare practice. *Ownership, cum-sensum, autonomy and elaboration* are purely psychological and relational tasks that can only be contemplated by inscribing "passages" in the same healthcare practice in which it is possible to consider the multiplicity of points of view and the way in which they contribute to configure the context. This goal requires a continuous work on the uncertainty that naturally arises within the healthcare relationship.

Scaffolding in the psychological tradition is that theoretical and methodological construct aimed at understanding the processes of development and learning through the mediation and support of an expert figure. This idea, first introduced by Vygostkij (1978) through the concept of a zone of proximal development, was later developed by Wood, Bruner and Ross (1976), who used the term "scaffolding". It is a way of conceptualizing development and learning processes, recognizing the importance and centrality of the function performed by adults in organizing their activities with children. Generally, mothers guide the attention of their children to the sequences of actions to be implemented, and they support the children's effort towards actions that at first they are unable to perform completely on their own. In fact, mothers take on the same function of a scaffold thanks to which the child can achieve a goal through gradual phases that make it achievable. It seems important to highlight how both the concept of proximal development zone and scaffolding emphasize the role of the relationship in making a competence development process possible.

This process is certainly recognized and valued in the same psychoanalytic perspective. Think of the *alpha function* introduced by Bion (1962) to define the process of digestion and elaboration of emotions by another psychic structure (generally the mother in the early stages of life of the child) which accepts and welcomes (as a container) the projective identifications of the infant. Then the mother returns back more elaborated and thinkable psychic objects (i.e. representations, symbols, images, etc.). It is worthy to observe that the effect of this process does not end in the immediate consumption of the processed object, but involves the development of the same "*psychic apparatus for thinking*" by the subject who has used the elaborative function of the other elder.

In this sense, the notion of Scaffolding, in reference to the medical relationship and the role of the psychologist in it, implies the reference to a learning model by gradually increasing the skills of the subjects who participate in it. We therefore start from the consideration that we are dealing with the interaction between an expert (the psychologist) and a developing intersubjective relationship (that between doctor and patient) with respect to its ability to integrate psychological functions.

In the building language, scaffolding is a temporary structure intended to support the workers and the materials needed for the execution of a work, as well as to give access to all work points. In the healthcare domain, the scaffolding function constitutes a temporary structure:

1. It supports the protagonists of the relationship in their ability to give voice and listen to their subjectivity and reciprocal positioning;

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2. It supports materials, understood by us as discursive codes, but also the introduction of actions to transform the practices that can catalyze some psychological functions;
3. It supports the healthcare relationship, as a whole with respect to its ability to have access to all points, understood by us as the ability to deal with the different systems of signification.

METHODOLOGICAL TENETS OF THE SCAFFOLDING PSYCHOLOGICAL INTERVENTION MODEL FOR THE HEALTH RELATIONSHIP

The scaffolding model assumed as a conceptual organizer for psychological intervention in healthcare settings is based on some methodological tenets that allow us to recognize the processual nature of the field of healthcare relations:

1. The bivariate relationship between health and disease
2. The orientation to the future
3. The integrative nature of the model
4. The consultative nature of the model
5. The contextual and local nature of the setting

The Bivariate Relationship Between Health and Disease

Our model of psychological intervention implies the shift from a dichotomous and polarized view of health and disease towards a dialectical and bivariate view (Bertini, 2012) (fig. 3). This means recognizing that the relationship between health and disease is not given once and for all but is always a function of contextual conditions, of the ability to use available resources (scientific, social, economic, cultural, etc.) and to deal with the limits imposed by difficulties and obstacles. Therefore, like any development process, there are inevitably fluctuations, crises and potential reorganizations. Health in this perspective can become the "way" (no longer the "means", and no longer the "end") with which people face difficulties, crises and obstacles day after day (Freda, De Luca Picione, Nedergaard & Salvatore, 2019).

Every vital process (in its complexity and biological, psychological, social and cultural interconnectedness) is always characterized in dynamic terms. The conditions of fixity, stasis and hypostatization are characteristic of all forms of discomfort and suffering (physical, psychic, community) that sclerotize the relational ties between people and their contexts. Therefore health and illness should be read as processes that present fluctuations and continuous re-equilibration and rearrangements in the same way as any development process that presents moments of crisis and rupture in order to reorganize new forms of relationship with the context, whose the prerogative is flexibility, transformation over time, contextual plasticity, continuous restructuring starting from its fractures, crises and discontinuities.

The Orientation to the Future

We believe that the scaffolding model responds to a logic of the "goals-oriented-to-the-future" type of human behaviors, choices and relationships. In fact, human action and the processes of thought and signification cannot be defined as "states" generated purely by past conditions. Rather, they always have a proleptic value that is oriented towards the future (De Luca Picione, 2020a, 2021a, 2021b, 2021c). This

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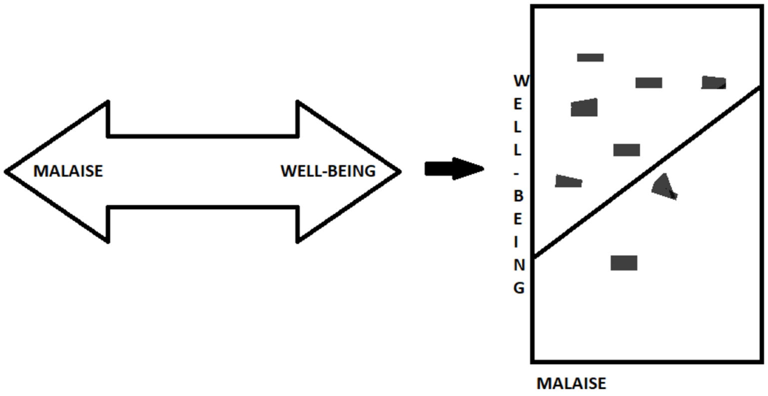
Figure 3. From an antithetic conceptualization to a dynamic perspective



openness to future is characterized by the fact the real outcomes are never exactly predictable and there is always an element of anticipation on the part of the subjects in interaction (Valsiner, 2005; Salvatore et al. 2021).

The Integrative Nature of the Model

The principles and methods of this model of psychological intervention lead us to consider the use of the scaffolding function as an "integrative model of psychological intervention". This model obviously distances itself both from the algebraic model ("by sum and difference" - which we defined previously) and from conceptually holistic models that consider the unity of the person as a fundamental and *a priori* value. The integrative model of psychological intervention that we propose differs from a holistic framework because we believe that the integration of the different meanings that organize relationships is a purpose to be achieved (obviously defined contextually) and not the starting premise of human experience.

The integrative intervention of scaffolding with the sensemaking processes in treating the constitutive uncertainty of development and therapeutic outcomes therefore combines the centrality of the operational task to which the healthcare relationship is called with the centrality of the emotional task to which all its participants are called. Medical functions meet and intertwine with processes of a psychological nature, which by their nature are relational, local, transitory and contextual.

The scaffolding function is well suited to the tasks generated by extremely complex situations and extremely rich in variables. The management of variability and uncertainty assumes a central importance. The multitude of stimulations and information coming from the context make it necessary to interpret and develop processes of meanings that can act as a guide, in terms of learning, of realizing habits to signify experiences but also to transform and build new domains of action and interaction. The scaffolding intervention model acts alternately over time both as a *reduction* of complexity (focusin on the task of the health relationship) and as an *expansion*, translation, transformation of the emotional aspects, recognizing them and putting them back into play in the same relationship, thus enlarging the complexity and intertwining of the situation.

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The Consultative Nature of the Model

The consultative nature of the model immediately clarifies its temporary aspect. The intervention is destined to end. The scaffolding must in fact be gradually subtracted. Scaffolding does not lend itself to being a continuous and / or infinite process, but as a consultancy and a temporary relational mediation, after which, in a consensual and participatory manner, the psychological intervention moves towards the dissolution of its function. Scaffolding as a temporary consultancy must not risk making the psychologist figure static but must allow the introduction and acquisition of a new function within the process. Retaking to the metaphorical view, we say that the scaffolding can be dismantled because the support has been internalized as a function. In this sense, scaffolding by developing relational skills in the direction of autonomy and meaning experience, performs the function of developing the semiotic capital available to the health relationship in terms of variability and flexibility (Salvatore et al, 2021a). Using a dynamic perspective implies that its genetic and transformative aspect becomes a central aspect of the model.

The integrative model of scaffolding for the healthcare relationship assumes that a "good healthcare relationship" is not by definition a competent relationship from the beginning. Rather, one must work towards developing the skills of its subjects in giving meaning to what is happening, in restructuring the meanings starting from the reflection on one's own positioning and on one's own emotional experiences. We do not enter as an "autonomous" subject in a healthcare relationship, but we work towards autonomization, towards shared decision-making, towards shared consent.

The psychologist – in its role - is a participant in the relationship, involved in the development of the relationship. The function as a facilitator of the sensemaking process is carried out through the non-pre-established step, by a work of joint listening, and raising issues and demands. Scaffolding is to be understood not as a defined procedure of sequential phases to be implemented, but as a dynamic model, based on the principles defined above, which, depending on the specific transitory or quiescent state of the relationship, carries out an integrative sensemaking process

The Contextual and Local Nature of the Setting

The consideration of the affective dynamics in a semiotic and relational key implies that it is not possible to treat the intervention model of psychological scaffolding for the healthcare relationship through the description of precise organizational and protocol intervention. Rather, as we are doing, it is necessary to refer to methodological and orientation functions, which can then take on specific organizational shapes and structures due to the contexts and problems they are called upon to deal with. Facing with this variety, however, it is possible to propose the need for dynamic methodological functions. They are of an oscillatory kind, in which moments of suspension of the productive action alternate with moment of promoting pragmatic choices and behaviors. The oscillating trend between thinking and doing organizes the relational context and the practices that are part of it as an object of reflection. Gradually, during the intervention process, it is possible to negotiate transformations of the same practices and / or the introduction of new practices useful for supporting an integration of psychological functions according to specific and variable methods according to the different health contexts. We proceed towards the possibility of "thinking" a "doing" in a perspective oriented to "accommodation" (and not just to "assimilation"!). This therefore orients to transform the way the relationship works.

In a research-intervention project aimed at supporting the relationship between pediatricians and families in the management of genetic metabolic pathologies, a relevant outcome has been achieved with

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the pediatric team in order to introduce a modification of the diagnostic communication practice. The purpose is synthetically expressed by the "*Back together on the diagnosis*". This change had the main function of transforming the diagnostic phase from a specific "event" to a "process". It has been possible to open a space to accommodate the questions and anxieties of parents and reduce the phenomena of medical exodus through the establishment of a second pediatrician-family interview after a short period of time from the first diagnosis communication. This project was realized by a direct collaboration between medical and psychological professionalism, (Freda, Gleijeses, et al. 2008; Glejieses, Freda 2009).

The scaffolding for the healthcare relationship does not start from the destructive attack of the constitutive asymmetry of the medical relationship. This model recognizes the importance of relational asymmetry (in terms of knowledge and positioning) between doctor and patient, of the expensive psychic work of treating uncertainties, of safety needs and directivity of the doctor and correspondingly the patient's need for custody and search for reassurance. It works in the direction not so much of the symmetrization of the relationship (in which the decision-making powers of the doctor and the patient come to clash). This model works in the direction of participation, of dialogue, of confrontation, of putting into words feelings, expectations, uncertainties, disappointments, hopes for the purpose of a participatory construction of consensus in therapeutic planning.

As already expressed, therefore, this requires that the psychological intervention is not addressed at the single individual; rather, it is addressed at joint action settings in those crucial moments and passages of the same relationship that can be the object of reflection and mediation between the different instances. We think of the moments of construction of anamnestic and diagnostic processes, the moments of delivery of a diagnosis (or of a particularly significant examination result), the moments of genetic counseling (Freda & Guerra 2012, Zaccaro & Freda 2011, 2014), the moments of evaluation and therapeutic choice (Freda, et. Al, 2014), or follow-up moments, etc.

These are all moments of particular centrality in which there is a great emotional ambivalence and in which multiple scenarios of meaning (as opposing frames of meaning) make it difficult to continue and develop the healthcare relationship.

The central aspect lies in considering scaffolding as an intervention for the development of the relationship and not as mere assistance to an individual. The purpose of psychological scaffolding is not only to provide support; rather, it is to work jointly in the direction of acquiring psychological and relational functions.

CONCLUSION: FROM THE REIFICATION TO THE REVITALIZATION OF SEMIOTIC PROCESSES

Faced with the disease, people experience a crisis of continuity of their systems of sensemaking, of their social and professional routines, and a discontinuity of their relational and affective ties. In general, a person struggling with an illness experiences a biographical event of discontinuity that puts his own subjectivity into play. We generally call this moments as turning-points (Bruner, 1990), rupture (Zittoun, 2006), liminality (Stenner, 2018; De Luca Picione & Valsiner, 2017). One of the greatest difficulties experienced by those suffering from an illness is the difficult to maintain the process of signification of this experience. This particular period is strongly amplified by the anguish of death, by the anxiety of no longer being useful, by not feeling one's own body, by the possibility of seeing their identity and affective ties disconnected.

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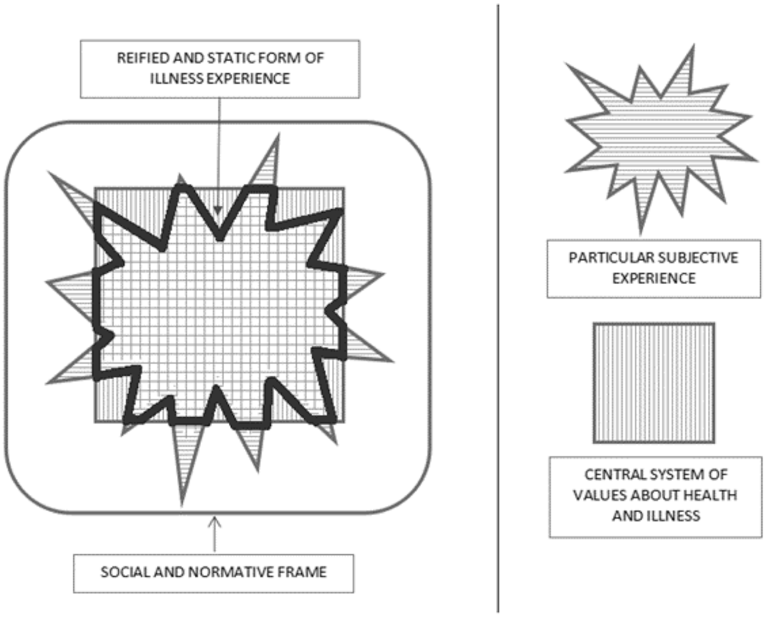
Figure 4. The reification of one's own experience of illness within a rigid normative frame
(De Luca Picione, Dicè & Freda, 2019, p.119)



This difficulty somehow represents a real developmental task for the sick person (Freda, De Luca Picione & Martino, 2015; De Luca Picione, Martino & Freda, 2017). A disease diagnosis – by means of naming the disease – generally performs a double function. On the one hand, it generates relief by enclosing under an ordered and shareable label a set of symptoms that until then were manifested in an incomprehensible and apparently chaotic way. On the other hand, the diagnosis, within the affective-cultural coordinates of the subjects involved, carries out an action of reification, or objectification of the disease, risking saturating the sense of the disease experience within the system of already available meanings and data.

The methodological orientation of the scaffolding intervention to the healthcare relationship puts in place psychological processes of mobilization and flexibility of what are the general categories of significance of health and disease. In fact, it is a matter of transforming reified systems of meaning into flexible and dynamic processes of sensemaking, that is, processes capable of creating, organizing and expanding the dynamics of signification.

In Figure 4, we observe how within a closed normative framework, the field of experience of the disease is subsumed in the general categorical domain. This classification contributes to implement a reified vision of one's own experience of illness. Yet, all the singular forms of this experience are not recognized and they remain outside the rigid boundaries of the system of values that inform the definitions of illness and health. The signification of one's own experience is blocked in the time (in some way it is already defined and prescribed by the reference system and its values). Namely, one's own experience is reified in a static and inflexible way, closed to any further developmental passage over time.

In Figure 5, a temporal dynamics of integration is presented between the subjective instances of one's own experience of illness and the general system that conveys medical values (on illness and health). The two fields (the subjective and the general one) in a continuous process of comparison, dialogue and

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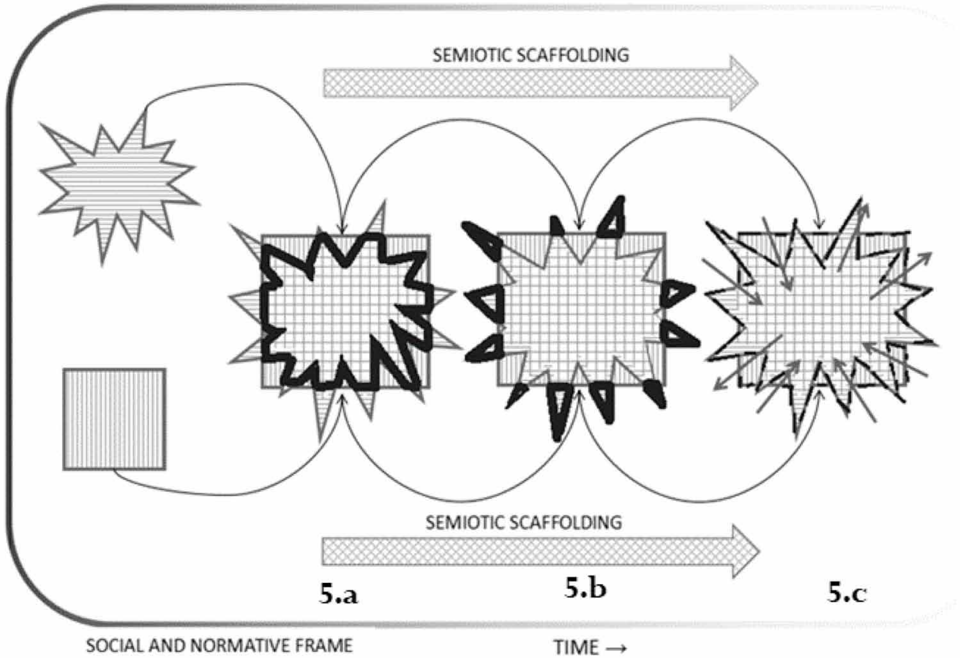
Figure 5. Enlarging semiotic process by means the psychological scaffolding
(De Luca Picione, Dicè & Freda, 2019, p.119)



reciprocal translation give rise to different forms of interaction over time. Starting from a form of inclusion of subjective experience within the general value categories (Fig. 5a), we move on to the recognition of singular subjective instances that go beyond the narrow boundaries of the general value system (Fig. 5b). A further step is that of a new form of integration of the subjective field and the general medical field (Fig. 5c), in which a new relational form is reached. Here the processes of signification realize a semiotic expansion capable of giving rise to open contextual and flexible forms. In this step, the same broader regulatory framework is not closed as in Figure 4; but it is redefined through the same form of integration achieved. In other words, it is no longer a generalized implicit "taken-for-granted" form but a contextual starting point for the reorganization of one's social relations.

This dynamic movement of development finds its possibilities of development thanks to the support of the psychological scaffolding offered to the health relationship. The methodological principles and intervention actions of scaffolding operate exactly on the relational field and the relationships themselves rather than on individuals taken in isolation. The position of "thirdness" of the psychologist (Salvatore et al., 2021) within the context of the health relationship fulfills this function of catalyzing, facilitating and promoting (Cabell & Valsiner, 2014; De Luca Picione & Freda, 2014) of the semiotic process of signification.

The psychologist in the healthcare context - engaged in the implementation of the scaffolding process - does not occupy only a residual function of listening and pure containment of the anxieties, fears, uncertainties of the individual patient or healthcare professionals. Rather, she assumes a role of integration between the plurality of multiple participants and different points of view.

Relational participation is promoted and supported through the centrality of semiotic processes of a dialogic and discursive nature. In this sense, the principles of *ownership* (recognition of the point of

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view), of the construction of "*cum-sensum*" (resource of shared meaning), of "*sharing of decision-making processes*", and of *affective elaboration*, all can be achieved gradually. This achievement requires the complex operation of recognition and transformation of the subjective, cultural and emotional dynamics that cross the normative field of the healthcare relationship.

It is worth to remember that these principles cannot be considered the starting point of the healthcare relationship, but an outcome that is realized starting from the development of specific dialogic and relational skills that all the participants in the relationship are called and supported to implement. Two different intervention logics are called upon to interact simultaneously.

The medical logic, founded on the provision of a competent professional action oriented to an outcome of care and healing, moves from a perspective that prioritizes the action and successful performances. It treats the environment as a product of the action exercised on it. The doctor's action is always and necessarily based on the conditions of an established agreement (an agreement taken for granted).

Psychological logic assumes a perspective that overturns the terms of this relationship. It is a logic in which practices are the product of a context of the socio-symbolic processes that run through and found it. This logic is able to tolerate and develop the contradictory and conflictual relationship between these processes. It is a vision aimed at the progressive clarification and sharing of the premises rather than at an action within them.

The support for the process of signification of the experience of illness - as a development process - does not imply a relationship of mutual exclusion and / or impediment between the logic of medical intervention and logic of psychological intervention but the search for a contextual integration of the two perspectives. Development concerns the process of sensemaking rather than the reification of individual meanings. It becomes central to promote processes of sensemaking that are capable of "recognizing" and enhancing contextual and subjective variability.

In terms of the expansion of the semiotic process, it is important to note that the development of sensemaking does not consist in changing the content of the system of signification, but in its overall ability to increase the degrees of freedom through which the experience is interpreted. The scaffolding intervention does not aim at the transformation tout court of the practices of the healthcare relationship. Rather, it enables to accept elements of environmental variability that arise both in the variation of the different health conditions and in the variation of the subjective perspective introduced by the individual patient.

The desired result does not focus on good or bad meanings, but on the reduction of automatic and protocol forms of giving meaning. It leads towards autonomous, broader and more flexible forms for contextual purposes that can be defined in a shared and participatory way. Then in this scenario of gradual semiotic expansion, the conditions of disease, health and well-being abandon their hypostatized meanings and they are transformed into articulated construction processes due to the ability of the relationship to achieve its goals and to deal with the critical passages of this process. .

The aim is to let the general categories of disease, health and well-being (supported by the medical discourse and by the normative social framework) able to find concrete singular and contextual forms without that implying an impoverishment of the subjective experience. Rather this semiotic development can enhance the value of these categorizations, their idiosyncratic aspects, the construction of new ways of relating and the gradual autonomization.

In contemporary scenarios, where chronic conditions are increasingly widespread and growing, the recognition of these semiotic dynamics connected both to the diagnostic / prognostic / therapeutic processes and to the psychosocial implications assumes a strong relevance. The risk of stiffening and

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reduction of flexibility to signify one's own experience within contexts is intrinsic to the condition of chronicity itself.

Processes of autonomy and recovery of ways of interacting with the most flexible and elastic contexts are the result of a development process in which not only all the actors are involved but the healthcare relationship itself is implied as a frame of reference and construction of the experience.

It is in the light of these considerations developed in our work that we have modeled psychological scaffolding to the healthcare relationship as a psychological intervention aimed at the relationship and not at the individual subject.

The integrative purpose of this model is considered not as the realization of a perfect and nostalgic harmony between the doctor and the patient, but as the gradual construction of a competence and autonomy of the different subjects through the support, the confrontation, the dialogue, the semiotic translation of the meanings acted out in the relationship. In this sense, scaffolding is not a procedural and prescriptive tool but a process and relational dynamics capable of developing and organizing new possible trajectories of relationship and transformation through the development of the skills of its actors.

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Chapter 5

The Relationship Between ESG Disclosure and the Cost of Debt in the Healthcare Industry

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ABSTRACT

In the last decades, attention to corporate social responsibility (CSR) has grown considerably. The new scenario characterized by greater attention to aspects of sustainability poses important challenges for companies operating in the healthcare (HC) industry due to both the high number of stakeholders with which these companies interface and their business model closely related to people's life and health problems. In light of this, companies operating in the HC industry are also called upon to provide an adequate level of non-financial information and in particular environmental, social, and governance (ESG) information to meet the needs of stakeholders. This study aims to examine the financial effects of ESG disclosure in the HC industry. In particular, it analyses the impact on the cost of debt. The results of the econometric analysis, conducted on a sample of 4,271 observations (an unbalanced data panel of 680 international firms for the period 2011-2020), show the existence of a negative association between the amount of ESG information disseminated and the cost of debt.

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INTRODUCTION

In the last decades, corporate social responsibility (CSR) has gained increasing importance among policy makers, professionals, and academics due to the central role played by the environmental, social, ethical, legal and economic objectives that companies should pursue beyond traditional financial goals. CSR can be defined as the integration on a voluntary basis, by companies, of social and environmental issues in their commercial operations and in their relations with stakeholders (Clegg et al., 2015). Companies should implement policies, practices and programs and use their resources to minimize the negative effects of their operations on the community in which they operate (Jamali et al., 2010; Vitolla et al., 2020). To this purpose, firms should rethink their business model, integrating CSR as a key part of their corporate agenda, in order to achieve the environmental and social goals (García-Sánchez et al., 2021; Raimo et al., 2021b). This scenario, characterized by greater attention to CSR, poses important challenges for companies operating in the Healthcare (HC) industry. According to Safkaur (2016), the HC industry is one of the most complex industries from an operational point of view because it must be facing a series of hard challenges such as the implementation of high-quality standards, strict regulatory compliance, complex administrative and financial procedures, costly and increasing technological advancements, and an intense labour shortage, as well as numerous epidemic diseases affecting the world population. CSR and respect for the needs of stakeholders take on particular importance in the HC industry for two main reasons (Demir & Min, 2019; Safkaur, 2016). The first reason concerns the presence of numerous categories of stakeholders such as government, customers, suppliers, workers, other industries and society. In particular, according to Russo (2016), “the relationship between HC and society is derived from a mandate that the former receives from the latter: to take care of patients” (p. 323). The second reason, on the other hand, concerns the business model of companies operating in the HC industry, which is strictly correlated with the people’s life and health issues. In this regard, companies operating in the HC industry must pay particular attention to the needs and rights of patients, because they deal with patients and not with customers and the patient’s status is ontologically different from that of the customer and this implies a different approach with respect to other companies (Russo, 2016).

The relevance of CSR is significantly increasing the importance of non-financial information (Vitolla et al., 2019; Nicolò et al., 2021). In fact, financial disclosure alone cannot guarantee a flow of information sufficient to meet the needs of the various stakeholders and potential capital providers (García-Sánchez et al., 2020; Salvi et al., 2020a; 2021). For this reason, the voluntary dissemination of non-financial information, and in particular environmental, social and governance (ESG) information, through corporate documents such as integrated reports, social reports or environmental reports is gaining growing importance worldwide (Raimo et al., 2020; Salvi et al., 2020b). According to Tamimi and Sebastianelli (2017), ESG disclosure is becoming increasingly important among firms due to its ability to improve corporate image, firm reputation and facilitate the investors’ decision-making process. It could be considered, in fact, a key activity for firms due to its ability to increase the knowledge of stakeholders about waste, pollution, emissions, labour standards, human rights, gender policies, as well as corporate governance (Raimo et al. 2020). In this regard, mandatory financial disclosure lacks to provide this kind of information (Jackson et al., 2020). Therefore, an accurate ESG disclosure allows investors to evaluate, in an adequate and transparent way, the firm’s future performance and the correlated risks and opportunities (Albarrak et al., 2019). ESG disclosure could play an important role in the HC industry because it allows to improve corporate transparency and create a better understanding between companies and stakeholders. In other words, it allows to clarify the strategies that HC firms intend to adopt in order to

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pursue ESG objectives. In this perspective, according to Demir and Min (2019), firms operating in the HC industry should "increasingly face the necessity to promote their economic, social and environmental activities, risks and impacts in discussing their value proposition to the stakeholders'" (p. 339).

A comprehensive non-financial disclosure can represent a useful tool for managers able to provide financial benefits for firms, including those operating in HC industry, in terms of firm value or access to finance (Fonseka et al., 2019; Raimo et al., 2021a). Despite the relevance of the topic, studies on the benefits associated with broad ESG disclosure in the HC industry are still limited. More specifically, the absence of contributions aimed at examining the effect of ESG disclosure on the cost of debt for companies operating in the HC industry is evident. This study aims to fill the existing gap in the literature by analysing the relationship between ESG disclosure and cost of debt financing in the HC industry on a sample of listed companies headquartered in US, Europe and Asia developed.

The remainder of this chapter is organised as follows: Section 2 analyses the literature in the field, while Section 3 develops the research hypothesis. Section 4 presents the research methodology while Section 5 presents the results. Finally, Section 6 discusses results and draws conclusions.

LITERATURE REVIEW

The effect of corporate disclosure on firms' cost of capital is an open debate among academics and practitioners (Botosan, 2006). In recent years, researchers focused their attention on the relationship between disclosure and cost of capital, paying particular attention to the relationship between disclosure and cost of equity capital, with little attention to the impact on the cost of debt financing (Raimo et al., 2021a). Past studies have examined the impact of different types of disclosure on the cost of debt.

Some scholars have analysed the impact of voluntary disclosure. In this regard, Francis et al. (2005), highlighted that firms with a superior level of disclosure benefit from a lower cost of debt financing compared to firms characterized by a lower level of disclosure. Furthermore, Chen and Jian (2006) showed that a superior level of corporate transparency is associated with a lower cost of debt. Orens et al. (2010), instead, studying a sample of firms headquartered in four European countries (Belgium, France, Germany and The Netherlands) found a negative relationship between non-financial information disclosed through corporate websites and the cost of debt. Abdi and Omri (2020) confirmed these findings. The frequency of voluntary disclosure is another driver able to impact the cost of debt financing as demonstrated by Talbi and Omri (2020) that analysed a sample of Tunisian listed companies. Despite this, there is a lack of unanimous consensus among researchers on the impact of voluntary disclosure on the cost of debt financing, as highlighted by Armitage and Marston (2008) that found mixed results in their study based on interviews with financial directors of British companies. Furthermore, Wang et al. (2008) failed to find a significant relationship between disclosure and cost of debt financing.

Past studies have demonstrated that financial disclosure can foster cost of debt financing reduction (Sengupta, 1998). According to Amrah and Hashim, (2020), *"financial reporting quality studies show that companies with high quality financial reporting can positively influence the lending decisions of creditors and lower the cost of debt financing"* (p. 395) due to the information risk created by poor quality reporting. The greater the perceived risk, the greater the return required by lenders. Bauwhede et al. (2015) analysed a sample of Belgian small and medium-sized enterprises highlighting that the quality of financial statements negatively affects the firms' cost of debt financing. In line with previous studies, Ding et al. (2017) showed that better earnings quality enhances firms' access to finance, foster-

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ing the cost of debt reduction. DeBoskey et al. (2017) added that a superior level of corporate political disclosure is able to reduce firms' cost of debt.

Other scholars have examined the impact of sustainability disclosure on the cost of debt. In particular, Shad et al. (2020) showed that overall sustainability reporting affects the cost of capital, using a sample of Malaysian oil and gas companies. The authors also analysed the impact of the different pillars of sustainability (economic, environmental and social sustainability) and their impact on both the cost of equity and the cost of debt, highlighting mixed results. Besides, Chi et al. (2020) found a negative relationship between CSR disclosure and cost of debt by analysing a sample of Taiwanese listed firms, while Najah and Jarboui (2013) highlighted the existence of negative association between the amount of social information provided and the cost of debt. Eliwa et al. (2019), by analysing a sample of international listed firms, underlined that the higher the sustainable disclosure the lower the cost of debt. Xu et al. (2019) used a quasi-natural experiment on a sample of Chinese listed firms and found a negative association between the level of CSR disclosure and the cost of debt financing.

Finally, other scholars have examined the impact of the last frontier of corporate disclosure – integrated reporting – on the cost of debt. In this regard, Gerwanski (2020) and Muttakin et al (2020) confirmed that the adoption of integrated reporting is a useful tool that managers can use to reduce firms' cost of debt.

The literature review carried out shows the presence of several studies on the relationship between corporate disclosure and the cost of debt. However, these studies have examined this relationship by considering different sectors and there are no studies focused on the HC industry. This study aims to bridge this important gap by examining the relationship between ESG disclosure and the cost of debt on a sample of international listed companies operating in the HC industry.

HYPOTHESES DEVELOPMENT

In recent years, the growing importance that ESG issues are assuming worldwide has highlighted the central role played by the reputational risk imposed by the borrowed companies in addition to the default risk. According to Eliwa et al. (2019), reputational and default risk can be an incentive for companies to integrate ESG disclosure into their business strategies. The mechanisms according to which disclosure affects firms' cost of debt are essentially three: a superior level of disclosure (1) improves the estimate of firms' default risk process by lenders (Eliwa et al., 2019), (2) reduces the information asymmetry between companies and capital providers (Gerwanski, 2020; Raimo et al., 2021a), and (3) improves corporate image and firm reputation (Bhuiyan & Nguyen, 2019).

Regarding the first mechanism, corporate disclosure can reduce the firms' cost of debt improving the assessment of the firms' risk profile and facilitating the investment decisions-making process. A complete and detailed disclosure policy is able to reduce underwriters and lenders' perception of firm risk and the associated uncertainty, and this would in turn reduce the firms' cost of debt financing (Sengupta, 1998). Furthermore, according to DeBoskey et al. (2017) a transparent disclosure policy "signals management's openness, reflects management's discretionary choice about how much information to share with parties outside the firm, and improves the confidence of capital providers, thereby resulting in a lower cost of debt" (p. 9). Firms with a superior ESG disclosure level are perceived less risky by market and investors, and this circumstance can reduce the firms' cost of debt because "new debt issues are priced using information about a firm's future risk choices" (Bhuiyan & Nguyen, 2019, p. 422).

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Voluntary disclosures could also enhance analysts' understanding of the firm's future prospects and strategies attracting new potential capital providers (Beyer et al., 2010).

Concerning the second mechanism, disclosure reduces the firms' cost of debt by reducing the information asymmetry between firms and capital providers, which in turn minimizes monitoring costs (Muttakin et al., 2020). This consideration is based on the agency theory (Jensen & Meckling, 1976), according to which there is a different set of information between principal and agent. In the event of a debt issue, the lenders (principal) lend money to the companies (agent) in order to receive back the capital lent plus the interest that must offset the risk of providing financial resources. In this case, insiders (managers or employees) have a superior set of information with respect to the outsiders (lenders) about a firm's performance and perspectives. Consequently, lenders tend to introduce restrictions and covenants in order to obtain greater collateral. This, as a consequence, increases agency costs and the final cost of debt financing (Muttakin et al., 2020). Disclosure can mitigate these issues, in fact, according to Bhuiyan and Nguyen (2019) the better is the firms' disclosure "the higher analyst coverage it can receive, which leads to a lower level of information asymmetry" (p. 421). In this perspective, detailed and transparent disclosure can foster the cost of debt reduction by reducing information asymmetries and agency costs (Dye, 1985; Diamond & Verrecchia, 1991; Healy & Palepu, 2001; La Rosa et al., 2018). Additionally, less information asymmetry allows companies to attract more potential investors, improving market liquidity and firm access to finance (Verrecchia, 2001).

Finally, the third mechanism concerns the ability of a comprehensive ESG disclosure to improve the corporate image and strengthen the firm reputation. According to (Bhuiyan & Nguyen, 2019), in fact, "firms with higher CSR commitment are more appealing to their stakeholders and hence, attain better reputation" (p. 421). A better corporate image and an improved firm reputation can reduce the cost of debt financing and guarantee easy access for borrowing, as demonstrated by Himme and Fischer (2014) and Cao et al. (2015).

The mechanism through which corporate disclosure can reduce the cost of debt could also apply to companies operating in the HC industry in light of the great importance that CSR and non-financial information assume in this industry. On the basis of the previous considerations, the research hypothesis of this study is the following:

H1: There is a negative association between ESG disclosure and the cost of debt for firms operating in the HC industry.

RESEARCH METHODOLOGY

Sample

In order to test the research hypothesis, this study analyses a sample made up of listed companies operating in the HC industry and headquartered in North America, Western Europe and Asia Pacific (developed). This geographic filter was applied in order to obtain a sample of companies operating in the most developed countries. More in detail, the North American region includes Bermuda, Canada, and United States; Western Europe includes Andorra, Austria, Belgium, Cyprus, Denmark, Faroe Island, Finland, France, Germany, Gibraltar, Greece, Guernsey, Iceland, Ireland, Isle of Man, Italy, Jersey, Liechtenstein, Luxemburg, Malta, Monaco, Netherlands, Norway, Portugal, Reunion, San Marino, Spain, Svalbard and

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Jan Mayen Islands, Sweden, Switzerland, and United Kingdom; and Asia Pacific (developed) includes Australia, Hong Kong, Japan, New Zealand, Singapore, South Korea, and Taiwan. The initial sample included 2,829 firms. It has been further filtered to only consider firms for which ESG disclosure score is available, reaching a sample of 803 companies. Finally, due to the lack of data, the final sample includes 680 companies. The timeframe of the analysis spans from 2011 to 2020, generating an unbalanced data panel comprising 680 international listed firms and a total of 4,271 observations.

Variables and Model Specification

The dependent variable used in this study is the cost of debt (CoD). The debt capital can come from public (banks for example) or private (debt markets) sources, and "in either case, the cost of debt is the applicable interest rate" (Sharfman & Fernando, 2008, p. 572). The cost of debt represents the average rate of interest the firm pays for its borrowing. Following prior studies in the field (Maaloul, 2018; Raimo et al., 2021a) the authors use the cost of debt directly provided by Bloomberg database, according to which the cost of debt represents "the weighted average cost of debt for the security, calculated using government bond rates, a debt adjustment factor, and the proportions of short and long term debt to total debt. The debt adjustment factor represents the average yield above government bonds for a given rating class. The lower the rating, the higher the adjustment factor. The debt adjustment factor (AF) is only used when a company does not have a fair market curve (FMC)" (Bloomberg, 2013, p. 18). Bloomberg database computes the cost of debt using the following formula (Eq. 1):

$$\mathrm{CoD} = [[(\mathrm{SD}/\mathrm{TD}) \text{ x } (\mathrm{CS} \times \mathrm{AF}) + [(\mathrm{LD}/\mathrm{TD}) \times (\mathrm{CL} \times \mathrm{AF})]] \times [1 - \mathrm{TR}] \quad (1)$$

where:

- SD represents the short term debt;
- TD represents the total debt;
- CS represents the pre-tax cost of short term debt;
- AF represents the debt adjustment factor;
- LD represents the long term debt;
- CL represents the pre-tax cost of long term debt; and
- TR represents the effective tax rate.

The ESG disclosure score (ESGD) represents the independent variable of this study. It refers to environmental (E), social (S) and governance (G) aspects of corporate sustainable disclosure. In particular, the environmental information refers to waste, water, emissions, energy and operational policies concerning the environmental impact of firm activities; the social information refers to products, impact on community, and employees and the governance information refers to the firm's political involvement, board function and structure, and executive compensation policies (Ioannou & Serafeim, 2014). Following the literature in the field (Nollet at al., 2016; Bernardi & Stark, 2018; McBrayer, 2018; Raimo et al., 2021a; 2021b) the authors use the ESG disclosure score directly provided by the Bloomberg database. Bloomberg determines the ESG disclosure score using direct communication, third party research, press releases, corporate documents (as annual or sustainable reports), and news items, concerning a wide range of indicators related to the sustainability aspects (Li et al., 2018). The sources used by Bloomberg to

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construct the score are represented, in addition to the aforementioned documents, by company websites and surveys directly conducted by Bloomberg. In the construction of the score, Bloomberg takes into account the sustainability peculiarities of the different industries, thus the score is able to "capture the disclosure activity of a given firm adjusted for the disclosure activity of firms operating within the same industry" (McBrayer, 2018, p. 1077). Furthermore, each sustainable pillar considered by Bloomberg in determining the score is weighted in terms of importance; each pillar takes on a different weight in the construction of the final score (Giannarakis et. al, 2014). The ESG disclosure score varies in a range spanning from 0.1 to 100 where 0.1 is assigned when a firm discloses a minimum amount of ESG data, and a score equal to 100 is assigned when a firm discloses every data point collected by Bloomberg (Li et al., 2018; McBrayer, 2018). The reliability of the ESG disclosure score provided by Bloomberg is demonstrated by the extensive use that researchers have made of it in recent years in order to study the impact of this variable on firms' performance (Giannarakis et al., 2014; Halbritter & Dorfleitner, 2015; Baldini et al., 2016; Nollet et al., 2016; Albitar et al., 2020; Raimo et al., 2021b).

A set of control variables, following the literature in the field (Bhuiyan & Nguyen, 2019; Eliwa et al., 2019; Fonseka et al., 2019; Muttakin et al., 2020; Raimo et al., 2021a), have been used in order to avoid biased results in the econometric analysis conducted to test the research hypothesis. In particular, the control variables used in this study are the following: firm size, leverage ratio, market-to-book ratio, and sales growth rate.

Firm size (LNTA) represents a proxy of the firm's dimensions and is computed as the natural logarithm of the firm total assets (Gerwanski, 2020). A negative relationship is expected between firm size and cost of debt because larger firms are characterized by lower monitoring costs and information asymmetry and less uncertainty (Graham et al., 2008). Consequently, larger firms are perceived as less risky by markets and investors (Bhuiyan & Nguyen, 2019) by having more assets to put in place in order to guarantee its solvency (Fonseka et al., 2019). Financial leverage (LEV) is calculated by dividing total debts by total assets. Firms with higher degree of financial leverage should pay a higher cost of debt because they are perceived as riskier by markets and investors: they have higher default risk due to heavier debt obligations (Zhu, 2014). A positive relationship is expected between financial leverage and cost of debt (Eliwa et al., 2019; Fonseka et al., 2019). Market-to-book ratio (MTB) is a measure of a firm's growth prospects and is computed by dividing fiscal year-end market value of equity by fiscal year-end book value of equity. Investors tend to associate higher market-to-book ratio with firms characterized by higher earning growth opportunities (Mazzotta & Veltri, 2014) and consequently less likely to default. On the contrary, according to Bhuiyan and Nguyen (2019), a low market-to-book ratio could indicate that "the stock price is low because the market is not positive about the future cash flow of the corporation" (p. 423). Based on these considerations a negative relationship is expected between market-to-book ratio and cost of debt. Finally, sales growth rate (SG) is used to control for firm growth opportunities and is obtained by comparing firm sales with those of the same accounting period in the previous year. Firms characterized by higher sales growth rate are less likely to default on loans, and consequently enjoy a lower cost of debt (Fonseka et al., 2019). A negative relationship is expected between sales growth rate and cost of debt.

All the variables used in this study have been collected from the Bloomberg database. Table 1 summarizes all the variables used.

In order to test the research hypothesis, the authors run a panel regression analysis based on a sample of 680 listed companies operating in the HC industry and headquartered in North America, Western Europe and Asia Pacific (developed), during a time period spanning from 2011 to 2020, generating an

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Table 1. Variables description

Variable	Symbol	Description	Source
Dependent variables			
Cost of debt	CoD	Firm cost of debt	Bloomberg database
Independent variable			
ESG disclosure score	ESGD	Level of ESG information provided by firms	Bloomberg database
Control variables			
Firm size	LNTA	Natural logarithm of a firm total assets	Bloomberg database
Leverage	DA	Total debt scaled by total assets	Bloomberg database
Market-to-book ratio	MTB	Fiscal year-end market value of equity divided by fiscal year-end book value of equity	Bloomberg database
Sales growth rate	SG	Change in sales (%) respect to the previous year	Bloomberg database

unbalanced panel dataset of 4,271 observations. The authors conducted a Hausman-test to select between random and fixed effects in order to obtain unbiased estimates. Results, in line with previous studies in the field (e.g. Nikolaev & Van Lent, 2005; Muiño & Trombetta, 2009; Reverte, 2012; Raimo et al., 2021a) indicate that the fixed effects model best fits in the econometric analysis. Furthermore, control for firm and year effects have been used. The model is reported in Eq. (2):

$$CoD = B_0 + B_1 ESGD_{i,t} + B_2 LNTA_{i,t} + B_3 LEV_{i,t} + B_4 MTB_{i,t} + B_5 SG_{i,t} + \varepsilon_{i,t} \text{ (2).}$$

RESULTS

Descriptive Statistics and Correlation Analysis

Table 2 presents the descriptive statistics and the correlation analysis.

The dependent variable, represented by the cost of debt, has a mean value equal to 1.37 per cent (st. dev. equal to 1.33 per cent) in line with previous studies in the field (Maaloul, 2018; Raimo et al., 2021a). The independent variable (ESGD), instead, has a mean value equal to 18.02 (st. dev. equal to 10.27), highlighting that companies operating in the HC industry disclose a limited amount of ESG information on average.

Table 2 reports, in the second part, the matrix correlation. The coefficients are quite low, in fact the highest value is 0.5628 between ESGD and LNTA. All the correlation coefficients are therefore below the threshold of multicollinearity (about ±0.8 or ± 0.9), identified by the literature in the field (Farrar & Glauber, 1967; Gujarati, 1995; Kennedy, 1999). The absence of multicollinearity in our dataset is further corroborated by the variance inflation factor (VIF) analysis, in fact the highest VIF value is equal to 1.48 (LNTA), a significantly lower value than the critical threshold of 10 indicated by Myers (1990) and Gujarati (1995). Based on these results it is possible to state that multicollinearity issues do not affect the dataset, and consequently the regression results.

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Table 2. Descriptive statistics and Pearson's correlation matrix

	MEAN	ST. DEV	VIF	CoD	ESGD	LNTA	LEV	MTBR	SG
CoD	1.3710	1.3320		1.00					
ESGD	18.0257	10.2658	1.40	-0.0311**	1.00				
LNTA	6.3551	3.3060	1.48	-0.1068***	0.5628	1.00			
LEV	0.2559	0.2909	1.05	0.2160***	-0.1018***	-0.1732***	1.00		
MTB	5.9969	9.5640	1.10	0.0673***	-0.0840***	-0.2255***	0.1698***	1.00	
SG	0.5036	0.2187	1.02	0.0183	-0.0891***	-0.1223***	0.0093	0.0459***	1.00

Note: ***Significant at the 1% level; **Significant at the 5% level; *Significant at the 10% level.

Regression Analysis

Table 3 reports the results of the regression analysis of this study. Findings highlight a negative relationship between ESG disclosure score and the firm cost of debt (-0.0127; p value = 0.000), confirming the research hypothesis: a superior level of ESG disclosure is associated with a lower cost of debt for firms.

Concerning the control variables, findings confirm the initial expectations. Firm size is negatively associated with cost of debt (-0.1025; p value = 0.000), confirming that larger firms can benefit from a lower cost of debt due their lower level of information asymmetry, greater economies of scales, lower monitoring costs and a superior ability to react when negative events occur (Petersen & Rajan, 1994; Raimo et al., 2021a). Leverage positively impacts the firm cost of debt (0.0024; p value = 0.015), confirming the hypothesis according to which firms characterized by a higher level of leverage have a higher probability of default and this is reflected in a higher cost of debt financing (Zhu, 2014; Eliwa et al., 2019). Market-to-book ratio negatively affects firm cost of debt, confirming that firms with higher earnings growth expectations benefit from a lower cost of debt because they are perceived less risky from markets and investors. A higher market-to book ratio, in fact, reflects lower uncertainty about the firm's future growth expectations (Boujelbene & Affes, 2013). Finally, the negative association between sales

growth rate and the cost of debt (-0.002; p value 0.008) is consistent with the argument that the higher the firms' sales growth rate the lower the probability of default on loans and, consequently, the cost of debt financing (Fonseka et al., 2019).

DISCUSSION AND CONCLUSION

This study examined the effect of ESG disclosure on the cost of debt for companies operating in the HC industry. The results demonstrated the existence of a negative association between the level of ESG disclosure and the cost of debt of these companies. This result shows that a greater degree of transparency in relation to the non-financial aspects of business management allows companies operating in the HC industry to benefit from a lower cost of debt.

The results obtained can be explained by the indirect mechanisms through which ESG disclosure favours a reduction in the cost of debt. They are connected to the ability of this disclosure to improve the assessment of the firms' risk profile and facilitate the investment decisions-making process, to reduce the information asymmetry between firms and lenders, and to improve the corporate image and reputation.

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Table 3. Regression analysis

	Expected Sign	Coefficient	Robust S.E.	*p* Value
Constant		*2.72583****	*0.2079341*	*0.000*
ESG	(-)	-0.0126672***	0.0033505	0.000
LNTA	(-)	-0.1024824***	0.0288647	0.000
LEV	(+)	0.0023578**	0.0009715	0.015
MTB	(-)	-0.004413**	.002227	0.048
SG	(-)	-0.0002288***	0.0000869	0.008
N. of obs.	4,271			
R^2	0.1840			
Prob > F	0.000			

Note: ***Significant at the 1% level; **Significant at the 5% level; *Significant at the 10% level.

In relation to the first mechanism, the dissemination of a greater number of ESG information allows companies operating in the HC industry to be perceived by the market and investors as less risky. In fact, ESG information is able to show the non-financial aspects of management and allow lenders to have an overview of the future prospects of companies. In relation to the second mechanism, a complete ESG disclosure reduces the information asymmetry regarding social, environmental and governance aspects between companies operating in the HC industry and lenders, thus favouring a reduction in the cost of debt. Finally, in relation to the third mechanism, the dissemination of numerous ESG information improves the reputation and image of companies operating in the HC industry and ensures easier access to loans, thus reducing the cost of debt. These mechanisms are therefore at the basis of the results obtained.

This study enriches the existing literature in different ways. First, it extends the knowledge relating to the relationship between corporate disclosure and cost of capital, showing the existence of a negative effect of ESG disclosure on the cost of debt. Secondly, it contributes to the knowledge of the financial effects of disclosure in the HC industry, which appears to be a field still unexplored by the academic literature.

The results of this study offer important implications for companies operating in the HC industry. The ability of ESG disclosure to allow a reduction in the cost of debt should lead these companies to become more transparent and adopt strategies related to broad ESG disclosure. In this regard, these companies should make further efforts to provide information related to aspects such as emissions, water, waste, energy, human rights, employees, products and impact on communities, executive compensation, board structure and function, and political involvement. Companies operating in the HC industry should also expand the communication channels through which they provide ESG information. In this regard, they should provide this information not only within corporate documents such as sustainability, integrated and annual reports but also through alternative channels such as corporate websites, social networks, direct communications and press releases. In fact, the expansion of communication channels could allow lenders to find ESG information more easily with lower costs and less waste of time.

Furthermore, the findings of this study also have important implications for policy makers. In fact, they should encourage and promote ESG disclosure among companies operating in the HC industry as an effective tool capable of increasing the efficiency of capital allocation and reducing the cost of debt.

In conclusion, it is necessary to emphasize that this work is not without limitations. The main limitation is represented by the use of secondary data downloaded directly from Bloomberg database. In fact,

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although this database represents a widely used source, the use of primary data could provide greater consistency to the study. However, this limitation, in addition to not reducing the quality of work, provides important ideas for future studies. In fact, they will be able to replicate the analysis by building new measures and indices to measure the actual amount of ESG information disclosed by companies operating in the HC industry. In addition, future studies will be able to carry out quantitative analyses based on interviews with managers of companies operating in the HC industry and with lenders in order to understand in depth the relationships between corporate transparency and the cost of debt. Finally, future studies will be able to test other consequences of ESG disclosure in the HC industry such as the impact on the cost of equity, market capitalization and firm value.

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Chapter 6

Telemedicine Services:
Opportunities and Developments in Italy

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ABSTRACT

Telemedicine services, with the collection and sharing of patient clinical data, have gone from an emergency response during the pandemic to an essential structural investment for the Italian health system. Telemedicine is a part of the main digital transformation process in healthcare and is establishing itself as a key technological tool to increase the efficiency and effectiveness of the system. Indeed, it can make the difference in each phase of healthcare, from prevention to access to care, up to the real patient care, helping to shift the center of gravity of the Italian healthcare system moving from the centralized care in the hospitals to home healthcare. Through a literature review, an overview of the telemedicine in the Italian context is proposed, discussing the factors that facilitate its development, the main barriers to its implementation, and the future prospects of these digital tools that are useful to support the National Healthcare System.

INTRODUCTION

In the 21st century, the healthcare provision is affected by many different types of factors: a) economic, limited budgets and restrictions on spending for the healthcare structures; b) social and health, from the aging populations, the increasing demands of healthcare as consequence of the diffusion of chronic (i.e. cardiovascular diseases, peasant respiratory diseases and diabetes) or new diseases (i.e. cancer, stress, anxiety) to the diffusion of the Covid-19 pandemic.

Certainly Covid-19 was not the start of the digital health revolution, but it has certainly been a major driver in its widespread adoption in the last two years. If, on one hand, doctors and specialists could

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not see their patients in person, on the other, people continued to need consultations, therefore moving diagnoses online was the only option to continue delivering care directly to patients.

Numerous studies have shown that information systems in the medical field are an important driver of organizational change. In fact, the measurement of the value brought by the use of technologies in healthcare, in particular considering electronic medical records, if carried out by adopting a different approach than the classic measurement in economic-financial terms, highlights how this tool can contribute to the improvement of performance of healthcare entities by increasing organizational efficiency and effectiveness and improving the quality of organization processes and services. In addition, the clinical use of some information and communication technologies (ICT) applications, such as Web 2.0 and Social Media, can easily involve groups of the population at risk or who suffer from chronic diseases, promoting an improvement of the relative quality of care. Furthermore, through the use of ICT, it is possible to simplify both the interactions among the various patients and those between the latter and health professionals and to offer patient-centered services with personalized treatment paths.

Sharing of information among various care providers is becoming an essential feature of health systems, and many countries are adopting policies to promote the exchange of clinical information, through the electronic transfer of data or information among healthcare organizations (Guerrazzi, 2020).

To this end, the implementation of electronic health records is also a relevant solution, which, in the literature, is associated with improvements in documentation, screening performance and the reduction of prescription errors (Priestman et al. 2018). Despite the potential benefits deriving from the adoption of the electronic health records, some studies show that in Italy the coordination mechanisms between the different levels of governance of the health system is slowing down its use (Cucciniello et al. 2014; Nasi et al., 2015; Cucciniello et al. 2016).

Telemedicine represents one of the major innovations in healthcare services, both for the economic and social perspectives and the technological point of view, playing a key role in the accessibility to healthcare services, and in the process implemented to improve the quality of medical care and organizational efficiency.

Despite its many advantages recognized by the literature (see Table 1), there are significant barriers and problems to the expansion and standardizing telemedicine. The main one, seemingly, regards the use of the Information and Communication Technologies in general and in the healthcare system, in particular. Data highlight that, despite there being a strong will to increase the activities of telemedicine, the latter still has a limited presence in clinical and healthcare settings, and it appears more developed in countries where healthcare is not public, where there is a high digital access and a good digital literacy. The main goal of this study is to promote the culture of digital healthcare, highlighting the need for an effective collaboration among different stakeholders involved in healthcare. To achieve this goal, they must be able to speak a common language and have a clear vision of the core concepts and terms that characterize a telemedicine program.

BACKGROUND

In the last decades, most economic sectors have embraced digital disruption as factor to consider in the corporate assets, not just as a tool for fighting competition, but also as an asset for survival. If compared to the few experiences that highlight the effects of the digital revolution - that certainly represent best practices in this sector – the healthcare sector lags.

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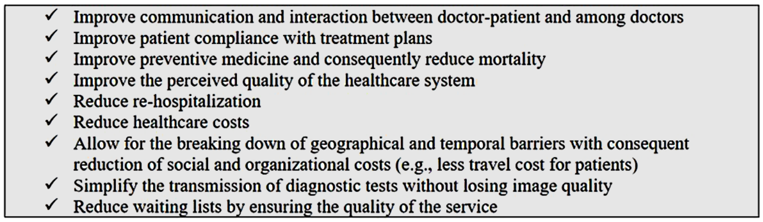
Table 1. Main Benefits of Telemedicine Solutions



- ✓ Improve communication and interaction between doctor-patient and among doctors
- ✓ Improve patient compliance with treatment plans
- ✓ Improve preventive medicine and consequently reduce mortality
- ✓ Improve the perceived quality of the healthcare system
- ✓ Reduce re-hospitalization
- ✓ Reduce healthcare costs
- ✓ Allow for the breaking down of geographical and temporal barriers with consequent reduction of social and organizational costs (e.g., less travel cost for patients)
- ✓ Simplify the transmission of diagnostic tests without losing image quality
- ✓ Reduce waiting lists by ensuring the quality of the service

Source: Adapted from: Hjelm, 2005, Darkins et al. 2008; Gailwad & Warren, 2009; Tuzii, 2017

Wickramasinghe et al., (2006), correctly, pointed out that if on one hand, "*healthcare represents the biggest service industry on the globe"*, on the other, "*it has yet to realize the full potential of the e-business revolution in the form of e-health"*. As Kraus et al. (2021) asserted, the digital revolution in healthcare can "*create new business opportunities and yields new business models to address issues in medical practice"*, creating value and benefits not only in economic terms, but especially in the field of care, monitoring and prevention.

The main tangible measures of the positive impact of telemedicine -considering the general Healthcare System, both in the private and public health structures and concerning patient care - are indicated in the table 1.

For all these reasons, sharing the thought of Ford et al. (2017) digital disruption plays a key role in healthcare service innovation; and as Dohan et al. (2020) pointed out, healthcare information technology must progress to continue to advance the way healthcare is delivered.

The emerging trend of digital medicine (Marques and Ferreira, 2019) - which is *today characterized more and more* by the use of digital and smart devices, big data and artificial intelligence – represents, in telemedicine particularly, as Bashshur et al. (2000) pointed out, *"a complex and radical change in the traditional practice of clinical diagnosis and treatment*".

Since the time of Hippocrates, medical practice has been based on the observation of events; over time, this criterion has progressed to arrive at the formulation of Evidence-Based Medicine (Sackett et al. 1996). It refers to the application of the best available research in clinical care, which requires the integration of evidence with clinical expertise and patient values. With this approach, the results of contemporary research are explored, evaluated, and systematically used as a basis to support clinical decision-making in the diagnostic investigation stages or in the management of individual patients.

The diffusion of digital tools and artificial intelligence in the medical practice adds to progress since it can be based on what is not evident to the individual human clinician, but what can become evident, for example with the use of deep learning techniques, which are able to consider and process much more information than is possible for a human being. These innovative tools and procedures can create a synergistic effort in which more data are monitored at the same time and can be reused to generate new knowledge for medicine.

As Papa et al. (2018) stressed, the use of mobile apps and smart devices to monitor health and well-being, the big data and the deep learning techniques have an enormous potential because it is possible to carry out predictive and preventive medicine long before the onset of symptoms. As is known, for pathological and progressive clinical diseases, this constitutes a considerable advantage. Instant access to

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the entire set of data makes it possible to predict the evolution of the clinical picture through supportive decision-making algorithms that make the entire process more efficient.

The diagnostic-assistance model, also based on personalized electronic health records, may be able to respond to requests for increasingly effective, efficient, and quality diagnostic, prognosis, and treatment services for the patient whose trade-off between the level of service and implementation costs, can be mitigated thanks to the application of innovative technologies, systems, and procedures for the management of the clinical process according to an e-Health Service Management logic (Marino et al., 2021). The creation of health records that are continuously enriched with the monitoring of remotely detected values, to allow many pathologies to be diagnosed at a very early stage, and so identify situations of risk and possible treatment.

Therefore the monitoring of the state of health, the prevention of critical situations and the support of daily activities are an emerging applications at the health level, especially with reference to frail people, the elderly and those with serious pathologies.

Although the literature proposes several papers with the genesis of the term telemedicine (Bashshur et al. 2000) and its various definitions (Sood et al. 2007; Harst et al., 2021), in this study we consider the one proposed by the World Health Organization (WHO) in 2009, that defines the telemedicine as

The delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities.

From this definition, the essential elements that characterize telemedicine can be highlighted: the geographical distance between patients and care professionals and the use of information and communication technologies to allow for a series of activities between patients and doctors and among the doctors themselves.

It is important to clarify that telemedicine sometimes is used as synonymous of telehealth but while the first refers specifically to remote clinical services that focus on a curative aspect of care, the second is broader in scope and includes disease prevention and digital health promotion—as well as curative care. Therefore, telemedicine can be considered a sub-domain of telehealth, or as Weinstein et al. (2014) more generically asserted "*telehealth is an umbrella term that covers telemedicine*".

Another clarification regards the use of the term 'connected health' that refers to a healthcare delivery model wherein telehealth and telemedicine technologies help to provide health services remotely. Connected health aims to maximize healthcare resources through optimal use and the provision of more flexible digital health options for consumers and clinicians to achieve better health outcomes.

It is important to stress that telemedicine is not a substitute for seeing and physically examining a patient; in fact, it does not replace traditional medicine practice, but supports it. To this regard, Haleem et al. (2021) identified *seventeen significant applications of telemedicine in healthcare,* but as Bashshur et al. (2011) asserted, *"the taxonomy of telemedicine can be presented in several different ways*" considering three main dimensions as the authors schematically indicate in Figure 1 below.

Regarding good practices in the implementation of telemedicine services, there are studies in the international literature that even come to propose models of approach to the design of telemedicine systems but are limited to the needs of specialized activities – i.e. cardiology (deWaure et al. 2012), mental health, endocrinology, especially for diabetes (Klonoff, 2003), chronic neurological disorders (Dorsey et

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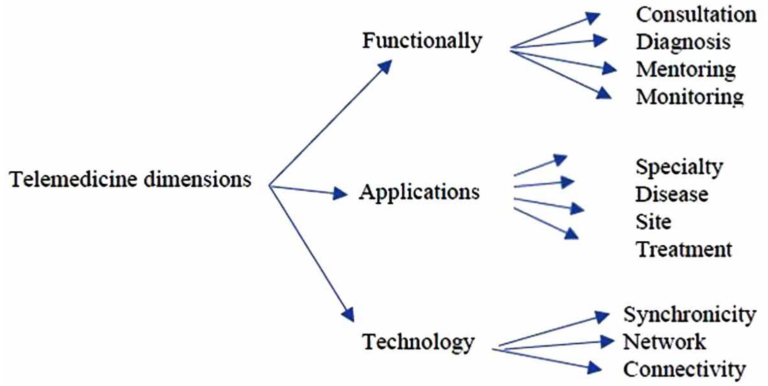
Figure 1. Dimensions of telemedicine and components
Source: Bashshur et al., 2011



al, 2013), in general chronic patients (Benvenuto et al. 2017) – or to the local needs considering current disasters or wars (Merrell et al. 2008; Doarn & Merrel, 2014). In this sense, telemedicine is considered a solution to provide easy medical access to patients who live in rural communities (Brick et al., 1997) or with geographical barriers that are many miles from good healthcare or live in developing countries that traditionally suffer from lack of access to healthcare (Scott and Mars, 2015; Penninga et al., 2019).

Furthermore, some experiences come from countries with mainly or exclusively private healthcare systems, where getting telemedicine care might appeal to someone with medical insurance who prefers to avoid the time and expense involved in getting to a doctor's office or urgent care clinic and paying a deductible (Charles, 2000; Sood et al. 2007), or anyway different from the Italian public healthcare system.

In general, there is talk of changes, even radical ones, in medical procedures and organizational processes. If not managed properly, these can lead to service failures rather than progress. For this reason, designing information technology and communication systems independently from, rather than integrally with, their environment impedes them from reaching their full potential as vital components in the delivery of care by creating a lack of flexibility, decelerating performance, and degrading the healing environment. In other words, the solutions that can be developed must be organizationally and economically viable but, first, they must be clinically valid. Developing effective digital healthcare is an intensive and challenging process that requires much effort considering the multidisciplinary nature of these activities and the multiplicity of interested stakeholders that usually speak different languages, while at the same time have the need to share experiences and expectations. As Kissi et al. (2020) stated, "*many researchers interpret healthcare management and telemedicine services as the intersection of information technology, healthcare, and information science*".

TELEMEDICINE IN ITALY

Digital tool technology, in particular the adoption of telemedicine and e-health, has accelerated in the last two years. Indeed, the development of telemedicine applications and e-health services has significantly helped to manage the worldwide pandemic better, especially contributing to assisting Covid-19 patients who do not need hospital care, minimizing the risk of Covid-19 transmission. Some studies (Comite,

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2020; Monaghesh, Hajizadeh, 2020; Haleem et al. 2021) have highlighted that this solution, especially using video conferencing or other virtual technologies, has limited any direct physical contact, provided continuous care to the community, and finally reduced mortality in the Covid-19 outbreak (Rockwell and Gilroy, 2020).

The pandemic has sped up the adoption of digital technologies and Governments are rethinking the role of digital technology in their overall healthcare system strategy.

In Italy, the design of telemedicine services has usually taken place in the form of local pilot projects, associated with specific funding, with activities to be provided for a limited period of time, to a certain number of patients and with a punctual accountability report of goals achieved.

At the end of these projects, however, the services were terminated, with the consequent loss of information, especially of a procedural and organizational nature, creating serious damage to the progress of Telemedicine itself. The loss of experience gained, especially that of many young professionals who are often specialized in the field has been even more damaging.

The continuation of this situation, managed at the local level without national coordination that would direct public initiatives towards system objectives selected based on scientific evidence, has ended up causing a stalemate in development and coordinated dissemination throughout the national territory.

There is a clear need for a radical change in the programming of the development of telemedicine services: adopting a holistic approach (see Figure 2), they must be based on national public e-health policies which, in agreement with the Regions, allow for the launching of telemedicine services based on technologies and procedures which have already been verified in order to provide telemedicine services on a routine basis, for many patients, in a potentially unlimited way.

These new strategic and holistic approaches require initiatives at national, regional, and local levels to ensure the sustainability of telemedicine program in terms of the technical, financial, and human resources. The developmental model of telemedicine to be implemented is not an easy one; it must take into account many factors: from the peculiarities of the Italian regulatory system to the technological infrastructure present on the national territory, to the regional autonomies regarding healthcare, to the local needs and culture of the population.

National Guidelines for the Provision of Telemedicine Services

In Italy, through the "National guidelines for the provision of telemedicine services" approved by the State-Regions Conference in December 2020, telemedicine services have become real health services equivalent to traditional ones. These guidelines, complement the 2014 national guidelines, and state that "*through telemedicine it is possible to guarantee the use of health services without the patient or the assisted person having to go to health facilities, caring for the patient through a secure exchange of data, images, documents and video calls, between healthcare patients and healthcare professionals, ensuring in some clinical-care situations the performance of professional services equivalent to traditional access* ".

The need to bring telemedicine activities back to the Essential Levels of Care (LEA) and therefore to the administrative rules that must be applied to these services (in terms of rates, reporting methods, cost sharing), has led to a further classification among the various types of services.

The first type is the televisit. It is the situation where the doctor interacts with the patient remotely, in real time. In this way outpatient services that do not require the completeness of the physical examination (traditionally consisting of inspection, palpation, percussion and auscultation) can be provided. At least one of the following conditions always needs to be met:

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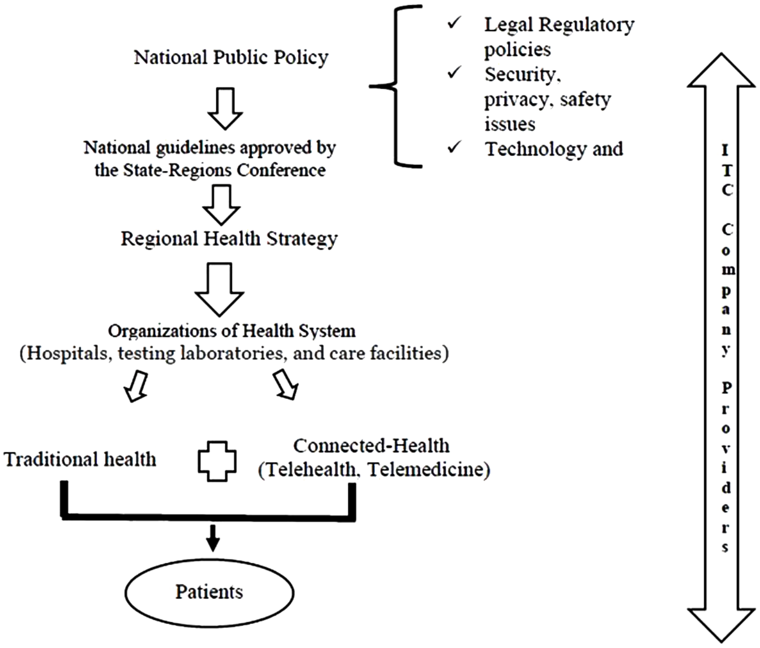
Figure 2. Holistic approach to the telemedicine services
Source: Authors Elaboration



- The service falls within an Individualized Care Plan or Diagnostic Therapeutic Assistance Pathway;
- The patient is in a follow-up path for a known pathology;
- The patient is suffering from a pathology that requires the control and monitoring of therapy;
- The patient needs an anamnestic evaluation for the prescription of diagnostic tests or the stagnation of a known pathology;
- The patient needs verification of the doctor of the tests performed.

Unlike traditional visits, televisits require the prior consent of the patient or a family member to confirm the availability of an electronic contact for the documentary / informational relationship with the specialist and access to a remote communication system according to the technical specifications and current regulations on privacy and security. In any case, the connection must take place in real time and allow the medical professional to see the patient and interact with him, possibly, if necessary, also with the support of the care-giver.

Anyway, televisits can never be considered the means to conduct the doctor-patient relationship exclusively at a distance, nor can they be considered automatically as a substitute for the first face-to-face medical examination.

The second is the teleconsultation or remote assistance. It is a medical act in which the professional interacts remotely with one or more doctors to dialogue, even though a video call, about the clinical situation of a patient, based primarily on the sharing of all clinical data, reports, images, and the audio-video concerning the specific case. Teleconsultation among professionals can also take place in asynchronous mode when the patient's situation allows it safely. When the patient is present at the teleconsultation, then

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it takes place in real time using the operating methods similar to those of a televisit and is configured as a multidisciplinary visit.

The third option, Medical-health teleconsultation, is a health activity, not necessarily medical, but in any case specific to the health professions, which takes place remotely and is performed by two or more people who have different responsibilities with respect to the specific case. It consists in a request for support during the performance of healthcare activities, followed by a video call in which the healthcare professional being consulted provides indications either to assist in making a decision and / or for the correct execution of assistance actions aimed at the patient. The teleconsultation can be carried out in the presence of the patient, or in a deferred manner.

The fourth is remote assistance by health professions (nurse / physiotherapist / speech therapist / etc). It is a professional act pertaining to the relevant healthcare profession and is based on the remote interaction between the professional and patient / caregiver by means of a video call, to which, if necessary, the sharing of data, reports or images can be added. The professional who carries out the remote assistance activity can also use suitable apps to administer questionnaires, share images or video tutorials on specific activities. The purpose of remote assistance is to facilitate the correct performance of assistance activities, which can be carried out mainly at home. Teleservice is mainly programmed and repeatable on the basis of specific patient support programs.

The fifth is remote reporting. It is a report issued by the doctor who has subjected a patient to a clinical or instrumental examination whose content is that typical of reports performed in the presence and which is written and transmitted by means of digital and telecommunication systems.

The activities related to telemedicine do not include triage or telephone consultancy carried out by doctors or health professionals towards patients in order to indicate the most appropriate diagnostic / therapeutic path.

Telerehabilitation, tele-certification and telemonitoring are not regulated by the document and will be subject to specific rules to be defined later. Especially for telemonitoring, this is a serious lack given the importance that this plays for patients who may have complications and continuous care needs.

The guidelines provide some indications on the basic characteristics that must be envisaged to provide telemedicine services. Among these are the availability of a network, the presence of a web portal that doctors access with their account to manage assigned patients, a web application that allows patients to log in easily, after verifying their identity, using the tools they have access to (computers, tablets, smartphones).

The guidelines require the certification of hardware and / or software as a medical device suitable for the type of service to be performed in telemedicine. This is an important aspect that few solutions on the market today possess.

The document emphasizes the need to ensure, electronically, the acquisition of any clinical documentation functional to the visit (laboratory test reports, instrumental diagnostics, etc.), favoring the integration of medical records and health records.

The clinician, together with the usual tools that support a face-to-face visit (appointment agenda, clinical documentation necessary for the ongoing evaluation, patient medical records), must have differentiated systems to communicate with the patient (SMS, email with encrypted texts, video communication), and a technical coordination center that manages telemedicine activities.

The patient must be able to provide a telematic contact for televisits with the specialist. If you do not have the necessary IT tools in your home, you must be guaranteed the possibility of accessing local structures of the Local Health Unit (ASL) or dedicated workstations made available by entities close

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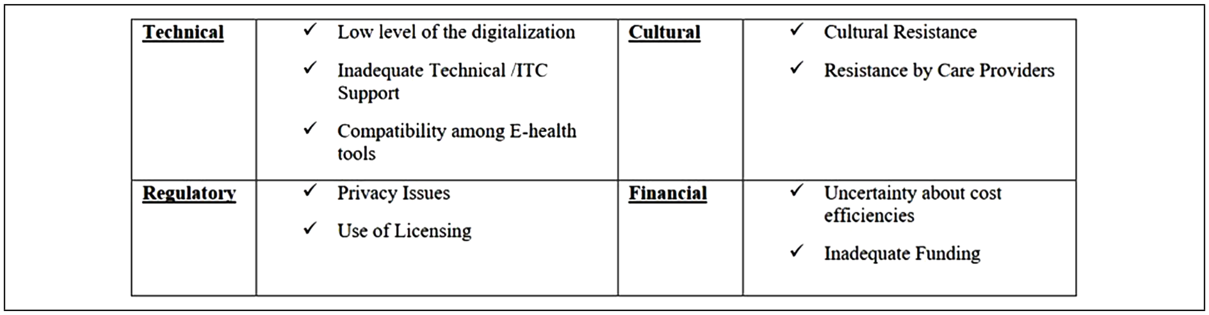
Table 2. Main Barriers to Telemedicine Solutions



Technical	✓ Low level of the digitalization ✓ Inadequate Technical /ITC Support ✓ Compatibility among E-health tools	**Cultural**	✓ Cultural Resistance ✓ Resistance by Care Providers
Regulatory	✓ Privacy Issues ✓ Use of Licensing	**Financial**	✓ Uncertainty about cost efficiencies ✓ Inadequate Funding

Source: Adapted from Melchiorre et al., 2018; Rogove et al., 2012

to the domicile of the same, such as pharmacies, or the general practitioners and pediatricians of free choice offices.

Problems

As showed in the Table 2 many are the barriers - that can be classify in four types: technical, regulatory, cultural, and financial - that hinder the dissemination of telemedicine.

Regarding the technical barriers the main reference is to the low level of the digitalization status of Italians and of the Italian healthcare system also deriving from the Italian digital divide compared to other countries.

As Pierce et al. (2021) stated for telehealth in Latin America, "*several elements are required for telemedicine innovations to take hold and scale, including adequate connectivity and technology infrastructure, supportive policy frameworks, measures, adequate security, a technology-savvy workforce, and protection of personal health information*". These considerations also apply to Italy.

Another technological limit is represented by the low level of digital literacy of Italians that does not allow for an adequate technical or ITC support.

As seen from what Parimbelli et al. (2018) asserted - "*the sheer number of available medical or health-related apps have raised debates involving legal implications and security requirements highlighting the low level of maturity of this area*" - the other technological barrier is represented by the privacy and the security access to smart devices and to the apps dedicated to health.

The cultural barriers, generally, as Rogove et al. (2012) found in their analysis, result "*from a lack of desire or unwillingness to change clinical paradigms through the use of telemedicine*". This occurs both on the patient's side and on the side of the care providers.

There are also many legislative and regulatory aspects to evaluate - the issue of privacy, confidentiality, and security of online data need to be addressed: professional responsibility, accreditation, and certification of providers - considering European legislation, and national and regional laws.

Lastly, as far as the financial barriers are concerned, two main elements need to be evaluated: the uncertainty about cost efficiencies, usually recognized in telemedicine, and the actual amount of money needed to sustainably support a telemedicine program that is not a local project, but which could, instead, be a solution for the entire Italian territory.

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The empirical evidence that analytically demonstrates the effectiveness of consolidated sustainable telemedicine is inadequate. Some studies – generally referring to E-Health - adopting different approach, highlight expense savings or economic resources released for other uses or intangible utilities (e.g., medical errors and therefore disputes), which therefore do not translate into actual financial income.

Telemedicine also poses legal issues such as the protection of the privacy of patients, i.e. the correct processing of data concerning their status.

The telemedicine program, as a part of the main digital transformation in healthcare, is achievable only if a solution is found for the problems mentioned.

SOLUTIONS AND RECOMMENDATIONS

As Paul et al. (1999) asserted, "*addressing technological barriers is a necessary but not sufficient condition if telemedicine is to fulfil its promise, and it is predominantly only after such barriers are addressed that the other barriers- professional, legal, and financial- come to the fore*".

To resolve the problems mentioned in the previous section, plan a valid national telemedicine program is need that involves and develops a shared vision among all stakeholders interested in the project, including the patients, the management of the health organizations, the doctors, the technology service providers in the healthcare system. To implement a valid digital innovation project of telemedicine, it is necessary to consider, in addition to the purely technological component, many other variables, such as:

- The revision of processes and organizational models, through the definition of functional procedures that ensure the multi-channel access, and the digitalization and dematerialization of the processes, as well as the re-engineering and the standardization of administrative procedures, so it is possible manage and share data, events, and electronic documents;
- The development of suitable skills for the involved professionals and the correct commitment of all actors (patients) who use these systems. A plan should be made in order to improve the training of doctors and nurses thanks to the promotion of systems related to the telemedicine.

Long-range strategic planning of a telemedicine program is based on goal setting and the periodic updating of the same. These steps require an ongoing assessment of activities relative to the service usage, to the analyses of financial and economic performance, to the quality-of-service assessments.

Long term investments by the government are required to pay for e-health and telemedicine: loans and private sector partnering can only bridge gaps temporarily. The resources necessary to financially support this project can be found thanks to the Recovery and Resilience Plan which focuses, concerning health, on two objectives: the strengthening of the territorial network and the modernization of the technological equipment of the National Health Service with the strengthening of the Electronic Healthcare Files and the development of telemedicine. In this way, it will thus be possible to define a perimeter within which the various regional health systems will be able to operate autonomously, while becoming intelligible and comparable to each other.

A detailed economic analysis should be carried out prior to any large investment in telemedicine using accurate clinical and economic key indicators.

Furthermore, in order to be able to define an appropriate investment plan, it would be necessary to correctly assess the economic benefits, economic returns and financial savings.

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Legal issues are essentially focused on the patients' privacy, on professional liability and on licensure problems. Essentially, Italian health structures, both public and private, which intend to activate telemedicine will have to equip themselves on the one hand with a reliable ICT tool capable of transferring images safely, and, on the other, of subjects who operate not only in compliance with health laws and rules relating to professional responsibility, but also all the legislation on the processing of personal data so that the dignity of the person and the right to confidentiality and integrity of his particular data are protected.

An interesting example of a solution came from the mobile health (m-Health) systems that, as Silva et al. (2019) asserted, "*offer mobility as precious resource to interact between mobile health systems and patient problems, outstanding the significance of privacy and managing data*".

FUTURE RESEARCH DIRECTIONS

Considering the problems highlighted in the previous sections and the different telemedicine programs implemented in the Italian regions, it is recommended that a database of case studies documenting best practices and success factors be developed. This could be particularly useful to help answer two major requests (Wilson and Maider, 2015): on one hand, *the high demand for particular clinical service*, on the other hand, the *high criticality need of clinical expertise to deliver the service* in some areas where there are none or where they lack quality.

Consequently, sharing the Pierce et al. (2021) thought, it is necessary "*to provide a uniform framework for identifying and rapidly replicating successful practices*".

Organizational issues in telemedicine programs are crucially important but have yet not received adequate research attention: it is essential to investigate what kind of resources are used for the implementation of the technology and what changes or consequences in the organization could be induced by the same technology.

Some evidence (Rojas & Gagnon, 2008; Seto, 2008; Ekeland et al., 2010) suggests that telemedicine has the potential to reduce costs. So far, from studies a reduction of the patients' re-hospitalization and of their social and organizational costs has emerged, usually related to travel expenses, but a rigorous downstream assessment is required to confirm these and highlight others.

In Italy, there has been very little published on the economic analysis of telemedicine interventions. This type of information is needed to influence medical policy makers to make informed decision and to evaluate the economic viability. Consequently, this aspect justifies further analysis to give more precise insights adopting a set of outcome measurement metrics.

A final suggestion is related to the implementation of a measurement system to evaluate the telemedicine tool. This measurement system, for example, may include four main dimensions: access to care; financial impact / cost; experience; effectiveness. For each of these dimensions, a set of indicators must be defined to make a correct assessment of the effect/impact of telemedicine program.

CONCLUSION

After the covid-19 emergency which necessarily required the adoption of telemedicine solutions, a path has begun for the Italian health system that requires the definition of well-structured processes with adequate

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technical solutions and professionalism. Telemedicine must be brought into the clinical and assistance context of healthcare system through a close technical, organizational, and professional integration.

There has been a pervasive tendency to treat telemedicine or telehealth as separate from the context of healthcare delivery: telemedicine is only a communication and informational tool and should not be considered as separate from other healthcare delivery activities. Sharing the Wilson and Maeder (2015) thought, "*telemedicine can evolve if, simultaneously, there are developments associated with three aspects: technology, clinical applications, and care models*".

The benefits stakeholders might potentially have from actual telemedicine programs and from the future increased use of telemedicine services are many. This is true especially in a country, as Italy, where there is high rate of seniority and many chronic patients in need of continuous assistance. Add to this the fact that healthcare decision-makers are consistently under pressure due to many factors and delivering quality care with limited resources is very difficult.

In this sense, telemedicine represents a valid opportunity to balance the quality of services and better manage the available resources of the Recovery and Resilience Plan.

In general, telemedicine can be an effective driver for the development and modernization of Italian healthcare and, particularly, of the less developed regions: these areas, in fact, can have more tangible benefits considering the ability of telemedicine to overcome the physicality of space through the remote use of the most advanced diagnosis and treatment technologies.

As Klonoff (2009) stated, "*telemedicine interventions will likely improve in their effectiveness as electronic medical records and decision support software become more ubiquitous and both clinicians and patients develop familiarity with their benefits and drawbacks"*.

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KEY TERMS AND DEFINITIONS

Digital Device: Wearable equipped devices with sensors and digital biomarkers that allow for digital transmission and collection of data that can be extremely useful for diagnosing a medical problem.

Digital Literacy: Skills needed to live in a society where communication and access to information is increasingly through digital technologies like internet platforms, social media, and mobile devices.

E-Health: Encompasses in a broader sense the use of information and communication technologies supporting the entire range of functions and operational processes that affect the healthcare sector.

Electronic Health Record: Electronic set of information on a patient's medical history, demographics, hospital admissions, surgical interventions carried out, laboratory data and other important clinical information.

Essential Levels of Care (LEA): Set of services to be guaranteed by the public sector are defined at a national level, while regions are accountable for their provision.

Recovery and Resilience Plan: Plan that each European State had to submit to the European Commission in which the reforms and investments that the State will implement using the European extraordinary fund by end of 2026 are set out.

Taxonomy: Scheme of classification, used to organize and index complex issues as, for example, the knowledge on the telemedicine.

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Chapter 7

The Psychological Impact of the COVID-19 Outbreak Among Healthcare Workers:

The Crucial Role of Psychological Functioning in Preventing Burnout

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ABSTRACT

This chapter reviews and discusses findings from studies on healthcare workers facing the COVID-19 outbreak. Previous studies have provided evidence for the role of psychological characteristics in predicting burnout and psychological distress among healthcare workers. Research conducted during the COVID-19 outbreak seems to confirm these relationships. Evidence has also revealed high burnout and psychopathological symptoms among professionals. Several factors were associated with a worse psychological impact of the COVID-19 outbreak, such as assisting infected patients. A growing body of research has pointed out the role of psychological characteristics in mitigating the psychological impact of the COVID-19 outbreak and its related restrictive measures. More research is needed to verify these relationships and to examine the long-term consequences on the healthcare workers heavily involved in the COVID-19 outbreak. Nonetheless, the implication of these studies concerns the implementation of interventions reducing the psychological impact of working during the COVID-19 outbreak.

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INTRODUCTION

The COVID-19 pandemic has strike hardly Italy causing 128.068 death as of 5 August 2021 (Italian Ministry of Health, 2021). Since the 9th March 2020, the Italian Government has adopted severe restrictive measures involving all the Italian population with the aim of decrease the spread of the COVID-19. For the first time, severe restrictive measures have concerned the entire Italian national territory. Such protracted lockdown, associated with the uncertainty of the duration, has had a great psychological impact on the Italian population, as well documented by empirical research. A study of Italian people who experienced the restrictive measures following the COVID-19 outbreak estimated the range of depression, anxiety, and stress prevalence between 24.4% and 32% (Lenzo et al., 2020a). Moreover, individuals' symptoms in this study were predicted by their psychological resilience ability. Analogous results were found in other cross-sectional studies, reporting high levels of psychological distress and poor sleep quality during the lockdown following the COVID-19 outbreak (Cerami et al., 2020; Favieri et al., 2020; Franceschini et al., 2020; Rossi et al., Schimmenti et al., 2020). More notably is that for healthcare workers and their mental health is needed special attention (Brooks et al., 2020). Since 27 December last with the Vaccine Day and the first Italian people vaccinated, the situation has now changed. On 8 August 2021, while the vaccination campaign proceeds, people who have completed the vaccination series represent 63.47% of the population over 12 years. The healthcare workers involved in the assistance to COVID-19 patients have paid a heavy toll throughout this period. The most recent estimate (8 August 2021) of the National Federation of Italian doctors reported 360 cases of deceased among healthcare workers. Healthcare workers that incessantly care for COVID-19 patients are fighting an unknown threat with a deep psychological impact on their own mental health (Lenzo et al., 2021a). To date, health authorities have made considerable efforts to prevent infection in healthcare workers, even though little attention has been paid to their mental health. In this chapter, we will seek to illustrate the psychological impact of the COVID-19 outbreak among healthcare workers and to discuss recent evidence on the role of certain psychological characteristics in preventing burnout and other negative consequences of work-related stressors. In the first part of the chapter, we will discuss evidence from research on burnout that focusing on the interplay between burnout and psychological characteristics. In the second part of the chapter, we will review the latest evidence on burnout among healthcare workers during the COVID-19 lockdown and its relationship with psychological characteristics. Parallelly, we will critically discuss the findings obtained and the implications for the prevention and treatment of burnout.

BACKGROUND

Herbert Freudenberger first introduced the term burnout in 1974 to define a specific state of energy exhaustion characterizing volunteers who work in the field of drug addiction. A few years later, Cristina Maslach gave a renowned definition of burnout after observing the phenomenon for which many healthcare workers experienced emotional exhaustion, a negative perception of their patients, and a professional crisis (Schaufeli, 1999). Burnout syndrome is a state of psychological and physical exhaustion caused by prolonged work-related stress (Maslach, Jackson, & Leiter, 1996). Many human services professions are vulnerable to this syndrome, such as healthcare workers assisting critical and/or chronic patients. In their theoretical model, Maslach, Jackson, and Leiter (1996) defined burnout as composed of three dimensions: emotional exhaustion, depersonalization, and lack of personal accomplishment. A

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decreased energy, together with fatigue and weakness characterizes emotional exhaustion. Cynicism, disengagement, and, more broadly, be unfeeling toward patients depict depersonalization. And, last but not least, a lack of personal accomplishment due to negative feelings on performance at work leads to reduced motivation and work productivity. Previous research has well documented a strong relationship between high levels of burnout and a dangerous hike in the incidence of health problems, including alcoholism, sleep disturbances, and depression (Salvagioni et al., 2017). High levels of burnout have also a negative impact on the perceived quality of patients and their satisfaction. A meta-analysis of 82 studies comprising 210,669 healthcare providers has found that burnout was associated with a poorer quality of healthcare provided and diminished safety for patients (Salyers et al., 2016). It is important to keep in mind that the effects were small to medium. Several variables including clinical setting, profession type, and psychological functioning of workers could account for this variance.

Because of its detrimental effects on the quality of care provided, burnout research has received increasing attention in the last years. First of all, when researchers investigate this phenomenon, it is necessary to distinguish between burnout and affiliated concepts such as compassion fatigue, compassion satisfaction, and resilience. Although there are some overlapping among these concepts, burnout specifically refers to cope with work-related stressors, whereas causes of compassion fatigue are mainly ascribed to secondary traumatic stress and vicarious trauma (Stamm, 2005). In other words, burnout is directly caused by a protracted period of emotional distress at work (Martins Pereira et al., 2011).

Several studies, over the years, have examined the interplay between sociodemographic factors and burnout, finding inconsistent results (e.g., Kamal et al., 2020; Rizo-Baeza et al., 2017). In this vein, there was a great deal of interest in the relationship between burnout and gender (O'Connor et al., 2018; Purvanova & Muros, 2010). Although burnout was frequently associated with the female gender (Burns et al., 2019; Maslach et al., 2001), other research has not found gender differences for any dimension of burnout (Lenzo et al., 2020b). Analogous conflicting results were found for other sociodemographic characteristics such as age and marital status or work-related factors such as years of experience. Yet many researchers find it problematic to integrate the contradictory results of the burnout prevalence among healthcare workers. Evidence from palliative care, for example, has reported a prevalence of burnout among practitioners ranging from 17% to 39% (Kamal et al., 2020; Koh et al., 2015; Parola et al., 2016). These results could be in part dependent on the use of self-report instruments, even though reliable and validated as the Maslach Burnout Inventory (MBI; Maslach & Jackson, 1981). It is known that self-report measures can be influenced by social desirability, and for this reason, past studies have indicated that social desirability can result in underreporting of symptoms of burnout (Lenzo et al., 2020b). Other researchers have noted that burnout research has attributed the causes primarily to organizational factors (Lenzo et al., 2021b). Indeed, individual differences in burnout risk can be explained, at least to some extent, by differences in psychological functioning. It was assumed that psychological factors representing a vulnerability for the onset and maintenance of mental disorders could be associated with burnout and other work-related problems among healthcare workers.

In this vein, several studies have demonstrated the role of dysfunctional metacognitive beliefs in predicting burnout among healthcare workers. In the context of the Self-Regulatory Executive (S-REF) model, mental disorders are related to a non-specific style of thinking, or the so-called cognitive attentional syndrome (CAS) (Wells, 2000). The CAS consists of iterative and negative thinking in the process of worrying and ruminating, driven by the positive and negative beliefs about worry, concerns about uncontrollability and danger, and the limitations on executive control. There is plenty of research that has demonstrated the relationship between this kind of metacognitive beliefs and several indices

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of maladjustment among patients with chronic medical conditions (Lenzo et al., 2020), such as cancer (Quattropani et al., 2016, 2017a), multiple sclerosis (Quattropani et al., 2018a), amyotrophic lateral sclerosis and their caregivers (Quattropani et al., 2018b; Lenzo et al., 2020d), irritable bowel syndrome and inflammatory bowel syndrome (Quattropani et al., 2019). These studies have used the Metacognitions Questionnaire – 30 (MCQ-30; Wells & Cartwright-Hatton), which is a simple and reliable tool assessing a wide range of metacognitive beliefs and processes relevant to vulnerability and maintenance of emotional disorders (Quattropani et al., 2015).

Findings from research on healthcare workers have bolstered the transdiagnostic and transversal role of metacognition in maladjustment and, specifically, in burnout syndrome. In this regard, compelling pieces of evidence came from many settings. One of the first studies has examined the risk of burnout and its relationship with metacognition in a sample of palliative healthcare workers. Interestingly, while controlling for sociodemographic variables and work experience, results pointed out that negative belief about uncontrollability and danger, together with cognitive confidence in attention and memory made considerable contributions in predicting the risk of emotional exhaustion (Quattropani et al., 2017b). Another study comprising a sample of healthcare workers operating in a hospital oncology unit seems to confirm these findings with negative beliefs predicting up to 22% of scores for emotional exhaustion (Lenzo et al., 2020e). Furthermore, cognitive self-consciousness, that is the tendency to monitor one's own thoughts and focus attention inward, predicted a high personal accomplishment.

Dysfunctional metacognitive beliefs likewise represent a vulnerability factor of emotional distress in informal caregivers. A cross-sectional study involving a sample of informal amyotrophic lateral sclerosis caregivers has highlighted that negative beliefs about worry concerning uncontrollability and danger were in close correlation with state and trait anxiety, cognitive and somatic aspects of depression, maladaptive coping strategies, and caregiver burden (Quattropani et al., 2018b). Moreover, there is an even more interesting result inherent in this research. Results have shown no significant differences between informal amyotrophic lateral sclerosis caregivers and health subjects for negative beliefs about worry concerning uncontrollability and danger or other metacognitive factors (Lenzo et al., 2020d).

Taken together, these findings point out the importance of considering metacognitions for understanding and preventing burnout syndrome and other maladaptive indices among formal and informal caregivers. To recap, metacognitions can be view as a transdiagnostic process associated with the onset and maintenance of emotional disorders. Because dysfunctional metacognitive beliefs preexist the onset of psychopathological symptoms, disturbance in metacognition can be considered as a vulnerability factor. The studies briefly described above extend the interplay between metacognitions and psychopathology to the work context and, specifically, to burnout syndrome among healthcare workers. If metacognition is "the aspect of information processing that

monitors, interprets, evaluates and regulates the contents and processes of its organization (Wells & Purdon, 1999)," then it is reasonable to think a role in the risk of burnout, that is a syndrome stemming from prolonged work-related stress.

Another factor related to how an individual cope with adversity and distress is psychological resilience. Consequently, one hypothesis of particular relevance was to examine the interplay with burnout syndrome. An increasing number of studies have explored the contribution that resilience plays in the decrease (or increase) of burnout among healthcare workers (Ang et al., 2018; Back et al., 2016; Manzano García & Calvo, 2011; Gerhart et al., 2016; Treglown et al., 2016; West et al., 2020). Nonetheless, the lack of a clear operationalization of resilience and, then, the lack of consensus on the term, has determined a

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great difficulty in comparing the results obtained. It could be not accurate to use self-report instruments for evaluating a so multifaceted construct such as resilience.

A well-established theoretic and research framework that directly addressed the issue of resilience was described by Bonanno (2004). In this perspective, resilience is the ability to hold a stable equilibrium after adverse and stressful events. Bonanno stated that one of the biggest errors in past theories and empirical research was to assume that coping and emotion regulation strategies can be always categorized as adaptive or maladaptive (Bonanno & Burton, 2014). The adjustment to adverse events, on the contrary, depends on one's capacity to enhance or suppress emotional expression according to contextual cues. In other words, flexibility in emotional response to situations represents a key factor in the successful adaption to adverse events (Burton & Bonanno, 2016). Hence, the efficacy of a given strategy tends to differ across situations and individuals (Birk & Bonanno, 2016; Bonanno et al., 2004; Bonanno et al., 2018; Webb et al., 2012; Westphal et al., 2010). The three components of an adaptive response to stressful events are sensitivity-to-context, availability of a diverse repertoire of regulatory strategies, and responsiveness to feedback. Also, each of these components is a phase of this process. Past studies have demonstrated that the perceived individual's ability to enhance or suppress emotional expression among, that is expressive flexibility, is a central tenet of mental health in healthy subjects and individuals after exposure to traumatic or adverse events (Gupta & Bonanno, 2011; McGreevy et al., 2015; Levy-Gigi et al., 2015; Birk & Bonanno, 2016). One worthwhile implication is that healthcare workers able to modulate their emotional expression across situations have a lower risk of developing burnout. It is reasonable to hypothesize that these elements of resilience can have a crucial role in decreasing the risk of suffering burnout. A recent study involving a sample of specialist palliative care practitioners tested this hypothesis (Lenzo et al., 2020b). The Flexible Regulation of Emotional Expression (FREE; Burton & Bonanno, 2016) and the Context Sensitivity Index (CSI; Bonanno et al., 2018) were used, respectively, to measure flexibility in self-regulatory behaviors and the ability to identify cues to contextual demands across various situations. Differently from self-report instruments mostly evaluating conscious attribution, the FREE and the CSI are scenario-based. In other words, both instruments do not necessitate respondents to have a precise awareness of their own abilities (Bonanno et al., 2018). Simply put, the FREE and the CSI permit to assess the hypothetical ability instead of the reminiscence on involvement in regulatory behaviors. The results obtained seem to confirm a significant effect of flexibility in emotional response on emotional exhaustion.

Once again, psychological interventions taking into account resilience may be useful for reducing burnout among healthcare workers. For example, a simple assessment of expressive flexibility allows identifying the individual with a higher risk of developing burnout. Other variables such as age, profession type, or hospital ward can make more tailored this kind of assessment.

If dysfunctional metacognitive beliefs and psychological resilience had shed light on burnout research, other studies have linked psychological factors to the onset and maintenance of the syndrome. A salient example is the attachment theory, even though more attention to the implications is still needed. According to Bowlby (1988b), the founding father of attachment theory, attachment is an innate motivational system that leads individuals, from the cradle to the grave, to seek proximity with beloved figures to feel safe and secure (Baldoni et al., 2018; Schimmenti et al., 2019). One of the strongest consequences is that the attachment style developing during early childhood influences how one reacts to stressful life events during adulthood (Bowlby, 1988a). In subjects with a secure style, attachment represent an interior resource, especially under stressful circumstances. In contrast, people who have an insecure attachment feel less confident to get comfort or to depend on others. Hence, attachment theory applied to the study

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of work can help understand why some healthcare workers experienced burnout, while others do not. Over the years, a rising number of studies have depicted attachment styles as linked to the individual response to stress. Findings from attachment theory have also improved our understanding of individual differences in well-being related to work (Lanciano & Zammuner, 2014). In their classic work, Hazan and Shaver (1990) demonstrated that workers with a secure attachment style had higher levels of work-related well-being, were less concerned about relationships, and they experienced greater gratification in their work when compared to workers with an insecure attachment style.

Further studies have demonstrated a relationship between attachment style and burnout, even though the number of these studies remains limited (Kokkonen et al., 2013; Musetti et al., 2020; Pines, 2004; West et al., 2015). Clearly, taken together, evidence from these studies confirmed that workers with a secure attachment style experience a lower level of burnout. Workers with an insecure attachment style, in contrast, experience a higher level of burnout. To recap, differences in risk of burnout among healthcare workers can be understood, at least to some degree, by differences in attachment styles. A possible limitation regards the cross-sectional design of these studies. If the causal connection between attachment style and burnout can be theoretically grounded, evidence from the available studies does not allow to conclude from an empirical point of view. The paucity of studies involving healthcare workers can be considered another potential limitation. Notably, a recent study has taken into account a very stressful clinical setting such as palliative care (Lenzo et al., 2021b). Palliative care practitioners take care of chronic patients in an advanced stage of disease, while supporting their caregivers. So, it is reasonable to conceive palliative care as a very stressful work context, especially when care is provided directly at home. Moreover, because of the multidisciplinary intervention characterizing palliative care, where physicians, nurses, psychologists, social workers, physiotherapists, and other professionals are simultaneously involved in the assistance of patients, it can be difficult to identify a common factor for the prevention of burnout. Findings of this recent study add evidence to the relationship between burnout and attachment styles in the context of palliative care. In particular, higher confidence in self and others was related to lower emotional exhaustion, which is a core component of burnout syndrome. On the other hand, a higher discomfort with closeness, need for approval, and preoccupation with relationships was related to higher levels of emotional exhaustion. These results appear consistent with what could be expected regarding the interplay between attachment style and burnout. In fact, confidence in self and others describe one key component of a secure attachment style, whereas discomfort with closeness, need for approval, and preoccupation with relationships are inherent to the insecure attachment style (Feeney et al., 1994; Fossati et al., 2003). Nonetheless, the low-medium correlation coefficients lead to hypothesize a significant contribution by other variables. Regression analyses controlling for age, gender, and work experience, seem to corroborate in part these findings. Confidence in self and others predicted emotional exhaustion but not the other two dimensions of burnout syndrome, which are depersonalization and personal accomplishment. Years of experience at work was another predictive factor of emotional exhaustion. It is worthwhile to underline that confidence in self and others as a key component of burnout syndrome also predicted personal accomplishment, even though the model did not reach a statistical significance and no other predictors were found. These findings can enhance the understanding of individual differences in the risk of burnout among healthcare workers. One of the strongest implications concerns the prevention of burnout with the use of simple and reliable instruments to assess burnout and attachment dimensions.

Together, these pieces of evidence provide a multifaceted vision of burnout among healthcare providers. As mentioned above, presumably the biggest obstacle to understanding and preventing is that

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burnout was mainly reconducted to organizational factors. Consequently, strategies for burnout prevention have focused on the improvement of the work environment (Nantsupawat et al., 2016). This is surprising because several decades ago it has been demonstrated that occupational experience is linked to psychological functioning (Kohn & Schooler, 1973).

The evidence we briefly summarized in this paragraph confirms the role of different pre-existing psychological characteristics that contribute to the onset and the maintenance of burnout syndrome and negative consequences related to the work environment among healthcare professionals. In the next paragraph, we will deepen some of the evidence focused on the interplay between psychological functioning and burnout or other negative consequences during the COVID-19 outbreak.

MAIN FOCUS OF THE CHAPTER

During the first Italian lockdown, the healthcare system was heavily hit with healthcare workers facing an unknown threat. Roughly, while healthcare personal worked under pressure because of the excessive workload, front-line healthcare every day assisting infected patients experienced a strong fear of contagion and isolation of community. In Italy, unfortunately, the estimate of death among healthcare workers was high with 360 deaths until 8 August 2021 only by considering physicians (National Federation of Italian doctors).

Past studies referred to the 2003 outbreak of severe acute respiratory syndrome (SARS) reported symptoms of post-traumatic stress disorder ranging from 5 percent to 10 percent and alcohol abuse/dependence symptoms, with a higher percentage for frontline healthcare workers or who had been quarantined (Bai et al., 2004; Wu et al., 2008, 2009). A systematic review on the psychological impact of quarantine during past outbreaks such as SARS, Ebola, and Middle East respiratory syndrome-related coronavirus (MERS) has highlighted that healthcare workers merit particular attention (Brooks et al., 2020). Because of the prolonged contact with infected patients, healthcare workers are also exposed to an increased risk to be quarantined. Quarantine leads to isolation from loved ones and colleagues, together with the limitation of movement. Adequate organizational support seems to mitigate the psychological impact (Brooks et al., 2018), even though it may not be enough for a prolonged pandemic such as COVID-19. Past studies are referred to a defined and brief period of forced quarantine, mainly associated with a limited geographical area. Next to this, there is a lack of research specifically focused on burnout syndrome. Probably the reason is that burnout syndrome represents a psychological condition developing gradually over time (Schaufeli & Enzmann, 1998). Hence, anxiety, general distress, or analogous psychopathological symptoms may be more appropriate to consider as an immediate outcome. In fact, a longer period is usually required to observe burnout syndrome among healthcare workers.

To date, there is no shortage of evidence related to the psychological impact of the COVID-19 outbreak (Pappa et al., 2020), even though the long-term consequences on the healthcare professional (and the population) are still unknown. Nonetheless, early studies have pointed out alarming results. A recent study involving a sample of 1257 healthcare workers reported a prevalence rate ranging from 44.6 percent for anxiety to 71.5 percent for distress (Lai et al., 2020). The authors also reported a higher risk for frontline healthcare workers in the city of Wuhan. About 48% of frontline healthcare workers reported secondary traumatic stress in a study comprising individuals from 45 different countries (Orrù et al., 2021). The prevalence was about 30% among healthcare did not assist COVID-19 patients. A study conducted in Japan has pointed out a wider difference (Nishimura et al., 2021). While the prevalence of

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burnout among healthcare workers assisting COVID-19 patients was 50%, the prevalence among those who did not assist COVID-19 was only 6.1%.

Another study conducted at the beginning of the pandemic in the city of Wuhan reported that about 60 percent of healthcare workers had a mild-to-severe mental health disturbance, without adequate access to mental health services (Kang et al., 2020). Among all participants, only 17.5% had participated in group psychological counseling, while the others have had psychological materials (36.3%) or online psychological resources such as books on mental health or messages on self-help coping methods (50.4%). Although these methods can be of immediate value to help individuals, alone are not enough to prevent the disorder from becoming chronic. Next to this, it is not possible to exclude pre-existing mental health disorders among healthcare workers who participated in these studies (Gold, 2020). In other words, a positive anamnesis for mental health disorders or even only an antecedent psychological vulnerability can worsen the psychological impact for workers during the pandemic. Cross-sectional research design extensively used during the so-called “first wave” did not allow us to take into account underlying mental health disorders or medical conditions.

It is not surprising that psychological symptoms tend to be associated with physical symptoms. A multicenter study on a sample of 906 healthcare workers from Singapore and India has found that the presence of physical symptoms predicted higher scores on depression, anxiety, and stress (Chew et al., 2020). The authors explained these relationships highlighting a bi-directional path between psychological and physical symptoms.

Since December 2019, when the COVID-19 occurred in China, many other countries were rapidly involved. Specifically, evidence from the Italian context highlighted the risk of emotional exhaustion and somatic symptoms among healthcare workers facing the COVID-19 outbreak (Barello et al., 2020). Anxiety and fear of contagion seem to be the main preoccupation for healthcare workers needing psychological aid interventions (Maldonato et al., 2020). Healthcare professionals who assisted COVID-19 patients are twice as likely to demand psychological support as those that did not assist COVID-19 patients (Trumello et al., 2020). In light of this perspective, Conti and colleagues (2020) stated that the need for psychological support stem from the psychological distress, depression, and anxiety among the healthcare workers during the COVID-19 outbreak. In this vein, a study found a prevalence rate of moderate to extremely severe symptoms about 9 percent of depression, anxiety, and stress, with individual resilience mitigating the psychological impact (Lenzo et al., 2021a). Findings of this study comprising a sample of 218 Italian healthcare workers have shown significant relationships between psychological distress and flexibility in emotion regulation (Lenzo et al., 2021a). Moreover, the ability to enhance emotional expression contributed to explaining depression, while the ability to suppress emotional expression was a significant predictor of stress among healthcare workers. On the other hand, the ability to accurately perceive contextual cues made a significant contribution in predicting stress. Higher percentages of psychopathological symptoms were found by Conti and colleagues (2021). Most of the sample had high levels of depression, anxiety, and post-traumatic symptoms with, respectively, 57.9%, 62.5%, and 55%. Moreover, it was reported that 25.61% of the respondents had burnout, even though findings are referred to the first wave. Hence, burnout could be pre-existing and not strictly related to COVID-19. In fact, data was collected from 30 March to 3 May 2020 and, so, during the first peak of contagion.

Another study has examined burnout risk among Italian general practitioners during the COVID-19 outbreak (Di Monte et al., 2020). Findings pointed out a significant impact of the COVID-19 emergency, even though resilience contributed to mitigate it. Being the front line for patients with COVID-19 symptoms, general practitioners were those most affected by the contagion with the high number of

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deaths among medical specialties (Lapolla et al., 2020). If there is a consensus on the role of resilience in mitigating negative consequences of traumatic events, other studies have examined various psychological factors related to stress management. Moccia and colleagues (2020) have reported, for example, a prevalence rate of psychological distress of 20 percent in the Italian population with attachment style predicting the reported symptoms. The authors concluded that insecure attachment would be considered a risk factor for moderate-to-severe distress. Therefore, the first findings from healthcare workers during the lockdown following the COVID-19 outbreak seem to confirm these relationships briefly outlined in the previous paragraph.

As time goes by, researchers have continued to verify psychopathological symptoms and burnout levels experienced by healthcare professionals. A recent cross-sectional study involving a large sample of Italian healthcare workers has pointed out that a third of the participants reported severe state anxiety and distress, high emotional exhaustion and depersonalization, and low personal accomplishment (Naldi et al., 2021). Results have also revealed that pre-existing conditions were associated with higher scores on the burnout dimensions. Specifically, family division, increased workload, and job changes were associated with high levels of emotional exhaustion, whereas constant contact with infected patients was associated with high depersonalization.

The prevalence of psychopathological symptoms has continued to be high during the second wave. Once again, researchers have wondered what factors moderate its psychological impact. One of the most studied factors was still resilience. A study that enrolled 136 Italian healthcare workers assisting COVID-19 patients has underlined that 60% of them experienced burnout, without distinction between physicians and nurses (Stocchetti et al., 2021). Most of the participants were moderately or highly resilient, even though the results of regression analysis did not underline a relationship with burnout. This is quite surprising because previous evidence referred to the first wave has demonstrated how resilience mitigates the impact of the covid-19 outbreak among the general population (Lenzo et al., 2020a). The authors argued that resilience could be not sufficient to decrease burnout among workers in the Intensive Care Unit. Nonetheless, other studies have revealed a significant role of resilience in decreasing burnout risk. A study involving a sample of 267 Italian healthcare workers have found that individual with high-risk burnout had a lower level of resilience and greater problem in accepting the uncertainty than the individual with a low risk of burnout (Di Trani et al., 2021).

SOLUTIONS AND RECOMMENDATIONS

Individual psychological differences among healthcare workers could explain conflicting prevalence rates of burnout and other work-related psychological symptoms. Conflicting evidence on prevalence rate could derive in part from the role of certain psychological characteristics in preventing burnout and other manifestations of psychological distress. A deeper investigation into the role of psychological characteristics towards work-related psychological symptoms in healthcare workers is thus greatly required.

FUTURE RESEARCH DIRECTIONS

Longitudinal studies could help to clarify the long-lasting influences of psychological characteristics on burnout among healthcare workers who faced the so-called second wave. Because of studies conducted

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during the pandemic have used web-based survey system to collect the data, it is not possible to discern the role of a positive anamnesis for mental disorders. So, preexisting psychiatric disorders could have influenced the results.

Moreover, it should be tested the efficacy of psychological intervention for burnout. Several studies have depicted the role of some psychological characteristics. Taken together, these findings should be used to approach burnout among healthcare workers facing the COVID-19 outbreak, especially professionals who assist infected patients. However, the first step remains to offer a full range of psychological services to healthcare professionals.

CONCLUSION

Burnout syndrome represents a state of emotional exhaustion, depersonalization, and reduced personal accomplishment (Maslach et al., 1997). The main theme of this chapter is burnout syndrome among healthcare professionals and the interplay with individual psychological functioning. Although there are overlapping constructs such as compassion fatigue, burnout is specifically associated with response to interpersonal stressors on the job (Maslach, 1998). Differently, compassion fatigue refers to healthcare personnel working with traumatized patients (Figley, 2002). In the past decades, causes of burnout were ascribed mainly to organizational factors. Maslach and Leiter (1997), for example, argued that burnout stems from a mismatch between individuals and their job setting. More recently, research has provided evidence for the role of psychological characteristics, such as metacognitive beliefs, resilience, and attachment style in predicting burnout and psychological distress among healthcare workers (Quattropani et al., 2017; Lenzo et al., 2020; Lenzo et al., 2021). These findings could be useful to a deeper understanding of psychological factors promoting mental health.

If research has provided evidence for the role of psychological characteristics in predicting burnout, several studies conducted during the lockdown following the COVID-19 outbreak seem to confirm these relationships. On one hand, findings have demonstrated significantly high levels of burnout and psychopathological symptoms among healthcare workers. On the other hand, several factors were associated with a worse psychological impact of the COVID-19 outbreak, such as assisting infected patients. Moreover, a growing body of research has pointed out the role of psychological characteristics in mitigating the psychological impact of the COVID-19 outbreak and its related restrictive measures. However, more research is needed to verify these relationships and to examine the long-term consequences on the healthcare workers heavily involved in the COVID-19 outbreak. The implication of these studies concerns the implementation of psychological interventions reducing the psychological impact of working during the COVID-19 outbreak. One of the strengths regards the possibility of tailored psychological intervention to prevent and treat burnout among healthcare workers who are facing the pandemic.

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KEY TERMS AND DEFINITIONS

Anxiety: An emotion characterized by feelings of tension, worried thoughts and physical changes like increased blood pressure.

Attachment Style: The characteristic way people relate to others in the context of intimate relationships, which is heavily influenced by self-worth and interpersonal trust.

Burnout: A form of job-related stress that has not been successfully managed.

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Compassion Fatigue: Stress resulting from exposure to a traumatized individual.

Depression: A mood disorder that causes a persistent feeling of sadness and loss of interest.

Metacognition: It refers to a person's ability to regulate their thinking and learning and consists of the self-assessment skills: planning, monitoring, and evaluating.

Psychological Distress: A state of emotional suffering associated with stressors and demands that are difficult to cope with in daily life.

Resilience: The process of adapting well in the face of adversity, trauma, tragedy, threats, or significant sources of stress—such as family and relationship problems, serious health problems, or workplace and financial stressors.

Stress: The reaction people may have when presented with demands and pressures that are not matched to their knowledge and abilities and which challenge their ability to cope.

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Chapter 8

The Sense-Making Process in Adjustment to Breast Cancer Experience in Younger Women:

A Clinical Healthcare Perspective

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ABSTRACT

The recent medical progress ensures high rates of long-term survival even in the face of illness previously with an unfortunate outcome: this is the case of breast cancer, which, to date, ensures more than 80% of long-term survival rates, and that for this reason can be interpreted as a chronic illness. In particular, the onset of breast cancer in under-50 women represents a potentially traumatic event that storms in the life of a young woman breaking the narrative sense of continuity, sameness, and integrity. This chapter discusses the role of narrative psychological devices for the understanding and the promotion of sense-making process and psychological adjustment to illness. Within a psychological risk preventive framework, the authors show findings from a longitudinal narrative research on the sense-making processes with breast cancer younger women highlighting narrative indexes of risks and resources during the first year of treatment. Implications for longitudinal support will be discussed.

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INTRODUCTION

To date, public health systems have to face new challenges and new demands emerging by the contemporary epidemiological scenario that is deeply different from that of a few decades ago. Relevant medical and demographic changes have characterized the last two decades and have made it necessary to make major economic and scientific efforts in order to make healthcare contexts the more prepared as possible to adequately respond to new health demands. These are especially related to the actual prevalence of non-communicable illness, which are non-infective illness characterized by their lasting nature, resulting in specific medical, social and psychological needs, which have to be recognized and addressed for an adequate sanitary assistance (Beaglehole et. al., 2011; Bennett et. al., 2018). The World Health Organization identifies cardiovascular illness, cancer, diabetes and chronic respiratory disorders as non-communicable illness.

Since some decades, we are witnessing progressive growth in the average life expectancy and, accordingly, in the ageing of population all over the world.

As the Global Health Estimates (WHO, 2019) over the past twenty years average life expectancy has globally increased from 66,8 to 73,3 years. This demographic change, however, has resulted in an increased of disability due to the prevalence of non-communicable illness: even if in 2019 people were living more than 6 years longer than in 2000, only 5 of those years were lived in good health. Indeed, most of older people often suffer from cardiovascular illness, diabetes, cancer and chronic obstructive pulmonary: these non-communicable illness have been collectively responsible for the reduction of healthy life-years and for the increase of disability from 2000 to 2019 (WHO, 2019).

The current prevalence of non-communicable illness is also due to social, economic and technological progress. Developments in these areas have in fact contributed to the increase of unhealthy lifestyles as the risk factors (Andreyeva et al., 2011; Fox et. al., 2019; Imam & Ismail, 2017; Lear et al., 2014; Lencucha & Thow, 2019; Willett et. al., 2006; Wu, 2019)

Finally, one of the major cause of the prevalence of long-lasting illness is medical progress. This apparently paradoxical affirmation finds its explanation in the fact that current progress in scientific, medical and technological fields have made possible the screening and the treatment of illness previously considered incurable and with a poor prognosis.

These advances, together with demographic and economic changes just discussed, have contributed to transform most of illness from acute to long lasting. Therefore, while until the second half of XX century medical demands were prevalently related to acute or infective illness, for some decades healthcare systems have more and more often faced challenges connected to long-lasting and non-communicable conditions (Epping-Jordan et. al, 2004; Graffigna & Barello, 2018; Holman & Lorig, 2004; McGrady & Moss, 2018). Acute illness are characterized by a sudden onset and a duration of few days or week. Therefore, like every other illness they consist of signs and symptoms and of some limitations of normal functioning, but their specific characteristic is that the duration of these symptoms is limited in time, due to quite fast healing or – as often happened until a few decades ago – to death (Scandlyn, 2000).

Long-lasting illness are instead characterized by their enduring nature: people have to live with them for many years (when not for their entire life), and have to face complex management and treatment plans while dealing with psychological effects of disability, loss of autonomy and changes in daily routines.

The medicine is capable of saving lives in many pathological conditions, but it is not yet able to cure some of these pathologies. The enormous increase in survival rates in oncological illness today generates an increase in people who face chronic conditions.

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These conditions are given both by living with a tumor in the cure or remission phase, and by living with cancer which, thanks to modern treatments, may have turned into a "chronic condition" to live with, taking drugs, undergoing regular checks.

"Long survival" can certainly be understood as a chronic condition. For all cancer survivors what begins as a crisis involving diagnosis and treatment gradually becomes a chronic illness characterized by lifelong follow-up medical care, psychological effects and changes in social and employment relationship. The chronic nature of the cancer was demonstrated by many respondents' continued numbness, pain, swelling, and other physical effects of the surgery; continued thoughts about recurrence and nervousness associated with medical follow-up; and concerns regarding health insurance coverage and the willingness of others to discuss the cancer and its long-term effects (Polinsky, 1994).

People with long-lasting conditions often express needs related to the continuous challenges they have to face: the need of being fully engaged in their medical treatment, the need of having easy access to sanitary services, and, not least, the need of formal and healthcare contexts adequately prepared to respond to their emotive and psychological needs (Holman & Lorig, 2004; Robinson, 1990). Undoubtedly, the complex needs of these patients require complex organizational strategies in order to be addressed: one of the main challenges of healthcare systems for the last decades have been to plan and carry out these strategies, trying to take in account the multiple levels – medical, psychological, relational, social, economic – of the experience of living with a long-lasting condition. An effort in this direction is, for example, the recent emerging of narrative medicine (Charon, 2008, 2017), a paradigm aimed at addressing psychological experience of patients by giving voice to their stories, and specifically to needs and expectations connected to their illness. Considering patients' narratives can help physicians to set up interventions based on scientific knowledge as well as on psychological experience of patients. In this sense, narrative medicine represents a possible – tough partial – answer to contemporary challenge of providing a holistic healthcare assistance especially to people who live with long-lasting conditions. .

In this chapter, the authors will address the psychological concerns related to a long-lasting illness in particular: breast cancer in younger women. Then, they will introduce the psychological narrative paradigm as a useful framework to both understand psychological experience of people living with a medical illness, and support their psychological, social and physical adjustment to illness. Specifically, the authors will address the narrative paradigm in clinical health psychology with a specific attention on narrative and longitudinal sensemaking process by which people make sense of critical experience of treatment, as can be breast cancer.

In the last part of this chapter the authors will describe a research project with the aim of exploring longitudinal processes of sensemaking in under-50 women with breast cancer through an ad hoc narrative interview. On the bases of the research results, the authors will suggest a specific theoretical framework for understanding and supporting psychological experience of under-50 women with breast cancer, based on the relevance of sensemaking process and on the usefulness of narrative devices to support the ongoing treatment experience within a preventive point of view to empower the long-survivorship.

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BACKGROUND

The Under-50 Women and Breast Cancer Experience: Psychological Impact Trajectories

To date, breast cancer is the most common cancer affecting women and the primary cause of mortality due to cancer in female around the world, even if, thanks to progress in screening and treatment programs, its 5-years survival rate in developed countries is estimated to be of 80% (Akram et. al., 2017).

Despite these progress, incidence and mortality rates of breast cancer are expected to increase significantly the next years, due to the resistance to therapy and to the frequent delays in diagnosis: indeed, not enough women do self-inspection and clinical examination of the breast on a regular basis (Akram et al., 2017; Anastasiadi et. al., 2017).

That is to say, that breast cancer is undoubtedly a global health issue because it poses continuous challenges to healthcare systems. Indeed, these have to set-up complex and innovative programs of screening, they have to assure that the greatest possible number of women follow these programs, and, not least, they have to ensure scientific-based treatments, management and follow-up in order to provide an adequate medical assistance to women, also facing the problem of resistance to therapy.

However, contemporary medical issues related to breast cancer are also related to some recent changes in its epidemiology. Indeed, in recent years breast cancer has been frequently diagnosed in young women: specifically, epidemiological studies indicate that, in the last 15 years, the highest incidence of breast cancer was in the 34–49 age group (Global Burden Disease, 2018).

This trend results in additional challenges for health systems due to the medical and psychological characteristics of this sample of women.

With respect to medical concerns, young women are diagnosed with more advanced illness and have less favorable outcome than older women especially amongst endocrine-responsive tumors (Keegan et al., 2012; Partridge et al., 2016). In addition, breast cancer usually presents at later stages and with more aggressive and larger tumours in younger women, and it has a greater morbidity and a greater risk of local and systemic illness recurrence (Brinton et. al., 2008; Keegan et al., 2012; Shoemaker et. al., 2018). The type of surgery (mastectomy or quadrantectomy) have physical and psychological sequelae regarding body image; the consequences of treatments including premature menopause, impaired fertility, sexual dysfunction have far reaching impact for these women both medically and psycho-socially, thus, specific multimodality care is paramount.

Also, the BRCA1 and 2 genetic mutations are a specific area of vulnerability of younger women because they have a "chronic risk" of a second primary breast cancer as well as a primary ovarian cancer and they must make prevention decisions (Ahmad et al., 2015; Kenen et al., 2006).

The challenges connected to breast cancer in younger women are also related to social and economic issues: indeed, his the incidence accounts for significant excess costs in medical treatment and lost productivity (Paluch-Shimon et. al, 2017).

Finally, studies also state that hereditary predisposition is more common amongst young women and it pose an additional psychological burden. Indeed, a genetic predisposition not only affects the clinical management, but may also impact on decision making related to other family members due to the risk of the possible hereditary transmission of the illness. In addition, women with a hereditary predisposition syndrome often have to cope with physical and/or psychological invasive medical procedures for the

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reduction of future risk of cancer, procedures whose clinical utility is not yet well established (Paluch-Shimon et al., 2017).

According to the ESO-ESMO 3rd international consensus guidelines for breast cancer in young women (Paluch-Shimon et al., 2017), despite the fact that the young breast cancer patients are more vulnerable to psychosocial distress at diagnosis and later during their illness trajectory and despite there have been identified different areas that need prioritization by the medical community, young women are underrepresented in contemporary multidimensional research and the actual scientific knowledge are based on data about older women.

The medical concerns just discussed highlight that under-fifty women with breast cancer are a more vulnerable target showing specific needs and clinical aspects that cannot be overlapped with data present in the literature, which mainly focused on the target of women over 50 years of age (Authors, 2015c, 2016a, 2016b, 2018, 2019c, 2019d; 2019e, 2020, 2021a; Chou et. al., 2012; Cordova et al., 2007; Koopman et al., 2002). In addition, the medical aspects of illness contribute to give shape to psychological experience of living with breast cancer at a young age: this can be considered a repeated critical experience that starts from the illness onset which has characteristics of intangibility and chronicity (hereditary or possible relapse) (Gurevich et al., 2002) and continues during the different phases of treatment (Authors, 2016a, 2016b) and along survivorship (Fernandes-Taylor et al., 2015).

Every medical phase is constituted as turning points of the protocols related to medical treatment, and at the same time they reflect psychic turning points of the meaning of relationship with illness over time. Specifically, form a clinical psychological perspective, the onset of breast cancer before the age of 50 represents a critical, potentially traumatic event that storms in the life of a woman, with physical and psychic consequences that seem to acquire specific characteristics both in terms of impact and in adaptation to illness in a phase of life characterized by important achievements (Authors 2017,) when women are performing development tasks with greater strength and physical endurance (e.g. career, family responsibilities and care of children) compared to a subsequent phase of the life cycle (Di Giacomo, 2019).

The clinical psychology perspective still appears to be lacking both in terms of understanding specific characteristics connected to the impact and crossing the experience of breast cancer during a younger age both in terms of proposal of personalized support practices for a target defined as vulnerable by early stages of the therapeutic path (Chou et al., 2012; Cordova et al., 2007; Koopman et al., 2002). Starting from our previous literature review (Authors, 2021b) authors have highlighted 3 peculiar aspects of this experience: clinical psychological risks; the feminine-specific concerns; resources between individual and relational aspects.

A younger age emerges as a vulnerability factor that predisposes the women to more traumatic outcomes or to a greater risk of developing post-traumatic stress disorder (Cordova et al., 1995; Koopman et al., 2002).

Among the clinical psychological risks in women under 50, authors highlight more emotional distress, anxiety, depression symptoms, lower vigor for the aggressiveness of the chemotherapy received, regardless of the surgical procedure or tumor evaluation time (Broeckel et al., 2000; Coyne et al., 2004).

One of the reasons for less psychological adaptation, both during and after treatment (Ahmad et al., 2015) is the “fear of recurrence”, described as “the fear or worry that the cancer will return or progress in the same organ or in another part of the body” (Simard & Savard, 2009; Vickberg, 2003) and younger women are particularly vulnerable (Costanzo et al., 2007; McGinty et al., 2012; Mehnert et al., 2009; Taylor et al., 2012).

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In exploring the fear of recurrence's predictors in younger women, the literature recognizes the levels of anxiety and illness representation, particularly the perception of breast cancer as intruding into life with negative physical, social and economic effects (Lebel et al., 2013). This perception is greater at a younger age because the illness is completely unexpected and interrupts a rich planning of life.

The concept of FRC and its measurement are presented to the psychological attention as an element of clinical relevance.

In addition to the clinical psychological risks, the young women with breast cancer have the specific concerns from multiple family/social roles compromised to feminine- specific areas such as fertility, body image and sexuality.

When a woman under 50 becomes ill with breast cancer, she must contend with a continuous balance between her roles as a working woman, wife and mother (Adams et al., 2011) and the priority of surviving cancer. She has *a sense of having to be strong* (Coyne & Borbasi, 2006) for the benefit of the family, often hiding their feelings, which remain unexpressed. Younger women report fighting to address the dependent children's needs, including how to communicate to them about illness in a child friendly way (Walsh et al., 2005). Younger women are also concerned with the possible transmission to their children of mutated genes that predispose to breast cancer. These are the experiences of "social separation": feelings of isolation, emotional distance and reduction of communication with children and family.

In medical terms, an age before of 50 at diagnosis is reported as a negative prognostic factor for the fertility. Adjuvant systemic therapy is recommended for most women and has been demonstrated to reduce the risk of recurrence and increase survival. However, there may be a negative effect of this treatment on ovarian function and fertility - an early menopause, temporarily or permanently - as well as on subsequent quality of life (C. H. Lee et al., 2010; R. J Lee et al., 2011).

Fertility-related concerns of under-50 women with early breast cancer are menstrual changes and potential infertility, attitudes and decisions about pregnancy, breastfeeding, contraception and fertility information needs (Peate et al., 2009). The literature shows that treatment-induced infertility can change women's concept of their femininity and be particularly difficult for single women who are not mothers, who are perceived as potentially undesirable for a future partner (Connell et al., 2006; Dryden et al., 2014; Shaw et al., 2016). Discussions, information, options and emotional support about fertility should be provided in the diagnostic phase (Dicé et al., 2020). For example, thinking of having a child after breast cancer is associated with the fear that pregnancy can increase the risk of recurrence, and that breastfeeding can interfere with the detection of breast cancer (Ganz et al., 2003)

However, it is important to actively involve women in decision-making during the treatment in order to improve psychological adaptation to the illness (Bruera et al., 2002; Dicé et al., 2018).

The body image and sexual function, whose co-occurrence is even more traumatic for the psychological adaptation of younger women (Fobair et al., 2006; Paterson et al., 2016; Rosenberg et al., 2013). The complex concept of body image in women who have been treated for breast cancer includes three dimensions (Hopwood et al., 2001): the affective one (feeling feminine and attractive), the behavioral one (avoiding people because of physical appearance) and the cognitive one (satisfaction with physical appearance or with scars). Also, this construct includes facets of perception, cognition, behavior, and emotion as they relate to the function of the body after diagnosis and treatment for breast cancer (Fingeret et al., 2013). Body changes resulting from treatments - hair loss, breast loss, weight gain - and physiological symptoms associated with early menopause - vaginal dryness, libido loss, hot flushes, mood swings, short-term memory loss, sexual dysfunction - have a strong negative effect on women. Women who have better basic conceptualization of their body image can deal with the effects of the

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illness better (Han et al., 2010). However, in the latest literature it can be found a few studies indicating that this issue is worse in younger women.

Only a recent review (Paterson et al., 2016) shows how prevalent body image-related concerns in younger women occurred after different types of treatment. This demonstrates the most traumatic effects of radical surgery that transform the woman's corporality and question her identity. In addition to the treatment's effect, the physical symptoms (loss or weight gain and muscle pain) and psychological symptoms (anxiety and depression) are correlated with poorer body image.

Sexual dysfunction in YWBC is characterized by vaginal dryness, dyspareunia, amenorrhea, loss of sexual desire, decreased frequency of sexual activity, difficulty reaching orgasm, and anxiety about sexual performance 26,27. Champion et al. (2013) found that nearly half of young women reported a decrease in the following domains of sexual function: Sexual interest (48%), arousal (44%), lubrication (52%), orgasm (38%), frequency (41%), ability to relax (41%), and fantasies (41%). In addition, 41% of young women indicated that their sexual relations had worsened and 40% that their sexual enjoyment had diminished 7. Sexual difficulties are present during treatment and continue through the follow-up period in the majority of patients. However, concerns about sexuality seem to be more frequent at the beginning of treatment, specifically during chemotherapy and trastuzumab therapy, than during hormone therapy and follow-up

Changes in a couple's sexual life are obvious. However, if the partner is supportive and sympathetic, the sexual functional changes can be integrated and a sexual relationship can be resumed during treatment. Sexual regulation is associated with how much the woman feels she can openly discuss her feelings and desires with her partner.

In fact, taking into account the aspect of individual and relational resources, it is highlighted that the variability of women in the process of adaptation to the diagnosis and treatment of breast cancer is related both to aspects of personality, such as the style of coping and to the forms of support that women received and perceived.

For younger women, perceived social support, both emotional and practical, is an important predictor of long-term adaptation (Peate et al., 2009), especially when received by her mother (Ali et al., 2014) and her partner, while single women miss having a partner during the illness (Corney et al., 2014). positive cognitive restructuring (2.78), wishful thinking (2.38) and making changes (2.24). Being religious is also considered as a source of support that can help in understanding and addressing this illness positively (Almeida et al., 2015; Tarouco et al., 2009). Also, the literature indicates the tendency of younger women to use "emotional ventilation" and fight spirit as coping strategies (Mosher & Danoff-Burg, 2006). A possible role of mediation between the age and the fear of recurrence is provided by the self-efficacy, defined as women's confidence in the ability to manage symptoms and emotions related to having breast cancer, including the ability to ask for help, to know how and when to report symptoms, and to do what is important after breast cancer treatments are completed (Ziner et al., 2012).

Among the resources, ti can be noted the importance of the trauma processing interventions. These data allow us to highlight the importance of diachronic psychological interventions - in the single phases of cancer treatment - aimed at the cognitive and emotional processing of the traumatic experience in order to support the identification of resources for the coping of experience. Narrative psychological perspective is a useful framework for the theoretical and methodological development of these interventions.

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Make Sense of Breast Cancer: The Narrative Point of View

Narrative Paradigm for Understanding Critical Medical Experiences

Since some decades, narrative paradigm in psychology has been a relevant theoretical and methodological framework for addressing meaning-making and sensemaking processes through which people construct and signify their experiences (Authors, 2015a, 2015b, 2020, 2019b; Bruner 1987, 1990, 1991; McAdams 1988; McAdams & McLean, 2013; Sarbin, 1986; Smorti, 1997).

In fact, since the'80s, the positivistic paradigm of knowledge was questioned in favour of a more constructivist one within various scientific disciplines, according to the need to better understanding the complexity of human, social and physical systems. Specifically, in social and human sciences this shift resulted in a partially transition from quantitative to qualitative research methods: many scholars began to be more interested in deep understanding of subjective experience through qualitative research, than in discovering universal laws for human thinking through experimental methods (Atkinson, 1997; Hyvärinen, 2006, 2010; Murray, 1997). Sociologists, anthropologists, philosophers and psychologists have found especially in narrative an interesting qualitative method through which explore people's experiences. From a psychological point of view, narrative can be considered as a thinking process though which people make sense of their critical experiences: as Bruner (1990) pointed out, narrative thinking plays a major role when people face unusual events, namely events that can not be understand in the light of previous personal meanings, goals and values. A critical experience questions – at least momentarily – what people know about themselves, their environments and their ability to act: they are not able anymore to understand what's happening through usual way of thinking. In this case, narrative thinking works in order to find a possible answer to the question *«what's going here?»*. Creating – not necessarily verbally – a story about a critical experience means creating new connections between self and experience, in order to restore the canonical state of things apparently disrupted by the unusual event (Bruner, 1990, 1991). Through narrative, people organize their experience in time and space, found an explanation – in terms of mental states, objectives, motivations – to what have been happened to them, and construct new universe of meanings within which the critical experience may be included. In this sense, narrative thinking is strictly connected to meaning-making and sensemaking processes through which continuity and coherence disrupted by adverse experiences can be restored (Neimeyer, 2001).

However, narrative in psychology is considered not only as a way of thinking, but also as a qualitative research method through which psychologists can gain insight into people's experiences – most of all critical ones – as they are constructed and signified by who live them in first person. Indeed, many scholars use narrative interviews as a means by which understand personal meanings through which people interpret critical experiences (Atkinson, 1998; Authors, 2019a, 2019b; Lysaker et. al., 2002; McAdams, 2008).

In addition, narrative in psychology is also a methodological framework useful to set up support interventions aimed at promote processes of adjustment to critical experiences by sustaining the gradual emerging of new points of views and new meanings (Madigan, 2011; Neimeyer, 1999).

As readers will have noticed, narrative in psychology – considered as a way of thinking, as a research method, or as a methodological framework for support interventions – is strictly connected to critical experiences. However, since its origins, narrative paradigm in human sciences have been interested in a specific type of critical experience: serious medical illness.

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Sociological and anthropological studies about the role of patients' narratives for the full understanding of medical illness have been extremely relevant for the development of a specific psychological framework. Indeed, many studies within these fields have suggested that paying attention to contents of patients' stories about their illness could have been useful for understanding the way by which they make sense of their experience. In this sense, narrative contents have been considered the gateway for understand how people organize their illness experience, that is to say how they make sense of their symptoms, how they integrate functional limitations in their daily life, how they come to terms with the profound changes in their social and working roles, how they project themselves in the future despite the illness, and, finally, how they negotiate social and cultural rules connected to illness (Bury, 1982; Frank, 1995; Hydén, 1997; Mattingly & Garro, 2000).

These theoretical contributes have highlighted the role of narrative in the interpretation of illness and in the psychological adaptation to it. Therefore, they have laid – alongside the contributes of the narrative psychology – the groundwork for the gradual emerging of *Narrative Health Psychology*. This can be considered both as an application of the principles of narrative psychology for healthcare issues, both as a specific qualitative research and intervention method within the field of health psychology (Sools et. al., 2015). However, narrative health psychology provide a specific theoretical and methodological framework aimed at understanding illness and health conditions as they are constructed and signified by patients. It is interested in contextualized understanding of psychological human functioning rather than in quantitative variables connected to health and/or illness. In this sense, this discipline contributes to provide relevant insights to the recent perspective of narrative medicine that – as authors have briefly referred – constitutes an attempt by medical field to specifically address patients' needs by paying attention to their illness stories (Charon, 2008, 2017).

Furthermore, narrative paradigm provides a useful framework for medical disciplines which have gradually began to be interested in using qualitative and narrative methods not only in order to understand the subjective experience of illness, but also to address a wide range of issues connected to healthcare, such as physician-patient relationship or quality of sanitary services (Freda et. al., 2017; Stephens, 2011; Tsianakas et al., 2012).

Apart from the role of narrative in medicine, within a clinical perspective of health psychology narrative paradigm has at least two possible fields of application: the understanding of psychological experience of illness through patient's narratives, and the promotion – through narrative interventions – of sensemaking processes aimed at improving psychological adjustment to illness, meant as a critical experience (Petersen et al., 2005; Piana et al., 2010).

Serious Illness: Biographical Disruption and Narrative Reconstruction

The authors believe that the critical experience of illness can be meant as a non-normative transition in the sense proposed within the perspective of Life Span Psychology (Baltes et. al., 1999). According to this perspective, a transition is an event occurring during the life that requires relevant changes and efforts of adjustment, while a non-normative transition is specifically an event that not all people of the same age, sex, culture, and social context necessarily experience. A serious illness can be meant as a human non-normative experience: it occurs in most cases unexpectedly and requires psychological processes of adjustment specifically due to its extraordinariness. Indeed, it has a critical – and sometimes, but not always, traumatic – dimension because it inevitably questions the main values, roles, assumption and objectives that have, until then, constituted the taking-from-grant dimensions of people's life. In addi-

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tion, it may threat sense of continuity, sameness and coherence of patients, questioning relevant aspect of their identity (Aujoulat et. al., 2007).

From a medical point of view, serious – and especially long-lasting – illness are often characterized by continuous changes: they evolve over time and so do the physical, social and psychological consequences due by them, as well as medical symptomatology and medical procedures needed for their treatment (Charmaz, 2006). In addition, symptoms often appear discontinuously and this often implies delays in diagnosis; however, even after the diagnosis, physicians don't know how the illness are going to specifically evolve for the single patient: this may generate uncertainties and insecurities that is not always easy to cope with. Results emerging from studies on patients' narratives highlight that the uncertainties connected to medical aspects of illness are in addition to the uncertainties specifically related to profound changes in personal and social roles (Authors, 2021). Indeed, people implicitly assign a value to their daily activities in account of how they are relevant for their identity. For example, if a person considers his work as a fundamental dimension of his life, that means he is totally engaged in his working activity, lot of his memories are related to his work and his plans for future are strictly connected to that, probably a illness that imposes an at least partially reorganization of working habits constitutes a profound disruption of a self-marker, namely a meaningful aspect of his identity. (Aujoulat et al., 2007). This is obviously true for all the other activities and/or roles that constitute relevant markers for self and that may be questioned by a diagnosis of serious illness.

Therefore, a serious illness can be meant as a *biographical disruption* (Bury, 1982), or as an *ontological assault* (Crossley, 2000, 2003a), because it constitutes a threat to some basic presuppositions of human life. First, it constitute a threat to at least two fundamental dimension of patient's identity: knowledge about his own body and knowledge about his working, social and functional roles. Furthermore, it challenges common sense knowledge about canonical behaviours, beliefs and conventions that normally guide meaning-making process by which people give sense to their reality. Finally, a serious illness often disrupts one's sense of time, because plans and goals for future have often to be suspended, at least momently. Therefore, the experience of patients living with a serious illness is often blocked in an idealized past or in a present marked by sufferance and pain: their narratives are characterized by a temporal organization lacking of future perspective (Crossley, 2000; Davies, 1997; Ezzy, 2000).

After a diagnosis of a long-lasting illness, people may experience a strong sense of powerlessness due to challenges just discussed (Aujoulat et al., 2007). In particular, from patients' narratives emerge that the sense of powerlessness is especially related to the loss of control over one's body, emotion, environment and time. Indeed, physical symptoms made one's body a sort of new land, characterized by unknown processes, needs and demands that may generate feelings of anxiety, fear and distress. Furthermore, new necessity connected to illness often makes difficult to devote time to habitual activities – not to mention that loss of control over time is also connected to the fear of death – and make necessary to depend, at least to some respects, to one's environment, entailing profound changes in one's social, familiar and working roles. In addition, sense of powerlessness often experienced by people with serious illness may be related to the fear of transmitting illness to descendants, and this is most of all true in the context of illness with a hereditary component, such as breast cancer (Aujoulat et al., 2007).

As Miczo (2003) pointed out, the disruptive dimension of illness is also related to the impairment of one's health: indeed, health is not only considered as the good functioning of one's own body, but also as a personal and social resource that allows people to engage in relevant activities, as well as a social positive value. This means that a physical illness disrupts identity not only by questioning relevant knowledge about one's self, body and environment, but also by questioning the image of self as a healthy

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person. This is especially relevant because health is often, even if implicitly, considered as a moral value, therefore a physical illness could threat the perception of self as a worthy person (Crossley, 2003b).

The biographical disruption imposed – at all these levels - by the illness, requires a biographical work in order to be addressed, understood and finally repaired. Like Corbin e Strauss (1985) pointed out, a medical illness requires the patient to engage himself not only in a medical work, that is the work needed to carry out medical treatments, and in in a daily work, that is linked to the changes in daily routine needed for the management of the illness, but also in a biographic work. The biographic work relates to the set of processes needed to come to terms with the identity changes imposes by illness and to engage oneself in a better psychological adjustment to it. These processes can be meant as narrative processes by which people reconstruct their disrupted identity and their past, reorganize both future plans both relation with self, body and others, and fundamentally try to give sense to changes and challenges connected to their illness (Miczo, 2003). Therefore, the biographical work needed for psychological adjustment to illness can be meant as a narrative work, and can be addressed and improved by narrative methods. As it is been discussed here, when people narrate their illness experience, they make sense of it: that is to say that narrative not only *says* something about the meaning of illness constructed by patients, it also *do* something, namely is has a function. Specifically, its function is related to sensemaking processes through which people construct meaningful connections between self and the critical experience.

One of the first and most relevant theoretical contributes about the function of narrative in the context of medical illness is provided by Hydén (1997). He stated that, through narrative, patients could integrate their illness into their identity, can explain both to themselves and others the perceived causes of illness, and can interact with others in order to reach their goals - this can me meant as a strategic use of narrative. Finally, narrative entails to transform illness from a personal through collective question: this is especially true for medical illness related to relevant social question, for example AIDS. These different narrative functions allow people to construct a *"world of illness"* (Hydén, 1997). Indeed, illness's characteristics, also medical ones, are not totally objective because they assume importance and meaning in account of specific desires, goals, beliefs and expectations of the person: this means that functional limitations imposed by illness have different meanings for different people, because they interweave with different habits, desires, social roles, in the end with different subjective worlds. In this sense, narrative – meant as illness stories as well as narrative thinking - constitutes a tool by which these limitations may acquire subjective meanings. Narrating one's experience enables to construct links between illness's world and self's world: through narrative, people not only create a story about illness, they instead create a new subjective world within which illness can be collocated (Garro, 1992).

If illness can be meant as a disruption of the map that people have used, until then, to orient themselves in their experience, narrating can be meant as the active process through which new maps can be reconstructed (Frank, 1995). Indeed, Williams (2000) introduced the concept of "narrative reconstruction", meaning the way by which people *normalize* their illness through narrating it. The process of normalizing is meant here in his literal meaning, as a movement towards the construction of new norms useful to interpret the illness, and/or towards the representation of illness in a way that is consistent with the basic norms of oneself existence. As the authors have previously discussed, narrative thinking is activated especially in response to events that disrupt canonical order of things, that is to say challenges habitual norms: in this sense, a serious illness imposes a narrative urgency to the mind, because it requires new norms in order to be understood. Therefore, trough narrative, illness can be subjectively interpreted, and new normality can be constructed, including also changes and identity transformations due to illness. Talking about one's illness and narrating its story to oneself and to others enable patients to understand

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its origins and reconstructing the story of one's life so that illness can be included in it (Williams, 1994). In this way illness can be framed into the movie of one's existence so that links between past, present and future can gain meaningfulness. Therefore, narrative process can be seen as active process of *emplotment* (Crossley, 2003a), namely a process through which people make sense of their story as it continuously evolves and progress. In this way, people can reflect upon their past experiences and their role in influencing present, they can active engage themselves in the temporal dimension of present, and they can finally imagine their future as it's shaped from present, that is in turn influenced by past, that is in turn reconstructed in the light of present and of future plans. Therefore, narrative *emplotment* entails to create connection between past-self, present-self and future-self in the light of actual illness.

Furthermore, narrative has also the function of giving voice to pain and suffering emerging from the body: the language of illness is first of all a visceral, affective and embodied language, which through narrative can be translated into a declarative and shareable one. This means that, through telling stories about their illness, people can *see* the changes occurred in their body and can reflexively integrate them in their identity (Frank, 1995).

Finally, narrative in the context of serious illness has a social and cultural function. Indeed, through stories people can share their experience with others trying to gain social support and to show – more or less consciously – a desirable image of themselves to others (Riessman, 1990; Werner et. al., 2004). However, the link between narrative and culture have been conceptualized also in the opposite direction, namely from culture to narrative: the stories people tell about their illness are deeply rooted in their social and cultural contexts, so they contribute to reproduce the cultural representation of illness in the space of social relationship and, at the same time, they have the power to gradually change this representation. In this sense, culture give form to narratives and narratives give form to culture (Murray, 2000).

In conclusion, the theoretical contributes discussed here highlight the role of narrative in allowing people to reflect upon their experience, capture significant turning points, put order into uncertainties, fears and bodily perceptions connected to illness and to interact with others. This means that narrative performs function of reflection, socializing, and identity and temporal reconstruction, which interweave each other giving rise to processes through which people give sense to their illness or, better to say, to their life transformed by illness (Borden, 1992; Garro; 1992; Lillrank, 2003).

In this sense, the relevance of narrative within clinical health psychology is strictly related to sense-making processes activated by it: through narrative thinking, people can gain insight into their illness experience, reconstruct self and coherence and integrate illness into their universe of meanings. At the same time, listening to patient's narrative can help clinicians – both psychologists and physicians – to understand illness as it has been signified and constructed by person himself. Finally, through narrative psychological tools, sensemaking processes can be explored and transformed: for example, a narrative expressing a representation of illness based on conflict and suffering, can gradually be addressed, understood and transformed in a different narrative, expressing a representation of illness based on integration and adjustment. The authors are not suggesting here a distinction between "good" and "bad" narratives, but instead a distinction between sensemaking process less or more functional for a good adjustment to illness. Therefore, the focus is here on process (narrating) instead on result (narrative) (Schiff, 2006, 2012).

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IMPRONTE PROJECT: A LONGITUDINAL RESEARCH ON THE SENSE-MAKING PROCESSES OF THE ILLNESS EXPERIENCE WITH BREAST CANCER YOUNGER WOMEN

Contest and Aim of IMPRONTE Research

The research project IMPRONTE: BREAST CANCER WOMEN: INNOVATIVE MODEL for PROCESSING TRAUMATIC EXPERIENCE was conducted within a collaboration between Department of Humanities of Federico II University Naples (Italy) and the National Cancer Institute "*Fondazione G. Pascale*", Naples (Italy), which is the national reference for the treatment and care of neoplastic illness. The research was conducted in the frame of Programme STAR, financially supported by *UniNA* and *Compagnia di San Paolo*. The research was co-constructed in collaboration with the hospital's psychology service and breast unit surgery and approved by the medical committee of the National Cancer Institute.

The aim of the research was about the possibility to understand in deep the natural process of narrative sensemaking that mediate the relationship between the young women with breast cancer and the experience of illness during the different phases of medical treatment (one year) (Authors, 2019c, 2019d, 2019e, 2020, 2021).

The women who took part in this research were identified from medical reports and qualified according to the following:

- Eligibility criteria: First access to the hospital before the age of 50; diagnosis of infiltrating ductal breast cancer; voluntary participation.
- Exclusion criteria: Metastatic illness (stage IV); psychotherapeutic treatments in progress.

The recruitment of the women was conducted through a 1-day meeting in the hospital to explain the whole path and the aim of the research.

Women's participation was voluntary; they provided informed consent, and privacy policy was approved by the hospital. The meeting with women was conducted during different medical phase, constituting a turning point of the medical treatment protocols, reflects turning points in the meaning of the woman's relationship with Brest Cancer over time and the psychic challenges (Authors, 2019c). In Phase I prehospitalization (T1): facing the unknown, the woman is still undergoing diagnostic investigation of a suspected nodularity. In Phase II counselling post-operative (T2): impact of the critical valence of the illness, the woman learned about the severity of her pathology (receiving histological examination), has undergone surgery for malignant nodularity, and decides the therapeutic path to be taken. In Phase III adjuvant therapy (T3): relationship with a changed body identity, the woman is faced with postoperative chemotherapy or radiotherapy treatments that affect her relationship with her body. In Phase IV follow-up (T4): construction of a new continuity, the woman returns to the daily routine of life and integrates the maintenance phase, which will last for at least five years. During Phase IV, the woman finds herself recovering spaces of autonomy and gradually reducing dependence on the medical institution since she only goes for follow up.

It has been recruited in the first phase of research 50 women during the prehospitalization phase. During the study the women undergo the four longitudinal phases are: 10 women, below 50 years old (M = 44.4) during the pre-hospitalization phase (T1: 40–60 days before surgery) and then researchers met them again during the postoperative counseling phase (T2: 30–40 days after surgery) that is when

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the women received the response of the histological examination, during adjuvant therapy phase (T3: 25–35 days after the start of therapy can differentiate into chemotherapy, radiotherapy, hormone therapy) and at follow-up phase (T4: first check-up after about 8 months after medical treatments).

Narrative ad Hoc In-Deep Interview

Authors constructed an original *ad hoc* narrative interview, named the Early Breast Cancer-Processing Interview (EBC-PTI), to explore young women's narrative sensemaking processes within the BC experience (Authors, 2019e) in every phase of their therapeutic path.

The narrative interview, repeated in the same format during T1, T2, T3, and T4, involved nine open questions that start from the initial request to narrate the illness's experience from the moment it appeared until the time of the interview. Each question was intended as a narrative prompt able to open construction of sense at each stage of the ongoing experience.

The interview was constructed to activate different ways of declining narrative discourse.

There is the alternation between questions that open up episodic narratives (e.g., *I would like you to choose three words/adjectives/idioms that come to mind when thinking about this phase of the experience. There is a particular event/episode to which you relate when she says … We are interested in knowing, what happened, where she was, who else was with her, what she felt, what she thought at the time*) and semantic narratives (e.g., *People sometimes imagine or have ideas about why they got sick … do you have any idea about it or imagine something?*), thus activating the different narrative functions as modes of functioning of narrative thinking.

The questions are ordered to allow a gradual immersion in the critical experience, opening, in the final parts, a space for dialog on resources and changes (e.g., *Could you tell me if there is someone or something that you have felt to be particularly helpful? How? With whom do you find yourself talking about it? Of our meeting … Could you tell me if there is one thing in particular that you feel you can draw from going through this phase?*). The interview was conducted in an *ad hoc* room of the hospital; it has an average duration of approximately 45 min and was recorded and then transcribed verbatim. The interview was conducted by two women psychologists who are experts in clinical psychology and narrative methodology. The same gender membership has represented a key point to promote the narrative of women. The researchers were young women; this allowed them to construct an empathic and exchange relationship with the patients.

Narrative Device and Narrative Functions

Semiotic Perspective to Interpret Narratives Within the Medical Field

In this research, authors are interested in a "process" vision, and for this reason, they will embrace, alongside a narrative constructivist perspective, a semiotic perspective.

The focus of this research is on exploring sensemaking processes articulated in the relationship between emotion and thought. Based on the narrative functions, which will be presented below, there is a generalization of the affective process.

The semiotic perspective allows to pay attention to sensemaking processes and to the relationship between affectivization and its declination.

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The basic process of sensemaking is given by the role of affects that have a primitive nature and can be understood as embodied meanings. Therefore, sensemaking is a constitutive function linked to subjection, to the body, to embodied affects. Meaning-making performs an attributive function, associating semantic predicates with predetermined entities of external words. Meaning is an associative process between a sign and a referent of reality or the internal world, configuring itself as a function after sensemaking (Authors, 2011).

In other words, the meaning emerges from the sense, that is, from how the signs connect since meaning is not a question of content but associative link potentiality.

It is precisely in the transition from sense to meaning that the generalization of affect intersects with thought, finding its discretization. The narrative functions created below allow the moving from affective generalization to the organization of thought with dimensionality.

By the term function, authors mean the process that allows information to be manipulated at multiple levels and to respond to the ever-changing demands of the environment, processes that are essential for the individual's adaptation in support of mental health (Piaget, 1964; Bion, 1984; Winnicott, 1945; Vigotskij, 1962). Starting from the mentioned literature, authors highlight the five key functions that define the process of semiotic connection among the different objects of the experience, which all constitute the fundamental aspects of adaptation and coping with the BC experience (Authors, 2018). Therefore, the narrative functions represent different ways of functioning of narrative thought (Bion, 1984).

Organization of temporality. This function refers to the possibility to organize cancer experience by subjectively connecting different temporal plans of own life, connecting and discussing the plan of the "before" and "after" the illness as a watershed that the onset of BC brings to the fore. The narrative embeds BC in a time frame, id est, the insertion of elements of the story of BC within a spatial and temporal framework (the temporization process) (Bulow & Hydén, 2003). Narration allows to bring together, in a tridimensional way, the different lines of time, past–present–future, giving to this link a subjective meaning (Authors, 2015; Brockmeier, 2000).

Search for meaning. This function refers to the connections in the interpretation of the event "BC," finding meaning in the world in the face of a critical event, rebuilding shattered worldviews, and constructing connections between continuity and discontinuity (Bonanno et al., 2004; Davis et al., 2000; Janoff-Bulman, 1989, 2004) In other words, this function tries to construct a narrative meaning around what is happening. It refers to searching for an answer to the question "Why me"? and what relationship or perspective can be created between oneself and the experience of the onset of cancer (Sherman & Cohen, 2006).

Emotional regulation. This refers to the narration process as a dynamic multilevel system regulating the relation between emotion and thought and the connections between emotion and event. The narrative device allows a process of labeling emotions and realizing the important roles that these emotions play in the BC experience. The narration process is an opportunity to label the emotions and connect them to events in light of the present. The connection between emotion and event, mediated by the narrative device, establishes the basis and containment for emotional regulation processes (Tronick & Beeghly, 2011; Valsiner & De Luca Picione, 2017) and meta-reflects on the new version of the experience.

Orientation to action. This refers to the relationship between oneself and the action meant to cope with BC. This function is the narrative construction of the ability to make decisions and choices and undertake behaviors that impact events. Therefore, the narration is an open and dynamic process of constructing, regulating, and transforming its agency (Authors, 2018; Brockmeier, 2009).

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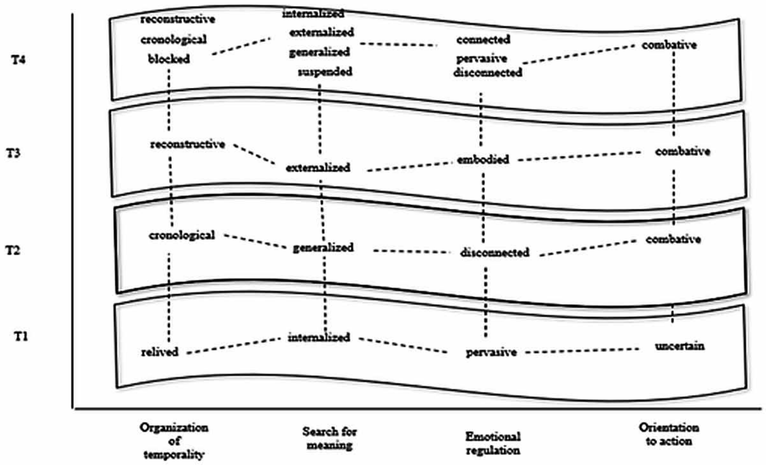
THE NATURAL STORY OF LONGITUDINAL SENSE-MAKING PROCESS OF THE BREAST CANCER EXPERIENCE WITH YOUNGER WOMEN

A longitudinal theory-driven analysis show the way in which the different narrative functions evolve and transform over time and the different way of functioning of functions in a specific phase of therapeutic path.

Figure 1. Natural flow map of sense-making process during breast cancer experience



By looking through the narrative functions in the different phases of the illness, authors have observed the quality of the trajectories that emerged through repeated narration during four phases. They found and interpreted the sensemaking process that each function goes through in different ways according to the experience.

This study, in an innovative way, unfolds through a binocular look: the method of analysis, that is, the functions and different modalities that emerged, on the one hand, offer a vision through the functions in every phase of the illness path and, on the other, a vision through the phases in the different functions

On the one hand, these narrative functions, intended as markers of the narrative sensemaking process, signal a progression in which the narrative device activates specific psychic functions in each phase of the experience. They tend to integrate and construct an internal synthesis of meanings between the self and the world, activating previously unexplored strategies to face the illness.

On the other hand, these markers give the chance to reflect on the most critical modes, which tend to be rigid and to crystalize, representing areas of risk as in emotion regulation function. Specifically, in the transition from T1 to T2 and in the transition from T3 to T4, authors have noted a difficulty in connecting one's emotions to the events that are going through, which stands in a disconnected mode. This result allows to highlight the critical issues in constructing the link between emotions and events, which starts from the moment of communication of the histological report and from the beginning of invasive and long-lasting therapies and which persists over time. These markers indicate the rigid structures of relationship with the events that are likely to remain during the crossing of different treatment times, possibly affecting the quality of life and adaptation to the experience.

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Authors want to highlight how the sensemaking process's trajectories show a common feature in the different functions (organization of temporality; search for meaning; emotional regulation) as illness experience evolves, highlighting a common trend. On the one hand, the functions related to the early stages of the illness experience (T1-T2-T3) highlight some specific modalities more clearly; on the other hand, at the end of the T4 illness experience, they more clearly highlight a variegated assortment of modalities (figure 1). This movement could be connected to a greater convergence of meanings linked to the illness's early stages and the medical process. At the end of the experience, the patient may articulate a greater variability of the experience related to the subjective to re-read it and configure the articulation toward a still uncertain future. It could also be linked to the aspects with which the woman articulates the relationship with her own experience in this phase and to the ways of reconstructing a new subjective position in her relationship with the illness, no longer mediated by the medical institution but subjectively connoted in her relationship with a new future (in remission and follow up).

Taking a look through the stages in the various functions, authors have also observed the specific aspects of every phase of the medical treatment; thus, it is possible to observe how not all the phases of the illness ring internally in an equal way in young women. It is possible to identify which phases of BC treatment appear to be more critical for women below 50 years old from a clinical point of view. Each phase is characterized by specific and peculiar psychic challenges, presented in the introductory part of our work that the woman must face. The research work presented represents at the same time a method of research and understanding of the experience of women in the different phases of the illness but also represents a method of clinical intervention to be developed in future works. As emerges from the analysis of the narrative, each phase of the illness generates specific processing tasks, adaptation to experience, and integration between continuity and discontinuity of experience.

Starting from these premises and based on the results that emerged from our analysis, authors can advance some hypotheses on a clinical level. Within a framework of clinical psychology of health, narrative intervention based on the promotion of health and well-being aimed at diachronic processing of the experience, aimed at all women, can be thought as a possibility to support the coping functions of adaptation. Let's think about the possibility of reading and interpreting the different functions and methods that emerge in their mutual relationship to give the current experience meaning by integrating all functions. A type of narrative and diachronic intervention based on the possibility of accompanying and supporting the construction of resources to elaborate the relationship with experience and face the psychic tasks that this relationship poses, from time to time, in salience (White & Epston, 1990). Guided by the most salient modalities that emerged in the different phases, authors can advance some clinical suggestions.

Regarding the first phase of the illness, one can think of an accompaniment to welcome and actively listen to the illness onset. This allows the woman to cope with the sudden emotional impact of the experience (pervasive mode), emphasizing what the current experience reopens and updates, in temporal terms, compared to similar experiences in the past (relieved). The work will aim to discriminate between past and current experiences, consider ways of coping with similar past experiences and possibly build connections with the waiting and uncertainty that is part of the current experience (uncertain).

Regarding the second phase of the illness, following the knowledge of the degree of malignancy of the pathology, one can think of an accompaniment aimed at building a narrative space capable of asking the question of "why me?", oscillating, and not crystallizing, between an intra-subjective position and an intersubjective position (generalized). The construction of the subjective meaning of the experience arises precisely from recognizing emotions (disconnected). The recognition, differentiation, and narrative

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labeling of the emotions at stake also play an adaptive value concerning the experience. This process can begin with putting the problem at a distance, which allows building new ways of relating to it and supporting an active position, already present, toward the illness (combative).

Regarding the third phase of the illness, one can think of an accompaniment to connect sensations, which now come from a body changed due to chemo and radiotherapy treatments, emotions, and events. Listening and speaking of the body's sensations will represent how to connect, on a more advanced level, with the emotions experienced (embodied). This connection process opens up to a re-crossing of the experience lived up to now (reconstructive) and a narrative reorganization to build a subjective emotional position toward events. This process allows regulating and balancing the relationship between emotions and events.

Regarding the fourth phase of the illness, the various modalities that emerged show a relationship based on the variability of the relationship with experience due to the illness's remission and an independent look toward the future. You can think of an accompaniment aimed at identifying the new links built up to now and meta-reflecting on them to integrate the experience into one's life story. This narratively allows the patient to transform and reorient, where necessary, her relationship with the direction of actions. With the integration of experience, she can adapt to a new version of herself. This process allows, by revisiting the events experienced, to start a process of re-evaluating one's experience and preparing for the future.

IMPLICATIONS FOR HEALTHCARE WITH BREAST CANCER YOUNGER WOMEN

Authors believe that this research gives some insight both for understanding of psychological adjustment to illness and for politic decisions about health topics.

First of all, authors want to reflect about the use of the narrative device: the ad hoc method of analysis of narrative functions can be used as a diachronic map of the relationship with experience, which, in terms of future development, can be used by giving it a prognostic value, on the one hand, and risk prevention on the other hand. The longitudinal study of the way in which the narrative functioning of young women is articulated in every phase of the illness experience allows to look at the natural story of a process of psychological adaptation to the breast cancer, thus identifying aspects of risks and resources that can be useful in promoting interventions, aimed at the possibility that an under-50 woman becomes an active promoter of her long-survival.

Second, authors want to reflect about the implication of this research's results for healthcare systems. Indeed, in this chapter authors reviewed the available research reporting specific areas of psychological impact of breast cancer in a distinct and vulnerable population of under-50 women in oncology. To identify these areas in a particular group of scientific interest, it is necessary to obtain information that is eminently useful to researchers, policy planners and all providers of healthcare for women. A clinical healthcare perspective recognizes the importance of developing a gender medicine attention: in a medical emergency that prioritizes treatments to safeguard life, an informative and emotional support is necessary looking at feminine-specific concerns and needs, fertility issues and possible options to preserve it. It is important to actively involve women in decision-making during treatment in order to improve psychological adaptation to the illness.

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It is necessary thinking about patterns of research and clinical psychological intervention that accompany women during the phases of illness treatment aimed to supply the resources needed to deal with the illness in a functional way. Implications for psychosocial oncology concern training practices addressed to all hospital staff (doctors, nurses, healthcare professionals, etc.) in order to sensitize the needs of this new type of patient.

CONCLUSION

In conclusion, authors believe that the narrative device fulfills different modes of psychic functioning within each phase of the breast cancer medical treatment and makes it possible to highlight risk elements for women below 50 years old by identifying the moment in which they can develop.

The narrative turned out to be both an exploratory tool, as used in research, and a longitudinal narrative assessment device capable of giving the clinician a trend in the relationship between psychic functioning and ongoing experience.

The overturning of the more usual view of literature aimed at exploring and supporting only the phase of long-survival, authors think that understanding psychic functioning and adaptation to experience during treatments can perform a preventive function and identify psychic risk and/or observation of psychic processes that find their natural evolution over time. Just think of the physiological fragmentation and narrative disorganization that occurs in the phase of impact with the news of a tumor.

Authors believe that this vision can allow women to be able to better manage not only the 12 months of invasive medical therapies but also the years of long survival that increasingly configure oncological illness as a chronic condition.

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KEY TERMS AND DEFINITIONS

Biographical Disruption: The threat to self-identity caused by a chronic disease due to the fact that it often impairs social, cultural, and relational experience of the ill person.

Clinical Health Psychology: A discipline resulted from the clinical perspective applied to health psychology; it highlights the role of sensemaking process in the health promotion and in the psychological adjustment to illness.

Critical Experience: A non-normative experience – for example the onset of a serious illness – that questions a person's basic assumptions, goals, and values, breaking his/her sense of continuity. It requires sensemaking process in order to be integrated and understood.

Illness: The psychological and subjective dimension of a medical disease.

Narrative Functions: The psychological tasks that narrative process allow the narrator to perform. Some narrative functions are search for meaning, organization of temporality, emotional regulation, and orientation to action.

Narrative Reconstruction: The process by which people, through narrating their critical experiences, can give them meaning and integrate them in the sense of self.

Noncommunicable Diseases: Diseases not directly transmissible from one person to another. World Health Organization include among them cancer, diabetes, cardiovascular diseases and chronic respiratory disorders.

Psychological Adjustment: The process by which people adapt themselves to psychic challenges and/or environmental changes.

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Chapter 9

Budget Sustainability and Integrity as Essential but Not Exhaustive Aspects of the Control of the Superior Insitutions of Control (ISC) on Health

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ABSTRACT

The health emergency led in 2020 to the definition of numerous measures involving interventions on the health system: measures with a specific financial allocation and aimed at affecting the most problematic aspects of care, which were mainly attributed to the choices made in recent years. This chapter analyses the measures launched to face the crisis. The chapter, moreover, emphasizes how the Italian healthcare system, despite the difficulties encountered, has withstood the impact of the crisis.

INTRODUCTION

The health emergency led in 2020 to the definition of numerous measures involving interventions on the health system; measures with a specific financial allocation and aimed at affecting the most problematic aspects of care, which were mainly attributed to the choices made in recent years.

The measures launched fall into four main areas of intervention

- Areas aimed at increasing staffing levels in health facilities that have been under severe pressure since the beginning of the pandemic and that had already suffered from a reduction in permanent

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staff and an increasing use of fixed-term contracts or consultancy services that did not allow them to maintain an adequate quality of supply;

- Areas aimed at immediately adjusting the availability of hospitalisation facilities in terms of intensive and semi-intensive care beds, in line with the growing numbers of the pandemic, interrupting the downward trend that had characterised the last decade in particular. These measures were accompanied by more structural measures for building and technological upgrading entrusted to specific programmes;
- Areas intended to strengthen the territorial structures that proved to be more exposed and fragile in the face of a sudden and unexpected phenomenon such as Covid;
- Areas aimed, finally, at reducing the undesirable effects of the strong concentration of assistance on Covid subjects and the blockage of activity due to lockdown. Particularly high costs in terms of the postponement of screening, the lengthening of waiting lists for specialist services, the postponement of non-urgent hospitalisation activities that have become necessary and which represent, after the loss of human life suffered, perhaps the most negative legacy that this crisis has left us from the health point of view. Naturally, these areas of intervention have been supplemented, starting in 2021, by that aimed at making it possible to implement the Vaccination Plan, which should enable us to emerge from the crisis in the coming months, but of which it is still too early to propose an assessment, even a partial one.

THE IMPORTANCE OF HEALTHCARE

The emergency that the country is currently facing has made clearer, if there were any need to do so, the importance of being able to count on efficient healthcare that is capable of responding to threats made more insidious by an increasingly open and globalised economic system. This experience has also highlighted its strengths and weaknesses, making it clear that, beyond the extraordinary emergency caused by an unexpected ‘enemy’, choices had to be made.

The success recorded in recent years in reabsorbing imbalances in the use of resources has not always prevented the emergence of critical points that must now be overcome:

- The unacceptable differences in the quality of the services offered in the different areas of the country;
- The lack of personnel due to the constraints imposed during the restructuring phase,
- The limits in the planning of the necessary professional resources, but also to a progressive flight from the public system;
- The inadequacy of territorial assistance in the face of the growing phenomenon of non-self-sufficiency and chronic illnesses;
- The slow progress of investments sacrificed in face of current needs.

These difficulties are made even more acute in perspective by the growing demographic imbalance with an ageing population with one of the highest life expectancies in the world and lower birth rates (as shown by the analyses released by ISTAT (2021) – Italian Insitute of Statistics - in February 2021) and the consequent burden on workers. It is well known that in just 20 years’ time, looking at the forecasts, the ratio will change to one pensioner for every two people of working age, reducing the wealth generated

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and the public resources available against an increase in health and care needs. In addition, the decline in the resources available to the younger generations at retirement raises serious questions about the possibility, also in the future, of making citizens bear increasing shares of health and especially social and health care costs not covered by the National Health System (NHS).

The growth of this share of health consumption is in fact only partly attributable to difficulties in accessing the public service due to waiting lists or imbalances in the tariff system. The ageing of the population and the increase in the number of cases of non-self-sufficiency (which require not only assistance in activities of daily living, but also the taking care of increasingly widespread chronic pathologies) and a greater awareness of the extent to which certain behaviours are correlated with the maintenance of health have contributed to this.

This has been compounded (and will be compounded even more in the near future) by the development of innovative treatments and robotics, which open up new spaces for more effective treatment methods. This trend is likely to accentuate the differences between citizens depending on their geographical areas and economic conditions.

Hence the need to consider what choices should be made, in the knowledge that boosting the financing of the public system entails reviewing the focus, which has prevailed so far, on measures involving direct monetary transfers or lower taxation. But also in view of the fact that the expenditure control exercise that has characterised these years, within the framework of an allocation of resources for guaranteeing essential levels of care decided also in relation to the needs of the public sector, has led to a reduction in the number of people with disabilities.

This is precisely to prevent inefficiencies and mismanagement from making it impossible to translate the increase in funding allocated to the health system into actual services for citizens, as has happened in the past. Hence the need to continue along the path proposed by the Health Pact, signed in December 2020, to strengthen the capacity to plan spending at the level of local communities. This is the aim of the projects launched in recent years, which can count on a wealth of information and knowledge that make the health system a leading player in the national framework.

The crisis has also, and above all, highlighted the risks inherent in the delay in strengthening local structures in the face of the strong effort made to recover higher levels of efficiency and appropriateness in the use of hospital facilities. While the concentration of hospital care in large specialised facilities was certainly justified in order to safeguard the health of the public, reducing the number of minor ones, which, in terms of the number of cases and the availability of technology, did not guarantee adequate results in terms of treatment (the Outcome data bank provided clear evidence of this), the lack of an effective system of assistance in the territory has left the population without adequate protection. If, until now, these deficiencies had been passed on to the families, not without problems, relying on private economic resources and on a form of assistance that was often based on a workforce with low social and health qualifications (carers), and ended up affecting the individual, this deficiency ended up representing a weakness also from the point of view of the overall defence of the system when a new and unknown challenge was presented. In fact, it is increasingly evident that an adequate network of assistance on the territory is not only a matter of civilisation in the face of the difficulties of the individual and of persons with disabilities and chronic illnesses, but represents the only means of defence for dealing with and rapidly containing phenomena such as the one we are fighting. The inadequacy of the resources allocated to the territory has made the first front, which should have been able to oppose the spread of the disease, find itself involved in the difficulties of the population, paying a very high price in terms of lives, disarmed.

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Attention to these issues was seen in the last budget law (Law 30/12/2020) with the provision of funds for the purchase of equipment for general practitioners' surgeries (Article 1, paragraphs 449-450), but it will still have to be implemented once the crisis is over, just as resources will be needed for investments aimed at restoring the efficiency of healthcare facilities. This is a requirement that requires a careful verification of the quality of expenditure. It is for this reason that this year too the chapter, after a quick look at the issues on which the debate was focused during the crisis, confirms its traditional approach centred on the results of the financial year just ended, on the examination of the measures put in place to safeguard the effectiveness and efficiency of expenditure and on the most recent results of the monitoring of the essential levels of care.

HEALTHCARE IN THE COVID-19 TEST

The health emergency in our country has brought the characteristics of the health system back into the spotlight. The health emergency in Italy has brought the characteristics of the health system back into the spotlight.

The health emergency in our country has brought the characteristics of the health system into the spotlight, highlighting not only its strengths but also the problematic aspects attributed above all to the choices made in recent years. years.

These aspects should be mentioned at the beginning of the analysis, before looking at the results of the exercise that has just begun. the results of the financial year that has just ended.

And this in order to draw useful elements to assess the reasons for these choices, the changes to be made to the management of the health system in the light of the the light of the Covid-19 emergency and the answers that may derive from the Health Pact signed between the State and the Regions at the end of 2019 (Conference of the Regions, 2019).

There are four aspects on which we have focused most:

1. the gradual reduction in public expenditure on health and the growing role of expenditure by citizens by citizens,
2. the contraction of permanent staff and the increasing use of fixed-term contracts or consultancies;
3. the reduction in hospitalisation and territorial care;
4. the slowdown in investments.

HEALTH EXPENDITURE BETWEEN FINANCIAL CONSTRAINTS AND NEW NEEDS

In addition to being recognised as one of the most efficient healthcare systems among industrialised countries, the Italian system is also among the most efficient given the limited level of resources mobilised.

In 2019, healthcare expenditure reached € 115.4 billion, with an increase of 1.4 per cent compared to 2018, lower than that envisaged in the Economy and Finance Document (DEF) 2019 (+2.3 per cent). the incidence in terms of output remains substantially unchanged compared to 2018.

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However, the changes introduced in the way expenditure is calculated make it difficult to compare it with what was envisaged last April with the 2019 DEF and updated in September in the DEF Update Note (NaDEF) (2021).

However, the change recorded during the year is very limited and confirms the stabilisation of this expenditure with respect to output. The increase of 3.1 per cent in outlays for labour income, also due to the signing of contract renewals for medical and non-medical personnel (and related arrears), is partly offset by the increase of only 0.3 per cent in expenditure for intermediate consumption, while expenditure for social benefits in kind (pharmaceutical assistance by agreement, general medical assistance, hospital assistance, specialist rehabilitation assistance) increased by only 1.4 per cent.

However, it should not be overlooked, especially when assessing future needs, that this result benefits from lower-than-expected growth both in expenditure on labour income, due to the postponement to 2020 of the renewal of non-healthcare management for the 2016-18 contractual period, and in expenditure on pharmaceuticals due to the collection in the year of the balance (following the agreements reached) of the resources owed to the regions for the breaches of the purchasing ceilings that occurred between 2013 and 2017, which reduced expenditure on pharmaceuticals.

On the basis of the 2019 results, the forecasts of the sector for the next two years were then defined in the DEF 2020. In the current year overall growth is estimated at 3.6 per cent, bringing expenditure to 7.2 per cent of GDP. Despite this, the weight of this expenditure on current primary expenditure is reduced, although only marginally (from 15.4 per cent to 15.3 per cent). The trend is driven by expenditure on intermediate consumption and purchases of goods and services from market producers (up 5.1 per cent and 4.7 per cent, respectively).

The increase in intermediate consumption is attributable to expenditure for pharmaceuticals but also to the purchase of sanitary equipment and related costs associated with the transfer of resources from the Civil Protection to the regions for the extraordinary needs of the Covid-19. Among the provision of goods and services, of particular note is the increase in general medical assistance (+11.7 per cent), due to the combined effect of the renewal of agreements that were not signed in 2019 and which are to be charged to 2020 and the higher expenditure incurred for the epidemiological emergency.

While it is true that, as indicated in the DEF text, this increase is partly offset by pension advances, it is also true that these pose a particularly significant problem on the care front. The reasons for the 4.2 per cent growth in private purchases (for specialist care, hospitals, etc.), also linked to the health emergency and just under a billion, are not specified in detail.

The increase expected in 2021 (+1.3 per cent) for healthcare expenditure, which is expected to reach 6.9 per cent of GDP, is much more contained. The impact on current primary expenditure remains constant.

Until 2019, before the explosion of the health crisis, it remained at levels well below the amounts allocated to the sector by the other large European economies in recent years. In fact, in international comparison, the trend that Italy recorded between 2009 and 2018 seems to persist: a particularly consistent reduction, in real terms, of the resources allocated to healthcare. Per capita spending at constant prices (2010 prices) went from € 1,893 to € 1,746, with an average annual reduction of 8 tenths of a point. This is a much smaller drop compared to other countries in difficulty (Greece -4.5 points per year), but one that differentiates us, while remaining higher in level, from the trend recorded in Spain and Portugal (respectively -6 tenths and -7 tenths), countries that, like Italy, have experienced significant financial difficulties. On the other hand, spending grew (still on average per year) by 2 per cent in France, 0.5 per cent in the Netherlands and 2.2 per cent in Germany.

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This results in large gaps in per capita public health expenditure (expressed in purchasing power parity). According to OECD estimates, in 2018 per capita spending in Germany and France was respectively double and 60 per cent higher than in Italy. However, this expenditure is still more than 8 per cent higher than in Spain.

The gap is still significant, but smaller, when looking at overall spending: in 2018 it was 8.8 per cent of GDP in Italy, similar to Spain (8.9 per cent) and significantly lower than Germany and France (11.2 per cent) and the Netherlands (9.9 per cent). The prolonged focus on spending, the processes of reorganising healthcare facilities across the territory, and the difficulties in adapting the public supply to the changing characteristics of the demand for care have been reflected, in fact, in an increase in household expenditure, which continued to grow between 2012 and 2018. In 2018, total expenditure was 154.8 billion, of which 115 billion was public and 39.8 billion private. While public funding accounted for 74.2 per cent of total expenditure, the private component was 23.1 per cent and that covered by funds, funds, insurance 2.7 per cent.

Direct household health expenditure grew by 14.1 per cent between 2012 and 2018, compared with 4.5 per cent for general government expenditure. The share of private expenditure reached 2.3 per cent of GDP. This is higher than in Germany (1.7 per cent) and France (1.9 per cent), but lower than in Spain and Portugal, where it is between 2.6 and 3.1 per cent of GDP.

The Public Administration (PA) continues to be the main funder of expenditure for all functions (more than 80 per cent of expenditure for care and rehabilitation is provided by the PA); however, in the same period, while public expenditure fell by 3.1 per cent (due to the drop in the component for ordinary hospital care, which is in turn explained by a progressive decrease in admissions), direct household expenditure rose by 25.1 per cent. Within it, it is outpatient care (+30 per cent) and home care (+32.3 per cent) that show the strongest changes, also due to the increase in waiting lists and cost-sharing charges, with the consequent reduction in the differential between rates paid in the public and private sectors.

Even long-term care expenditure is just under 77 per cent financed by the public operator, but in the six years observed, against a 10.4 per cent increase in that covered by the public, that paid by households increased by 14 per cent, influenced mainly by the increases in the component for hospital care (+11.5 per cent) and, above all, in outpatient and home care (+32.3 per cent and +32.9 per cent, respectively).

Expenditure on pharmaceutical products and other therapeutic devices is borne 56.3 per cent by the public administration and 43 per cent by households. The strong growth of publicly financed pharmaceutical products is, of course, in direct relation to the increase recorded in both the purchase of innovative medicines and the growing dynamics of medical devices. The latter item, which increased by more than 7.4 per cent during the period, is borne by households for more than 75 per cent and is destined for equipment and other medical devices that fall partly outside the provisions guaranteed by the Essential Levels of Care - LEA (e.g. corrective lenses, contact lenses, orthodontic appliances and others).

The increase in private health expenditure has been accompanied by an increasing role for tax expenditure (deductions). This is the case even if only part of the expenditure is able to benefit from deductions.

In view of the need to redress imbalances in the quality of services between territorial areas, of the growing needs arising from the ageing of the population and the increase in the number of cases of non-self-sufficiency (which require not only assistance in the activities of daily living, but also the taking care of increasingly widespread chronic pathologies), as well as from innovations in the field of care, which offer new opportunities but entail increasing costs and adequate investments, there is thus a problem of the resources to be allocated to the sector. As will be seen below, the possibility of addressing the structural and staffing imbalances that affect the very guarantee of levels of care depends on these resources. This,

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in the knowledge that the margins for shifting further expenditure onto households are limited. Beyond the more emergency measures that will increase the resources earmarked for healthcare in 2020 by an additional 1.4 billion euro (this is the amount of resources earmarked by Decree Law No. 18/2020), there is still the need to consider how to tackle these problems once the crisis is over. It is undeniable that this poses the need for difficult choices on how to strengthen the financing of the public system in the face of measures that have so far been aimed at direct monetary transfers or lower tax levies.

COOPERATION BETWEEN THE STATE AND THE REGIONS

The new 2020-2025 National Prevention Plan (PNP) (2020) represents the common framework for the objectives of many relevant areas of healthcare: together with the Regional Prevention Plan (PRP), it plays a role of governance and orientation, favouring the connection and integration between the actions provided for by laws, regulations and sector plans.

The most recent experience, linked to the Covid-19 pandemic, has revealed gaps in the system, especially as regards updating, monitoring and the effective capacity of the measures envisaged to respond promptly to the needs arising from emergency or critical situations.

It also highlighted the need for a coordinated and integrated network between the various structures in the area, starting with primary care, since hospitals cannot be the sole or main response to new social and health needs. It appears necessary to have flexible systems and organisations, with the capacity to rapidly call upon different and transversal human resources and skills to deal with emerging issues.

This capacity to react must be prepared through various actions: the specific training of operators in all sectors; the structural and technological strengthening of the Prevention Departments and the construction of a network of epidemiological competences the maintenance of a good level of regional information systems capable of guaranteeing interoperability not only between Regions, but also with other intra-regional information systems, and of providing timely and easily usable data to monitor the health status and needs of the population during and after the emergency; the strengthening and implementation of the population surveillance systems referred to in the Prime Ministerial Decree of 3 March 2017; the rapid resumption of ordinary activities (e.g. oncological screenings that have undergone an emergency); and the monitoring of the health status of the population. (e.g. cancer screenings, which have slowed down considerably), also as an opportunity for a general review and an efficient and stable allocation of resources (including infrastructural resources such as information systems and their integration with new technologies); the analysis of the indirect effects of the pandemic, in particular those related to health equity and the consequent definition of actions to counter inequalities. The pandemic has in fact highlighted the fragility of particular individuals: in addition to the elderly, people suffering from chronic illnesses, which are in turn unevenly distributed, growing according to social disadvantage.

This requires, as envisaged by the PNP and the National Chronicity Plan, on the one hand, a transversal and interdisciplinary approach, also by improving the training of the professionals involved, in order to increase participation in prevention programmes; on the other, a strong integration between primary care, centred on the general practitioner, and specialist care, as well as on the earliest and most proactive entry of the person with a chronic disease into the multidisciplinary diagnostic and therapeutic pathway, which ‘follows’ the individual even before he or she develops a pathology, from the moment he or she is identified as a carrier of risk factors. In addition to the pandemic crisis, the surveillance and prevention of epidemic events abroad continued during the year, in particular through the national and

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international networks and the sharing of data on infectious diseases subject to compulsory notification with international bodies.

Within the framework of the World Health Organization strategy Global Action on Vector Control 2017-2030, an agreement was reached on the National Plan for the Prevention of Arbovirosis (viruses transmitted by arthropod vectors, e.g. mosquitoes), which defines a global strategy aimed at strengthening prevention, surveillance and control interventions, taking into account regional specificities. In the prevention of communicable diseases, the focus on supporting vaccination programmes has remained high. Thanks to the actions undertaken, accompanied by a communication and promotion strategy on the part of the Ministry and the Regions, vaccination coverage increased significantly between 2017 and 2019, as shown by the surveys carried out at the end of the year, even though critical issues remain in some areas of the country.

Because of the emergency, 2020 marked delays, which are now being made up for. From the survey carried out by the Ministry of Health through questionnaires sent to the Regions it emerged that the impact was limited for primary cycle vaccinations, which were considered a priority and to which, in addition to an intense activity of communication with families to reshape the calendar, the available personnel had been dedicated within the limits imposed by the prevention measures.

On the other hand, there was a significant decrease in children's vaccinations for subsequent doses, for which it was stressed that it was important to proceed as soon as possible, including through the involvement of freely chosen paediatricians.

There was also a strong impact on vaccinations for adolescents, for the recovery of which, in addition to the use of general practitioners, collaboration with schools was proposed to strengthen the communication campaign. The focus on influenza vaccination in the 2020-21 season is high, given the overall epidemiological picture characterised by the circulation of Covid.

Indications have therefore been given to the Regions to anticipate and extend the vaccination campaign, prepare vaccine tenders and raise awareness through communication campaigns, while extending vaccination to age groups not previously included. Slowdowns, as a result of the pandemic, were recorded in the HIV and AIDS Intervention Plan, with a reduction in the number of tests and in-patient visits, with possible negative consequences on the levels of diagnosis, treatment and prevention. In fact, since the reorganisation of law no. 135 of 1990, the management and control model of the infection has been based on the central role of the Infectious Diseases structures, through an articulation of the care services in acute hospitalisation wards, day hospitalisation structures, dedicated outpatient clinics for taking charge and treatment, integrated home care services and outpatient reception structures. The impossibility of using this type of organisation in the normal way has caused a slowdown in surveillance and treatment, which is currently being monitored. At the same time, on the basis of international guidelines, recommendations were drawn up for the management of infected persons during a Covid emergency. Lastly, the monitoring and assessment of environmental phenomena that have an impact on health continued. The permanent system of epidemiological surveillance of populations residing in contaminated sites was implemented, with the participation in the Coordination Unit for the fight against fires in the Land of Fires and, with reference to the Site of National Interest in Taranto, with the inclusion of representatives of the Ministry in the Observatory for monitoring the implementation of the Environmental Plan for the steel plant and with the continuation of the actions of the Epidemiological Observatory. In the area of prevention of non-communicable diseases, particular attention was paid to neonatal screening for the early diagnosis of certain diseases. In implementation of the provisions of Law no. 167 of 2016, extended neonatal screening was included in the LEAs. The regulatory framework

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was subsequently supplemented by Law No. 145 of 2019, which extended the panel of pathologies to be researched, providing for their periodic review. In implementation of the regulation, which provided for the preparation of an operational protocol for the management of screening, patient care and access to treatment, in November the special working group was set up. Analyses continued on the efficiency and effectiveness of the hearing and visual screening protocols, envisaged by the new LEAs for all newborns, and the subject of a specific project financed by the Ministry and launched in 2019. More generally, with regard to actions to prevent the major risk factors and strengthen protection in early childhood, the State-Regions Agreement was reached on the Document, drawn up by the Technical Table set up at the Ministry, aimed at systematising the main knowledge and interventions available today in the first 1,000 days of life. As part of the strengthening of protection and inclusion policies for persons with disabilities, the Guidelines for the certification of disability in the age of development were defined, with the aim of encouraging school inclusion, in implementation of Legislative Decree 66/2017, and at the same time guaranteeing effective protection for pupils with certified disabilities and a simplification of procedures for families.

As part of the programme of the National Centre for Disease Prevention and Control (CCM) for the year 2019, a central action has also been planned to support the Regions in implementing the Guidelines, through specific accompanying measures for the acquisition of skills by the professionals of the National Health Service (NHS): medical commissions, specialist health services for children and adolescents, multidisciplinary assessment units of the NHS. Within the framework of the National Dementia Plan, the activities of the Monitoring Board continued, with the aim of formulating recommendations and guidelines for the promotion and improvement of the quality and appropriateness of integrated interventions in the sector. The activities of the CCM project, entrusted to the ISS, have continued, with the aim of a training and refresher programme for General Practitioners in the primary and secondary prevention of dementia and in patient management. At the same time the information system was implemented. The PNP 2020-2025 has incorporated the indications of the most recent European strategy, which is accompanied by thematic plans aimed at organising, in a participatory territorial model, assistance and support for companies in sectors where the risks are highest (PN construction, agriculture, biomechanical overload pathologies, occupational carcinogens and occupational cancers). The Plans are in turn supported by central CCM projects and actions.

HEALTH SPENDING IN THE COVID YEAR

As expected, the Covid-19 emergency resulted in a large increase in health spending in 2020. National accounts data show an even higher growth in expenditure to cope with the pandemic during the year than expected (and expected in the NaDEF pre-calculations last September). At the end of the year, health spending reached €123.5 billion, an increase of almost €7.8 billion (+6.7 per cent) compared to 2019, higher than expected by more than €2.6 billion. As a result, its impact on output increases to 7.5 per cent (and not 7.2 per cent as planned) compared to 6.5 per cent in 2019.

The change recorded in the year is therefore very large and marks a sudden interruption of the process of stabilisation of expenditure recorded in recent years. Expenditures for labour income (those for the direct production of services), which in 2019 had increased by approximately 3.1 per cent, also due to the signing of contract renewals for medical and non-medical health care executives (and related arrears), show a further increase, albeit small (+1.5 per cent). However, it is above all the increase in

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expenditure for intermediate consumption, +12.8 per cent, that affects the overall result of non-market healthcare services, which show an overall variation of 9.1 per cent. This is due to the growth of 4.2 billion in goods for the direct production of services, while the increase in administrative services is limited (+200 million).

Also contributing to this result was the sharp drop in revenues (down by approximately € -1.3 billion), attributable mainly to the drop in demand for non-Covid healthcare services (suspension of normal specialist visits), with the related reduction in revenue from co-payments (by approximately € 500 million), that from intra-medical services (approximately € 300 million) and the drop in the number of patients in the hospital (approximately € 1.3 billion), also income from international mobility, income from treatment of foreign patients (about -200). All of these amounts have been deducted from expenditure.

The contribution to the change in expenditure for market services is more limited, but still significant (+3 per cent). This result is the result of very different trends among the components, precisely because of the different incidence of the pandemic and the measures taken to combat its spread. Expenditure on specialist services grows by 3.2 per cent and, above all, expenditure on general medical assistance by 12.7 per cent, affected, as envisaged in the DEF, by the renewal of agreements not signed in 2019 and to be charged to 2020, in addition to the higher expenditure incurred for the epidemiological emergency.

On the other hand, expenditure on hospital care provided by private entities has decreased (-1.25 per cent) and, above all, expenditure on pharmaceuticals and rehabilitation assistance (down 3.6 and 4.6 per cent, respectively). These trends at least partially offset the increases, keeping the contribution at more contained levels.

These changes are attributable to the slowdown and, in some periods, the lockdown of care activities necessitated by the pandemic and social distancing measures. Once the emergency phase is over, it could be recovered and/or require (as in part already happened in 2020) the identification of extraordinary interventions to absorb foreseeable tensions on the waiting list front.

In reading the results for the year and, above all, in comparing them with those attributable to the individual territorial realities, it should also be considered that during the year the role of expenditure managed directly by the Extraordinary Emergency Commissioner was significant. According to the first, limited reports available, over 2.4 billion lire was spent for the purchase of materials for everyday use, such as masks, glasses and other items, supplied to local health structures and used in public hospitals to provide the health service.

These sums account for approximately €1.4 billion of the increase in intermediate consumption of direct management1.

In the health account, but among central government expenditure, there are also purchases of materials for current use such as masks and other personal protective equipment provided to schools. An activity that affects the health accounts, and is classified in national accounts terms under benefits in kind corresponding to goods and services produced by market producers for just under 1 billion (942 million).

On the basis of the 2020 results in the DEF 2021 (Economic and Finaancial Document, 2021), the sector's forecasts for the next four years have recently been defined. In 2021 overall growth is estimated at 3 per cent, bringing expenditure to 7.3 per cent of output. The trend is driven by expenditure on intermediate consumption and purchases of goods and services from non-market producers (up 4.6 per cent and 6.4 per cent, respectively). The increase in intermediate consumption is only partly attributable to expenditure on pharmaceuticals, the largest share being due to the purchase and administration of vaccines. The increase in income expenditure is affected by the higher expenditure already provided for under current legislation to tackle the epidemic emergency. Only marginal expenditure recoveries

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in market services. The increase for general medical assistance (+2 per cent) is affected by the higher expenditure recognised for the administration of vaccines. The figure for other forms of assistance is affected, on the one hand, by the lack of expenditure incurred last year by the Civil Protection and, on the other, by the rules introduced by the budget law that recognise refunds of up to 90 per cent of the budget assigned to private accredited structures that have suspended ordinary activities. In the following three-year period, the weight of the expenditure in terms of output declines rapidly to settle at the end of the period at lower values in 2019 (6.3 per cent in 2024 against 6.5 per cent in 2019). This trend, however, does not seem to reflect the postponement of treatment and the accumulated delays, nor the higher current expenditure related to the investments for the expansion of healthcare envisaged by the National Recovery Plan.

CONCLUSION

The Italian healthcare system, despite the difficulties encountered, has withstood the impact of the crisis. This has entailed significant costs, not only of a financial nature, which require that the attention devoted in the year just gone to this sector should not be reduced. It is still too early to take stock of what legacy the pandemic will eventually leave us. The crisis is not yet over and, above all, it is not yet clear what adjustments and costs our regional systems will be subjected to in the not too short period of ‘living with’ the virus.

Health expenditure reached 123.5 billion in 2020, an increase of 6.7% compared to 2019. In-depth analyses of individual cost and revenue items highlight the different ways in which regions have responded to the crisis. The analyses also point to the negative legacy in terms of missed services both at hospital and outpatient level; a phenomenon that affects all regions and on which little has been done, for now, by the financial interventions introduced.

An in-depth analysis of the individual cost and revenue items highlights the different ways in which the regions have responded to the crisis. These differences reflect the fact that in the emergency they had to move by focusing on the most immediately available options and how the starting conditions of the regional systems were affected. Differences in the quality of the services offered, staff shortages due to the constraints of the restructuring phase, limits in the planning of the necessary professional resources, but also the gradual withdrawal from the public system, the inadequacy of local assistance in the face of the growing phenomenon of non-self-sufficiency and chronic illnesses, the slow progress of investments sacrificed by current needs. Looking today at the indicators that form the basis of the LEA monitoring allows us to focus on the conditions before the crisis and to understand the problems from which it is necessary to start again.

A number of measures were introduced in 2020 aimed at affecting the most problematic aspects of care. Measures aimed at increasing the staffing levels of facilities that had already been suffering from a reduction in the number of permanent staff, which made it impossible to maintain an adequate quality of supply; at immediately adapting the availability of beds in line with the growing numbers of the pandemic; at strengthening territorial facilities; and at reducing the undesirable effects of the lockdown. The resources made available are considerable: over 8 billion, of which 3.6 billion managed directly by the regions.

The size of the commitment made is immediately reflected in the 83,000 operators in the sector involved in various capacities in the emergency: the more than 21,000 doctors and 32,000 nurses involved

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make up 21% and 12.5% respectively of the existing force at the start of the pandemic. Good results were also achieved in the definition of new structures, the USCA (Special Continuity Care Units), which, after the initial difficulties, represented an important element in strengthening territorial assistance. On the other hand, the degree of implementation of other measures, such as the use of community nurses, the inclusion of social workers and psychologists, and the activation of the Regional Operations Centres, has been limited. The results are also uncertain as regards the strengthening of home care or the recovery of ordinary activities, which is perhaps the greatest burden that the pandemic is now forcing us to face.

The studies prepared by the Ministry of Health effectively point to the negative legacy in terms of non-performance at both hospital and outpatient level, a phenomenon that affects all the regions and on which the financial interventions allocated to it have so far been unable to do much. The results also show how different the response capacities have been at a territorial level and how the repercussions of the pandemic have been amplified by the different conditions of the regional systems. The delays already evident in some areas have made them more exposed to structural consequences. The damage that will be caused by the worsening health conditions of the most fragile parts of the population as a result of the impossibility of maintaining and respecting screening and treatment times is still not ‘quantified’. On this issue, the attention of associations and the monitoring carried out by the National Screening Observatory (ONS) provide important initial results.

These are important aspects that should lead to a challenging redesign of the healthcare system. With the strong impetus that will come from the Recovery Plan, it will be called upon to seize an opportunity for change that is certainly significant and unique, but it will have to overcome the limits that have so far held back investment.

An important contribution can be made by technology, not only in adapting and modernising structures, but also in making available, as the central administration and the regions are doing, tools for planning the use of resources that are attentive to the actual needs of care and, therefore, able to avoid duplication of supply and organisational inefficiencies.

This will not prevent us from maintaining our focus on the issue of the resources to be allocated to the sector. The crisis and the consequent increase in debt have aggravated difficulties that were already significant and which, in perspective, will become more acute due to the growing demographic imbalance. However, the need to structurally increase certain components of health spending, both current and capital, has also been highlighted. This leads to the resumption of the debate on important issues, such as long-term care, which is an integral part of the redesigning of territorial care that should take shape with the implementation of the Recovery Plan, but which requires adequate choices also in close connection with other reforms on the Government’s agenda, such as tax reform.

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Chapter 10

The Relational Dimension of Care at the Foundation of the Rights of Pupils With SEN:

Between Inclusiveness and Substantive Equality

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ABSTRACT

The relational dimension of care becomes the foundation of the rights of pupils with SEN when considering the asymmetry that may exist in the relationship between the teacher and the pupil with special educational needs. This asymmetry can, in fact, find the pupil with vulnerability in an inferior position compared to the teacher. This, by analogy, is the same asymmetry that can also be found in the relationship between doctor and patient. From the awareness of this derives the need for an ethical approach to care (of the pupil with SEN, as well as of the patient), which is identified with that moral attitude of the individual who tries to meet the needs of those with a vulnerability. An ethical approach cannot stop, however, in considering only the medical-biological dimension of the subject with vulnerability. It must also address all the dimensions that make up the nature of the human person.

INTRODUCTION

In a recent volume, the pedagogist Nicola Paparella clarified that: "The expression SEN applies to all those cases for which the request for special attention, however determined and in any case configured, can be assumed. Whether it is a question of social disadvantage or cultural hardship, specific learning disorders or specific developmental disorders, or even just difficulties related to the condition of an immigrant lacking sufficient knowledge of Italian culture and language or whether it refers to a temporary disorientation due to a sudden change in some life patterns, in all these cases and in many others one

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can speak of special educational needs for which educational intervention must be able to offer an effective response.

For these reasons, the definition suggested by D. Ianes still seems useful. The Special Educational Need - he said - is « any developmental difficulty, in the educational learning field, expressed in an operation (in the various areas of health, according to the ICF model of the World Health Organization), problematic also for the subject, in terms of harm, obstacle or social stigma, regardless of etiology, and needing a special individualized education »". (Paparella, 2020, p. 3).

If we start from this definition by Ianes (2005, p. 33, cited in Paparella, 2020, p. 3), in some respects more reductive than the picture drawn by Paparella, one cannot fail to refer to a more general concept than that of the need for an individualized education: that is, to the concept of care for the other person (to care in the Anglo-Saxon context, understood not only as treating someone's pathology, but also and above all, in a broad sense, taking care of the other person), which can form the basis of the above definition. This is the aspect on which the reflections in this paper will mainly focus.

To explain more clearly what has only been briefly mentioned so far, it can be said that within the general concept of care, the position expressed by Ianes, precisely because broadly speaking the reference made to the ICF model, by analogy, finds greater acceptance within the functionalist theory of medicine which places less importance on the need for an ethical approach by the physician to patient care, and which is consequently opposed to another model, equally present in the general concept of care, which is the model of traditional / hippocratic care. According to the functionalistic model the best doctor will be the good clinician, the good therapist who is best able to treat the biological dimension of man and not, instead, the doctors who, hippocratically, will love their patients, who will use a supportive approach with them and who alongside the biological component of the individual, will also take care of all the other ontologically constitutive components, such as: psychological, relational, affective, family, religious, etc.

Consequently, as will be seen better later, it could be said that, if the outcome of the functionalist model were accepted, ethics could remain outside the door of the doctor's training.

ETHICS OF THE RELATIONAL DIMENSION OF CARE AND NEW TECHNOLOGIES

Therefore, starting from what has just been said, by analogy, if we start from the idea that ethics could remain outside the doctor's training, we could ask ourselves whether the function of a specialized support teacher for pupils with disabilities (who in the writer's opinion is called on to take care of the vulnerable pupil continuously) can be compared in a certain sense to that of doctors, and therefore, as for doctors, we must ask how much ethics such teachers need in their training.

Certainly there is no simple answer to that because, while there are numerous positions in favor of one model of care rather than the other, there are also numerous positions that attempt a mediation between the extremes constituted by the two models, that is, the hippocratic and the functionalistic. For example, D'Agostino points out that, on the one hand, there are many doctrinal positions that attempt to mediate between ethics and scientific competence. On the other hand, he also recognizes that the mediation between the two extreme positions mentioned above is often rejected in favor of the choice of a permanent conflict between the two. And this contrast, unreasonably, makes us lose sight of the authentic relevance of the issue at stake. This is because, according to D'Agostino: "The point is that the real question we have posed must be grasped exactly in its exact extent, which is exactly *epistemological.*

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In fact, strange as it may seem, the questioning of morality in and of medicine, while it opens specifically moral questions, does not open questions internal to moral reflection: the ethics of the doctor (the ethics that qualifies him precisely as a doctor, and not as a good citizen) is not really a problem for moralists, it is not a chapter of that discipline we call *moral philosophy* "(D'Agostino, 2019, pp. 118-119). This is because it belongs, instead, to the sphere of medical knowledge itself.

In fact, in the field of medicine, still according to D'Agostino, true knowledge of things depends on "a fundamental axiological orientation, in the absence of which the very knowledge of reality is altered, lost or even unable to emerge. This orientation can be condensed in the expression *respect for reality* (for that specific dimension of reality, which is the specific object of each individual discipline). In other words, to know reality it is necessary to respect it, but what leads us to respect reality is none other than the authentic desire to know it "(p. 119).

And one of the specific dimensions of respect for reality that D'Agostino identifies is the respect for relational dynamics, which allow the perception of reality, and which are central to the argument tackled in this paper. The other dimensions that he identifies, incidentally, are: the respect for empirical data and the necessity of the multiplicity of the dimensions of language. These last two dimensions however will not be examined here as they are outside the scope of the present paper. More specifically, regarding the dimension of respect for relational dynamics, D'Agostino goes on to say that the functionalistic formalism of modern science seems to have eliminated relationality, because it is irrelevant for the purposes of understanding and knowledge. With a contradiction, however, arising from modern science's own practice by which researchers present the results of their research to (no less) the *other* members of the scientific community for their judgment on its correctness.

From another angle of observation, it can also be noted that functionalist formalism has found a strength, which has facilitated its diffusion as a theoretical model, in the technological-information revolution. This revolution today finds a point of arrival above all in algorithms, artificial intelligence and big data, but also allows a very rapid recovery in the theoretical development of these new technologies and their consequent practical application.

On this last point, going beyond what has been said so far, Amato Mangiameli's argues that, in the face of the exponential growth of data and their treatment, classification and analysis through the use of algorithms and artificial intelligence, the logical-deductive paradigm ends up becoming obsolete. This happens to the advantage of a preference for the purely statistical approach, considered more capable of analyzing and classifying the large amount of data that can be accessed today and, often, even of suggesting to the legislator the legislative choices that derive from this analysis and classification. This purely statistical approach, far removed from that of functionalist formalism described above, will, however, be able to relate to the dimension of relationality and emotionality to which D'Agostino was referring.

However, Amato Mangiameli also underlines another aspect: the fact that (against a background of the constant possibility of a technoscientific drift, which could also be followed by a socio-political structure of technocracy within the States) the advances today lead to the ever increasing use of artificial neural networks. Such networks, far removed from any form of relationality, and destined to assume pride of place even within educational contexts, bring undoubted advantages but at the same time raise doubts and constantly prompt ethical and ethical-juridical reflection. In this regard, Amato Mangiameli writes: "Algorithms, artificial intelligence, big data, three key expressions that are the axis of today's techno-scientific progress, which continues on the path of neural network development, taking biological networks as the reference point, and using so-called learning algorithms. The latter may be of various kinds supervised learning algorithms (starting from a set of inputs to which known outputs correspond,

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the network learns the link that unites them and learns to generalize, i.e. to calculate new correct input-output associations by processing inputs external to the training set); unsupervised learning (starting from a set of input variables, the network creates representative clusters to categorize them); or reinforcement learning algorithms (it is from the interaction with the environment that neural circuits learn and they carry out a series of actions, of which those that come close to the result are considered reinforcement, while others are eliminated because they are a signal of error)" (Mangiameli, 2019, p. 108).

As mentioned, artificial neural networks therefore certainly represent an advance in the developmental course of human technological capabilities, and present undoubted advantages in terms of speed and precision in the classification and processing of the immense amount of data by which the individual is now submerged. This gives rise to their "diffusion in the most disparate sectors in which data mining, elaboration of predictive and simulation models, classification etc. are required. With these, in fact, large amounts of data can be processed without particular expenditure of time and energy, it is possible to operate very often correctly despite inaccurate or incomplete inputs, and when they are well implemented they are able to self-update in the presence of environmental changes. [but, *ed.*] Naturally, artificial neural networks also have limitations, for example their computation cannot be fully analyzed, the administered outputs very often do not present the perfect solution, and they are not currently capable of solving certain categories of problems"(p. 108).

And another limitation of artificial neural networks, to which Amato Mangiameli also refers, is their non-neutrality. According to the author, the algorithms are written by men who, however, can set the parameters of these algorithms and the programs that must produce them differently from time to time. And in extreme cases we may also find that: "Sometimes, then, the algorithm can even start from prejudices: just think of Google Photo which cataloged the image of two people of color under the term "gorilla", at other times the algorithm is used to collect data on (good / bad) citizens, such as the Chinese government's Sesame Credit program" (p. 109).

After giving further examples in support of her argument, Amato Mangiameli concludes by underlining that alongside the undoubted benefits that algorithms can bring, it is also important to consider the critical aspects of relying on such technological applications. Chief among these are "the information asymmetry between a company offering a service and the user, the lack of transparency regarding the principles and parameters underlying the functioning of the algorithm, the creation of a sort of filter bubble, so that only the information that the algorithm has calculated may be of interest to the user is shown, or on the contrary, that it has deemed for various reasons not to provide. Hence the inexistence of neutral algorithms, of algorithms that merely reflect reality, indeed they propose their own version made up of classifying formulas, of the weight attributed to the individual parameters entered, of the procedures that determine the result "(p. 109).

If one thinks about it, the categories of problems for which artificial neural networks and algorithms are not a suitable solution tool may include many of the problems relating to the inclusion of pupils with SEN and, more generally, to the relational dimension of the concept of care referred to earlier with D' Agostino. Here there are extremely strong emotional effects, which by their nature are changeable, differing from individual to individual, and thus, being difficult to compute, they elude categorization within big data.

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NEW TECHNOLOGIES: PRIVACY AND DIGNITY OF VULNERABLE PUPILS

Similarly, the artificial neural networks and the algorithms mentioned in the previous section are not a suitable tool for solving the problems relating to pupils with SEN, and, more generally, for those relating to all pupils with vulnerabilities. This is also due to the fact that the processing of the data of these types of pupils can encounter problems with the respect for the privacy of the individuals concerned, leading to inevitable repercussions on their dignity.

Here we do not propose to examine the legal issues underlying the problems that may arise from the respect or non-respect of confidentiality regarding the data of pupils with SEN or in any case of vulnerable pupils, nor will we analyze the legislation and jurisprudence on this issue. In the wake of the reflections of Amato Mangiameli mentioned earlier, in this section we will specifically suggest some points for philosophical-legal reflection on the ramifications of these problems for each individual's sphere of privacy, also in its dimension of relationality in society. Within the limited space that this paper can devote to this topic, we will refer to what D. Ruggiu and A. Stizia write in a recent volume entitled *Health of the population, big data and integrated systems. An ethical proposal* (Mariani et al., 2019).

In the book just cited, the reference is to the second chapter, entitled *Big data, genomics and artificial intelligence in healthcare: the Bexsero case and the challenges for privacy at national and European level*, which, with a systematic analysis of the legislation at both national and European level for the protection of the privacy of individuals, highlights (the risks that can arise when the treatment, conservation, cataloging and the uses of personal, sensitive and even genetic data of individuals are at stake. While, in fact, there are undoubted advantages in the development of knowledge that can derive from the use of big data in the medical / biological field, there is also no doubt that: "The integrated and automated use of large amounts of data including information Genetics, however, raises several questions regarding fundamental rights such as privacy and protection of personal data in relation to the European context represented by the European Union on the one hand and the Council of Europe on the other and in relation to their impact on the Italian landscape itself. With the entry into force, first of all, of the new "European data protection package" (EU regulation 2016/679 and directive 2016/680, otherwise known as General Data Protection Regulation or GDPR) it is necessary to evaluate the transformations made by this on the current code of privacy above all in light of today's challenges of artificial intelligence, and of the availability of genetic data in the context of Big Data Analytics in the healthcare sector. In this context, a further indication is constituted by the parallel legislative framework of the Council of Europe centered on the European Convention on Human Rights and on all the decisions of the Court of Strasbourg on the subject of privacy and by what is taking shape at European Union level "(p. 46).

In sum, here, in the opinion of the writer, it is easy to understand that, with the violation of the personal rights of confidentiality, the attack is on human dignity, that is, as we have stated more fully in a book, to which reference should be made for further information (Tarantino, 2018, pp. 1-2), on the moral superiority that distinguishes the life of a member of the human species from that of other living beings. Dignity, in short, is the ontological status of human persons, which comes to them not from their biological-evolutionary path, but from the possession of that ontological cognitive power which, in the Aristotelian sense, is specified in intellect and reason. Dignity, again, which in the Kantian sense is expressed in the second formula of the categorical imperative, which states: "Act in such a way as to treat humanity, both in your person and in the person of everyone else, always as an end and never solely as a means " (Kant, 1980, p. 61). The Kantian imperative which, as Abbagnano states (Abbagnano, 2013, p. 287), "establishes that every man, indeed every reasonable being, as an end in itself, has a value that is

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not relative (as, for example, a price), but intrinsic, namely, dignity." On the fact that strong protection is needed for all information concerning individuals, their health, their political or religious beliefs, etc. there appear to be very few doubts, also in the light of the endless bibliography that has been developing for some decades now, and which has often constituted the epistemological basis on which in Italy the Guarantor for the protection of personal data has based its measures. What has been said is also a consequence of the close interconnection of individuals' personal information (which today too easily constitutes Big Data) with freedom itself, and therefore with the dignity of each person, which would certainly be harmed if one came to think, for example, of a social classification of the subjects on the basis of their data, their characteristics, their economic or health conditions.

RESPONSIBILITY OF THE SCIENTIST AND INCLUSION: FOR A RETURN TO THE HUMANUM

The respect for human dignity, to which I have just referred, which cannot be omitted when algorithms, artificial intelligence and big data are used, also in the field of inclusion of pupils with vulnerabilities, inevitably raises once again the problem of the scientists' responsibility for their action. Scientific action must in fact take into account the respect for human dignity.

More specifically, the scientist's responsibility is a general theme that in our opinion remains closely connected with the particular problems often mentioned in this paper relating to the care of pupils with SEN and with vulnerability. This is especially so when the paradigm of care chosen to meet the needs of vulnerable pupils is not the Hippocratic kind, but a scientist-functionalist type inspired by the ICF to which reference was made earlier. In this regard, while the possible violation of privacy that can derive from the use of the new technological applications has been mentioned, it must be said for the sake of completeness that the right to privacy is not the only individual right that can be harmed by the use of algorithms, big data and, more generally, artificial intelligence. In the relationship with these new technologies it is human rights as a widely understood category that often run the risk of being compressed in their extension.

Faced with these problems, reflecting on the scientist's need for responsible action is therefore topical. As we have already stated (Tarantino, 2018, p. 91), the major problem that arises is the idea that it is acceptable to grant full autonomy to scientific action that does not bother to respect any ethical norm and, consequently, not even the ontological dignity of the human person (remember in this regard the reference made earlier to the second formula of the Kantian categorical imperative). The hypothesis of full autonomy for scientific action is often supported without asking whether such an action on the part of the scientist can actually lead to a greater degree of well-being for man and the natural environment that experiences it or, conversely, is instead only a harbinger of damage to man and nature.

If we start from the doubt concerning whether or not scientific action unhampered by ethics can lead to real progress for man, we can then thoroughly accept what Francesco Viola argued, when he wrote that: "science and technology increase our possibilities of action, but ethics must be able to discern between what can be done and what is good (or right) to do. Without this distinction there is no ethics in general, there is no lawfulness, duty, norm, or value. This means that there is no necessary concomitance between the progress of knowledge and moral progress, but also that the former requires an ever greater moral commitment" (Viola, 1997, p. 29).

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Starting from what Viola argued, if we move on to the level of care of the other person by the scientist, the doctor, and if we narrow down our focus in this paper to include the practice of caring for the vulnerable pupil within the general concept of caring for the other person, then one will tend to accept the need for ethically responsible scientific action. In concrete terms, it will have to be accepted that: "The researcher or the doctor have the duty to make use of their "ethical imagination" to the same extent as they use their "scientific imagination". Despite the enormous casuistic difficulties, scientists and medical professionals, it is argued, have a particular responsibility towards the patient [the vulnerable pupil in our case, ed.], society and the entire human race. Within well-defined limits and principles they are and should be the most suitable figures, by virtue of their vocation, knowledge and personal experience, to propose valid choices between different alternatives that can involve the destiny of humanity" (d'Avack, 2018, pp. 25-26).

The reference to the ethical limits/principles proposed by d'Avack, on reflection, is confirmed by the need for a Hippocratic approach to the action of those who are called upon to take care of those in need, in a state of vulnerability, referred to earlier with the words of Francesco D'Agostino. This is an ethical approach to treatment which, as will be recalled, D'Agostino deems necessary from the very start of the future doctor's training. Such training brings *humanum* and *humanitas* back to the center of the action of care and of the relationship between those who assist and those who are assisted, and is also applicable to the field of scholastic inclusion of vulnerable pupils, as we have tried to argue in this paper. This return to the *humanum* in the training of those called upon to care for others is also embraced in many respects by d'Avack, who goes on to say: "It is still believed that the humanistic training of the health worker presupposes the acceptance of essential principles borrowed from the moral, social and legal sciences, and that the principle increasingly applied holds that it is not enough for today's physician to know, do and be, learning and practicing only the secrets of the art, but it is also necessary to know how to know, to know how to do, to know how to be" (p. 26). However, in a pluralistic society, the problem remains of which morality should be the model in this humanistic training of the health worker, a model that the law is called upon to impose. D'Avack himself wonders about this, and is aware that it is hard to give an answer, since a "majority decision" is not enough, being easily attributable to the desire to impose an unacceptable state ethics. In this case the generalizing, universally unifying capacity of law would be lost at the cost of an authoritarian choice, the sharing of which is completely marginal" (p. 33). And in support of what he states, d'Avack then cites Uberto Scarpelli, for whom: "The law must not serve to immediately manifest our moral positions, but must be established and judged as an instrument for realizing states of affairs and relationships in which certain goods are in fact protected, certain evils in fact avoided [...] It may therefore happen that in the legal context, in the game of prediction of the effects, to avoid worse evils, we must conform to norms, which in the moral context we reject " (Scarpelli, 1998, p. 246).

SYMMETRY AND ASYMMETRY IN THE CARE RELATIONSHIP

If we return now to the request for special attention for pupils with SEN discussed at the beginning of this paper with reference to Paparella, it must be said that this special attention perhaps finds its best expression if we consider it within the ethics of care, according to which the relationship is a priority both morally and epistemologically (Held, 1995, p. 41). And many of the elements that make up the

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ethics of care theory, upon reflection, are implicitly found in what has been stated up to now. But we will return to this, briefly, later.

In the meantime, we want to remember that the priority of the relationship, oftenmentioned in this paper, is not always accepted by the various thinkers. For example, it appears not to be obvious if one accepts the significance of eugenic theories and their rejection of the *different*. In this regard, we recall what S. Colazzo underlined, in his thoughtful comments on the concept of noism (which denies, as is well known, the need for a relationship outside a group of similar people, and instead opposes the Other, as different). In a broader analysis focused on the phenomenon of human migration, Colazzo specifies that the genetic differences between the various human communities present in various places on Earth and throughout the evolutionary history of man are minimal, while also pointing out, however, that: "Nonetheless, our cultural systems are deeply imbued with racism and speciesism. It was racism that inspired, between the end of the nineteenth century and the beginning of the twentieth century, the idea of a biopolitics based on eugenics. Galton, in the mid-nineteenth century, advocated the possibility of creating a superior breed by encouraging the crossing of individuals with superior qualities. By preventing the reproduction of immigrants, alcoholics, the handicapped, the operation would then be completed, preventing the spread of unfavorable genes [...] [but] these biopolitical devices, as Cavalli Sforza rightly argues are far fuller of philosophy than biology: it is a policy theorized by minds nourished by an ideology founded on the distorted and improper use of genetics "(Colazzo, 2015, pp. 538-539)

After this aside, it is time to return, albeit only for very brief references to the priority function of the relationship in the ethics of care (Gilligan, 1982; Mortari, 2015; Palazzani, 2017; Tronto, 2006; Zanetti, 2004). To clarify this point, it can be affirmed that the relationship assumes centrality in the practice of care, especially if we consider that: "Care presupposes and implies an asymmetrical relationship: taking care means recognizing that someone else exists, but it also means recognizing that the relationship that can be established with the other person is not always equal or symmetrical, that is, on the same level as in a contractual relationship between individuals capable of stipulating a contract. The ethics of care differs from contractualism in the awareness that the need for care reveals an inevitable asymmetry" (Palazzani, 2017, p. 43). If we consider, that is, that those who require care are in a state of need, then we cannot deny the need for the ethical dimension in the doctor's training course to which reference was made earlier. Such ethics will more easily lead the doctor to enter into a relationship with the patient in need with benevolence, with the supportive attitude typical of the Hippocratic paradigm. The functionalist paradigm mentioned earlier, on the other hand, by removing ethics from the doctor's training, will push the latter towards a purely contractualist approach, which does not require an emotional relationship between the parties. But it must also be remembered that in this contract that is about to be stipulated, the parties in relation to each other are unlikely to be in a condition of equal strength, since not all individuals have the same ability to establish a symmetrical contractual relationship with the doctor, as they often find themselves in a condition of physical, social, psychological, cognitive vulnerability or fragility, etc. Similarly, this happens in pupils with a special educational need, due to the asymmetry of the relationship with those who are called upon to take care of them. This asymmetry becomes evident in view of the fragility and vulnerability that is also present in the pupil with SEN. And it is precisely from the observation of this condition of fragility of one of the two parts in the relationship that the need arises for an ethical, supportive and not coldly contractualist approach, which those who care must have towards those who are cared for. Once again it is a question of respect for reality, of a reality in which the ethical action of the carers becomes the first condition for respecting the dignity of those who receive the care, precisely because of the evident vulnerability and fragility of the latter.

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Fragility and vulnerability are also found in the *reality* of the pupil with SEN, where the asymmetry of the positions in the relationship that is established between those who care and those who are cared for, especially between support teachers and the pupils with vulnerability entrusted to them, is analogous to that which occurs in medical practice. There is also an analogy for many other aspects that unite the care / inclusion that the teacher conveys to SEN pupils with the care that the doctor provides for the patient.

However, following Daniele Cananzi's thought, it is easy to understand how the relationship of care between doctor and patient often becomes a *defensive* relationship, in which the doctor is in a position of advantage. This is because doctors, who are not in a state of vulnerability, suffering or inferiority, perform acts that in the course of treatment can also protect them from any calls to respond in court for any damage that their action of care can cause the patient. These defensive acts may, for example, include the doctor's request that the patient sign an informed consent declaration. At this point according to the regulations in force, the patients are only in theory called upon to co-constitute the act of care, forming a therapeutic alliance with doctors, but in reality, due to the state of suffering and therefore of the lack of clarity in which they finds themselves, in actual fact often rely on the decisions taken by their doctor. And this defensive tendency, says Cananzi, "means only one thing: that *the parts of the* (medical) *relationship* become *parts without a relationship*. The doctors, having explained the information as indicated, have in hand a formal and documented declaration with which they feel protected from being sued or with which they will defend themselves in the appropriate forums, also by carrying out all those investigations to 'cover' a diagnosis as broad as possible, sheltered by the protocols that the Gelli Bianco law (and previously the Balduzzi decree) actually envisaged precisely to attempt a response to the defensive approach. The patient has expressed a consent and signed a document, but in a moment of fragility that will be confused in memories, vague in the awareness of having chosen, consumed with the doubt that he or she may have been seriously wronged.

And here is where the alliance leaves the hospital and enters the court to ascertain its limits, terms, conditions and the presumed perpetrator and the presumed injured party, the defendant and the plaintiff, come face to face "(Cananzi, 2021, p. 26).

The solution to this defensive tendency of the care relationship is to be sought, also according to Cananzi, not so much in new legislative interventions, but above all in what is understood by many as narrative medicine. A narrative dialog must interweave the relationship of care between doctor and patient, from the medical history and for the entire duration of the pathology. And at what point will there be such a narrative dialog and this true alliance between doctor and patient? In this regard, Cananzi writes that: "The doctor-patient alliance is truly achieved if it is realized not so much on the basis of a conscious way of proceeding but if it is built on the *emergence of humanity*. The *fundamental trust* component is triggered: the doctor feels the responsibility to decide, which also means *instilling trust*; the patient feels the need *to trust*. At this moment they are person with person and each brings their own: the doctor's competence, the patient a personal history in which there is also disease. And at this moment, they share much more than knowledge and will: they *share humanity*, which perhaps [...] is precisely the crux of the medical act and the curative relationship" (p. 28).

The solution proposed by Cananzi is found, incidentally, also in the words of Borsellino, who, underlining the inconsistency of a truly informed consent, argues that it is "reasonable to believe that good results can be achieved if information is not intended merely as an obligation to be fulfilled by placing a pre-printed declaration of informed consent in the hands of the patient, nor, in any case, as an act to be performed once and for all. Rather, as a gradual process within an articulated communicative relationship, in the establishment of which with the patient the health worker must learn to recognize

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not only an essential phase of his professional activity, but also the prerequisite for the success of his performance" (Borsellino, 2018, pp. 162-163).

CONCLUSION

In conclusion, faced with the asymmetry of the relationship between doctor and patient, and the contingent vulnerability of the second, on which we wanted to focus our attention, and which is also found, in many respects, in the relationship between the teacher and the pupil with a special educational need, the ethics of care (understood this time not as a definite moral theory, but with reference to the broader dimension of the concept of care, which not only look at biological- medical care, but is identified with a moral attitude of the individual who tries to meet the needs of those who express a need, especially if in a condition of vulnerability), specifically considering the centrality of the relational dimension (Newton, 1997; Ricoeur, 1990), must lead the one who takes care of the other person, that is the teacher for the theme dealt with in this paper, to try as far as possible to bring the vulnerable pupil out of his or her state of inferiority, for example by trying to enhance the resources present in the vulnerable individual and in the context. This is confirmed by Paparella, who states that: "Anyone who expresses special educational needs today, even though they may be afflicted by discomfort, is still capable of providing adaptive responses and, despite their vulnerability, proves capable of interacting, assimilating, and letting themselves get involved in the learning experience in some way. Here the values and issues at stake are functional and, at the same time ethical and social, because it is a question of acknowledging the presence of potentialities that deserve to be stimulated and guided, mitigating or eliminating the criticalities that keep the person in a state of marginality and vulnerability.

Consequently, the perspective of analysis and evaluation - as well as that of proposals and following through - can only be a perspective centered not on limitations, but on functioning, not on deficit, but on active competence and therefore on the use of present resources" (Paparella, 2020, p. 6).

On the other hand, Paparella's belief finds support in his approach to public ethics, which, as Magni also points out (Magni, 2003, p. 497 and passim), has been defined as an *ethics of capability* (Crocker, 1992). It starts from the theory of the *capability approach*, theorized by A. Sen and subsequently taken up and developed by M. Nussbaum, from a partially different angle, which aims, that is, at the achievement for the individual of the potential of a limited number of fundamental capabilities (Nussbaum, 2001; 2002). Sen's approach is of a consequentialist type, Magni explains, in the sense that it tends to evaluate actions based on the consequences they produce and not on whether or not they obey the rules.

Indeed, Sen states that "the 'capability 'of a person is nothing but the set of alternative combinations of functions that they are able to achieve" (Sen, 2000, p. 79, cited in Magni, 2003, p. 497). Consequently, the best public ethics, capable of eliminating the criticalities that keep the person in the state of vulnerability and marginality to which Paparella referred, is the one that allows the maximum expression of the operations of which the individual is capable (both in their totality, as Sen argues, and in a minimum, fundamental number, as Nussbaum claims). This is because, as Sen affirms, "the capability approach is basically focused on the identification of objects of value and conceives the space of evaluation in terms of functioning and ability to function" (Sen, 1994, p. 68, cited in Magni, 2003, p. 498).

In conclusion, therefore, it can be acknowledged that the perspective of eliminating vulnerabilities and fragilities, and in fact inequalities, supported by Paparella, and the role of a public ethics that allows the full expression of every potential present in the individual, to which reference has just been made,

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only lead to the state of substantive equality affirmed as an unavoidable duty for the political decision-maker by art. 3 of the Constitution, which in paragraph 2 states that: “It is the duty of the Republic to remove the obstacles of an economic and social nature, which, by limiting the freedom and equality of citizens, prevent the full development of human person and the effective participation of all workers in the political, economic and social organization of the country “. Substantive equality and solidarity (and, therefore, relationality) constitute the founding principles of social rights. So it can be rightly said that “social rights are rights that find their justification at the same time in the principle of solidarity and in substantive equality. That is to say that these are rights to public benefits (solidarity) aimed at preventing some material or existential circumstance (health, poverty, unemployment, etc.) from hampering the full development of the human person and his/her participation in social life on a free and equal footing (substantive equality). This is consistent, however, with the quite widespread idea that social rights serve to ensure freedom through the state (Bobbio, Marshall) “(Pino, 2016, p. 19).

And the full implementation of substantive equality, as regards the argument that we want to put forward here, comes about through the effectiveness of the right to education, which is also provided for in the Constitution by art. 34. It comes about, in other words, primarily by effectively implementing that school open to all which is the wording with which this article of the Constitution opens.

And let us lastly add that the principle of substantive equality then found application in many of the rules issued by the legislator to increasingly protect the right to inclusion (like all other rights) of pupils with vulnerabilities. Such rules have marked the transition from separate schooling (the reference here, among others, to the discriminatory reality of special classes) to inclusive schooling, in a process that it is hoped will lead increasingly to full respect for the dignity of vulnerable pupils.

NOTE

The translation from italian of the parts in quotation marks in the text was carried out by the author of this paper.

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KEY TERMS AND DEFINITIONS

Algorithms: Sequence of instructions to perform operations on computer data.

Artificial Intelligence: Ability of a machine to reveal human intellectual abilities.

Care: Moral attitude that aims at the physical and spiritual support of an individual.

Relation: Correspondence or existential relationship between two or more individuals.

SEN Pupils: Pupils who need a special educational path.

Technocracy: Political-social condition in which technology prevails over every field of human life.

Vulnerability: Condition of fragility of an individual, due to which, for example, he can receive damage or discrimination.

ENDNOTE

[1] The technoscientific drift is the social, political and contextual situation of scientific research, for which, by subverting the traditional relationship that is established between science and technology, technology is allowed to take precedence over science, imposing on the latter the direction towards which to direct its research. Such a direction will often be the most convenient for the development of the technique itself. The next step, on the political-juridical level, will see the choices of the legislators bound by the results achieved by "techno-science".

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Chapter 11

Healthcare Risk Management:

A Marketing Approach

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ABSTRACT

For the healthcare organization, it becomes more essential implementing organizational measures that change the conduct of operators, through behavior and organizational culture, trying to promote the analysis of adverse events and thus to learn lessons from these events. Good risk management leads to safe care, which is also perceived as service quality. This is where the logic of healthcare marketing comes in, a tool that becomes necessary to communicate the quality and contextual safety of the services offered by healthcare companies. Marketing, which has long been neglected in health systems, plays a key role in this perspective. The user of health services must, in fact, be considered as a corporate client. This analysis aims to investigate how a more marketing-oriented approach in healthcare organizations can be particularly useful in promotion and customer focus strategies.

Safety must be one of the factors determining the quality of healthcare.

The aim of any health organization is therefore to raise awareness and increase the culture of "safe care" as much as possible.

It is essential for the companies to implement organizational measures to change the behavior of operators, to try to promote the analysis of adverse events, to learn from them and, finally, to use instruments able to communicate to public the efforts made in the safety research.

Good risk management leads to safe care, which is also perceived as service quality.

The users of health services must be considered as corporate clients in order to provide them with the highest quality, moving all those levers, both general and specific, determining customer satisfaction; that is the reason why, in the discussion, we will call them client/patient, implying them as synonyms.

In recent years, patients/clients have become more and more demanding; citizens are free to choose their place of treatment or their treating professional and the healthcare offer has become wider and wider, increasing competition for service providers.

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For this reason, the provider must increasingly take communication and marketing processes into account.

Researching how management can make use of communication - the cornerstone of marketing - becomes a priority for health systems in a so highly competitive sector, mostly because the customer appears to be particularly in need of information.

Present-day healthcare systems are like all complex organizations; i.e. they are deliberately constructed and/or reconstructed social units, with a structure of roles that are functional to the pursuit of certain objectives and explicit behaviors that allow these objectives to be achieved.

Complex systems, such as healthcare systems, can therefore be defined as dynamic structures - in permanent evolution - with a capacity for self-organization, composed by a large number of parts interacting with each other in non-linear ways that result in global behavior, which cannot be explained by a simple model (Czarniawska, 2007).

These systems therefore operate under conditions of uncertainty more frequently than in the past, and risks involving these systems have also changed.

Uncertainty is present in all human constructs and it refers to epistemic situations involving imperfect or unknown information. It applies to predictions of future events, to physical measurements that are already made, or to the unknown.

Uncertainty, as well as risks, are of course part of human life and their value is important in the organizations, particularly in the complex ones, such as healthcare systems. Precisely for this reason, at the present time, uncertainty and errors are part of the studies of risk management, i.e. the process of identifying, assessing and controlling threats to an organization.

Errors and uncertainty in healthcare, in fact, have a significant impact on the outcomes and on the patient care, precisely because of the complexity of the systems, not only due to failures, but also to human error.

Malfunctions, misinterpretations, errors, cognitive bias (systematic errors of judgment) and heuristics (cognitive shortcuts causing an error) can compromise the diagnostic process. Therefore, safety becomes one of the factors determining the quality of medical care.

Over time we have seen an ever-increasing focus on safety and the aim of every healthcare organization has therefore become to raise awareness and increase the culture of "safe care" as much as possible.

For the healthcare organization becomes more essential every day implementing organizational measures changing the conduct of operators, through behavior and organizational culture, trying to promote the analysis of adverse events and, thus, to learn from them.

This is when the logic of healthcare marketing comes in, as a instrument necessary to communicate the quality and contextual safety of the services offered by healthcare companies.

The healthcare system, over a long period of time, has traditionally been far from these logics, but, nowadays, risk studies, approaches to error and the ability to communicate to users are now taking on a new meaning.

Therefore, if we can say that studies on risk management, precisely in complex organizational systems, have had the tangible result of being able to identify the areas of risk and to determine procedures and standards to reduce the possibility of the risk itself materializing with a negative output for the organization, risk management, then, becomes a priority for every organization, which can be achieved by studying errors and devising a series of error prevention programmers (De Andreis et al., 2019).

Managing risks, in the health sector, (as well as in all complex organizations) means implementing a series of measures based on team management and the study of errors, as an advantage of operators

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and users but also as an economic advantage for the organization itself. Which role does marketing and communication play then?

After these important considerations on risk, it is central to state that safety should not only be sought but also communicated. We can affirm, in fact, that there is a link between the importance of risk management and the role of marketing and corporate communication.

Today, in fact, there is a new user of healthcare services and products, a user who searches for information, who compares, who evaluates, who selects, who increasingly behaves as a protagonist, as an "active player" in the system.

Consequently, safety communication has become a priority for healthcare systems; in fact, safety and quality must become, through marketing, business opportunities to be used as a competitive advantage.

The question of how this more marketing-oriented approach is developed appears to be essential in order to understand how risk management and risk communication to users can become useful tools for organizations.

Reviewing the studies on marketing, we can see that the value of marketing has changed over time and it has become more important, even in healthcare systems, where it was not normally considered in the past.

The second half of the twentieth century, as is known, is characterised by the introduction of development policies based on consumptions.

It was during this period and in these conditions that a frame of knowledge and techniques – marketing - is set up to harmonise relations between supply and demand, between business and the market, marketing.

In the pioneering period, from 1945 to 1960, marketing normally intervenes after the production process, dealing only with distribution and considering consumers passively.

In the second phase of its development (1960-1975) the consumer starts to be considered as the pivot of the economy and, consequently, there is a solicitation of consumption by identifying and satisfying the current and/or potential needs of consumers.

From 1975, we can identify the third generation of marketing, with the appearing of new media, with markets maturing or declining and radical changes in distribution, companies and strategies; strategies start to be aggressive with the objective of taking market share away from acquiring competitors.

Accordingly, taking up the studies of Kotler and Armstrong (1980) on the definitions and applicability of marketing, we can state that marketing is the business function of identifying unmet needs and desires, of defining the needs and desires of the market and of defining the needs and desires of the customer.

In addition, in this process it becomes crucial to assess the breadth of both needs and target audiences, to determine which targets to consider, designing the appropriate products, services, and programmes in order to serve them.

The term marketing, one of the most widely used terms, can be applied to various areas of social life, from culture to art, from economics to medicine etc.; more generally, the area in which marketing operates is that which refers to the activities that humanity carries out in relation to markets.

Therefore, when we talk about marketing we are also talking about all those activities that go with the product/service from birth to final consumption, since it intervenes in the exchange process, that is, when people decide to satisfy their needs and desires, giving something in return (normally money).

There is also a relationship-based marketing, called relationship marketing, which takes place when companies start to establish long-lasting relationships of mutual trust with customers and suppliers, so as to be facilitated in future negotiations, building up a relational capital of inestimable value.

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Specifically, from the point of view of our study on healthcare, it becomes necessary, to better analyse the marketing of services, i.e. intangible goods that economic agents render to other agents, whether they are units of consumption or units of production. These services include all economic activities whose output is not a physical product or artefact but is generally consumed at the same time as it is produced and provides added value in forms essentially intangible to the first purchaser (Zeithaml et al., 2009).

When we talk about marketing of services, healthcare marketing is also important. The healthcare in fact, is to be considered as a service and is based on the optimal management of the encounter between supply and demand for health, between the health structure and the service it offers, and between the health structure and the service it provides the patient/user.

Nowadays talking about marketing in healthcare still evokes a number of resistances and cultural misunderstandings, related to the interpretation of the concept of "market" and "profits", because marketing could be seen as a way of putting pressure on a user who, presumably, is already in a situation of discomfort due to illness.

The particularity of health marketing is linked to the complexity of the "health-product", that it is a primary need, involving an intense emotional load with benefits difficult to define and evaluate.

It is therefore necessary for health marketing activities to know the health market, to adapt to its needs, so as to be able to optimally conduct the health offer.

If we can therefore compare medical needs to consumption, we can also understand the value of marketing in this respect.

Specifically, we can affirm that marketing provides the companies with a methodology, a way of thinking and acting in relation to their market, their demand and their target audience. In addition, it allows the health organization to strengthen, through communication and promotion, its position and its health offer, differentiating the service from its competitors.

Finally, marketing helps to optimise the use of human, professional, financial and technological resources in order to achieve greater effectiveness of the services provided and to satisfy the community and the individual patient (Foglio, 2007).

In public health, marketing has only recently been introduced and is currently used in an a small but growing number of companies.

Thus, we could say that health marketing can be understood either as marketing of services, as customer satisfaction and, at the same time, as communication towards the public or again, marketing could be seen as social marketing, essentially understood as fund raising.

It is central to also highlight that the most important characteristics of a health service are exactly the same characterising a service: in fact, as intangible, the health service cannot be seen, touched, heard and used before the activity itself has been performed.

For example, when a patient requires surgery, he or she has no choice except for trust, not being able, for example, to make an assessment of the outcome before the surgery; this is where the greatest difficulty lies in undertaking marketing actions in healthcare, since any activity is based on the user's trust in the service provider.

It then becomes important for the provider to increase tangibility as much as possible, involving as many sensory activities as possible, through all the aids available (e.g. pictures, explanatory brochures, videos, slides, patients' testimonies, professional qualifications and diplomas, etc.).

In addition, it should be emphasised that the provider of the healthcare service strongly influences and connotes the service itself, and it is therefore impossible to separate the service from the provider (inseparability from the source).

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Health services are characterised not only by a high technical difficulty, but also by a strong emotional impact, therefore, the operator makes the difference, not only with the skills, but with the state of mind and with a greater or lesser availability or predisposition to communicate.

The good use of a health service also depends on the user/patient, i.e. on his/her compliance/adherence to the therapy or to the lifestyle etc.

Since there are so many variables affecting a single service, it is impossible for two health services to be provided identically and it is therefore very difficult to standardise and establish quality standards (De Andreis, 2017).

The aim is to make the services as homogeneous as possible by breaking them down into elements that can be measured and compared (procedures, protocols, guidelines, etc.), which will also help work planning, since the production and use phases coincide, and there is therefore no possibility of storage.

So which tools are present in health marketing? To better understand marketing it is necessary to refer to some basic concepts, applied to the healthcare environment.

- **Need-Demand:** Understanding the needs of possible users, in order to propose a useful and targeted service to those needs, so as not to waste resources. For example, in healthcare, over the years, users' needs have changed and so has the demand for services.

Users feel more and more like "clients" and less like "patients", in the sense of those who suffer without the right to reply, increasingly seeking information. It should be seen as a real need to be satisfied. The patient/user and his or her very personal needs must therefore be increasingly at the centre of the health system.

- **Service:** It must meet the needs of the demand. Obviously the client must be aware of the existence of the service and its usefulness.
- **User Satisfaction:** Constantly monitoring the degree of user satisfaction, it is possible to do a good job and therefore build customer loyalty. It follows that a tool which allows to have control also, but not only, of customer satisfaction is market analysis.
- **Price:** Healthcare provision, like any product/service has a value, called exchange value, which is commonly referred to as price, especially in private care. It contributes a great deal to the positioning of the good and to the qualitative perception of the service itself.
- **Market:** It constitutes the set of components operating in a given sector.

In marketing, it is essential to have as complete a picture of the characteristics of the user (e.g. expectations of the service, why the patient chooses that service rather than another, when they enjoy that service, etc.) in order to offer a targeted service ("you can't sell everything to everyone").

To do so it is necessary to understand the audience, i.e. the "target" (the patient) so as to offer a service that is as targeted and satisfied as possible.

The most widely used system in investigating the target audience is the "5 Ws" scheme, of which we can see below the relevance to health organisations:

- **Who:** i.e. who uses the service. Age, group, gender, cultural level, type of occupation, propensity to save, value perceived and attributed to health, are all characteristics to be investigated and useful to start defining the identikit of the user.

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- **What:** namely what the user expects from the service. Investigating expectations helps to have information on the positioning in terms of the perceived quality of the service.
- **Where:** or where a similar service is usually provided. Understanding the logistical habits of the patient allows to see which services could be substituted for those provided to which the patient could turn. There are services that can be provided by subjects other than the classic hospital structure (e.g. blood pressure measurements, ecgs can be performed in pharmacies, many medical examinations are carried out in outpatient clinics, blood tests can be performed at home, etc.). This evolution of places of care has therefore radically changed the logistical habits of patients.
- **When:** i.e. when the service is usually enjoyed. The demand for a given service has a cyclical pattern (hours of the day, months, seasons). It is important to know the seasonality of the service provided in order not to miss the opportunity to adapt the healthcare response to the moment of the request (e.g. administration of the flu vaccine in the autumn).
- **Why:** that is why the client should choose that service rather than another, i.e. to understand why a patient suffering from a certain pathology decides to go to a certain facility rather than another.

Having made these considerations, helps to understand which role marketing plays in healthcare and why it becomes a management instrument.

The answer has to be found in the marketing research itself, which consists of the design, collection, analysis and systematic presentation of data relevant to a given marketing scenario of the organisation.

It therefore becomes a “pre-requisite” to be able to satisfy the demand and to prepare and plan the necessary interventions to support the offer, becoming a management instruments.

The objectives of a correct research action allow the health structure to know and identify the reference health market, analysing the demand and the relative expectations of the users and preparing the most suitable offer. It also allows to know the competition, the positioning of the company and by analysing the health market trend, it supports the planning and the decisions that have to be taken.

It is important that market research is not left to chance and improvisation; it is essential, in fact, to follow a research methodology, based on 5 phases: 1. definition of the research problem and objectives, 2. development of information sources, 3. development of data collection tools, 4. sampling plans and 5. analysis of results.

Therefore, the marketing mix also comes into play in the health sector; we know that it is a set of instruments through which the company acts on the behaviour of potential buyers within a competitive market. In addition, it is also the combination of controllable marketing variables that the company uses in order to achieve the predefined objectives in the target market.

The elements that make up the marketing-mix are innumerable, but we can base, in the health sector, the classification on 7 macro-variables (4 with the McCarthy classification + 3 added by Boomer and Bitner valid for the marketing of services) (Goi, 2009).

The declination of these variables should lead to an analysis of all possible elements that can make up a marketing strategy.

- **Product:** i.e. the service provided. In it, we can include the range of services offered, the style with which they are offered and, not least, the pre- and post-delivery service.
- **Price:** price setting, i.e. the determination of pricing policies. In the case of healthcare is a very difficult component to determine since the healthcare organisation provides services in a field, that of health, which is rich in symbolic values (“health has no price”). The healthcare company,

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which has to manage pricing policies autonomously, has to take into account numerous elements that may condition it. The basis of good pricing management is the consumer's perception of the value of the service. The concept of a fair price, i.e. how much a service should cost, is always present in the minds of most citizens. It is largely independent of the cost of production, which is unknown to the user, and can vary considerably from place to place and over time (Gabor, 1988).

- **Promotion:** from the classic to the most innovative advertising, via public relations, everything is important and fundamental in the management of health services, of the "good name" and of the word of mouth.
- **Point of Sale:** the place where the service is used by the patient/user. (e.g. logistic-structural aspects such as the comfort of wards and clinics, supply of materials, etc.).
- **Personnel:** health services are delivered by people and, as mentioned above, the performer strongly influences and connotes the service itself. For a good result, the selection, training and motivation of the operators is important.
- **Physical Presentation:** this consists of the way in which the service is presented (e.g. the location it occupies in the city and therefore its convenience for users, cleanliness, etc.).
- **Processes:** i.e. the physical pathway (e.g. building, corridors, parking...) but also the psychological pathway (e.g. bureaucracy, booking procedures...) that the patient has to go through to get to the service. It greatly influences the level of satisfaction with a service.

Why then can risk management make use of this marketing approach? Marketing plays an important role in helping healthcare systems to create, communicate, and provide value to their target market. Modern marketers start from customers rather than from products or services, due to the dynamic evolution of life that has inevitably affected the healthcare systems generating significant changes and imposing healthcare marketing as an indispensable element (Purcarea, 2019).

In particular, marketing and quality are strongly connected in the adoption of a common perspective for business management, i.e. the creation of value by satisfying the needs and expectations of customers and, more generally, of other stakeholders.

When we talk about quality in healthcare services, this obviously also includes safety aspects, because patients' safety is part of the previously mentioned priorities.

Marketing plays a crucial role in the choice of the value proposition to be provided to the customer. Thanks to its cultural and methodological contribution, it interprets the needs of the subjects, i.e. what is defined as the quality expected by potential buyers; this interpretation is the basis for the definition of the quality of the corporate offer.

Given the importance of and the link between marketing and quality, there must be a fruitful dialogue between the two functions in healthcare enterprises.

What has changed over the years is, in fact, the patient, who can easily find information on the most diverse topics. At the present time it is possible to access a huge amount of information, unfortunately not always neutral and relevant to the research made.

The knowledge that the individual thinks to have, certainly leads to greater autonomy of the person, but with the real risk of errors, resulting from mistaken beliefs or superficiality. Therefore, there is a real risk of patients becoming confused between reliable information, harmful to the health of the patient. There are essentially four dangers of the uncontrolled use of "social health":

- The increase in "do it yourself";

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- The proliferation in the use of unhelpful drugs;
- The growth in the self-prescription of unnecessary diagnostic tests;
- The spread of pseudoscientific or unclear information on lifestyles (Cummins & Schuller, 2020).

It follows that this increase in the individuals' knowledge and capacity for discernment affects the management of health.

Over time, the doctor-patient relationship has changed and evolved, at first seen by the patient as "putting himself in the doctor's hands", and now is seen as the possibility and freedom of choice and participation in the therapeutic decisions. The patient, after having consulted all the instruments available (devices, social networks, internet sites, etc.) and having received various information on pathologies, can decide when to consult the doctor to solve a problem.

The user of health services is becoming more and more autonomous in the acquisition of knowledge and healthcare companies in their daily life have to deal with this "new" patient/user, who is able to make important and basic choices for his or her own health independently.

The best way to manage this new type of relationship is through marketing and through the instruments it offers; in this, communication plays a central role.

Transparent and honest communication of errors and adverse events is essential to promote and strengthen the doctor-patient-team relationship; a relationship that becomes fundamental when approaching health systems management.

In addition to ethical and deontological reasons, health communication of errors and adverse events is essential to enable the patient to obtain appropriate and timely control and treatment, to mitigate harm, to obtain informed choices from the patient and, if necessary, adherence to new treatments or changes in the care plan, to initiate compensation in the event of harm, to promote and strengthen trust and the doctor-patient relationship, to decrease the likelihood of litigation and finally to promote learning from error and to improve clinical practice.

When an adverse event occurs, transparency is important, as the more information provided, the less likely the patient or family will seek legal action.

It may also be helpful to explain the incident to the patient, to provide physical and psychological support.

Depending on the severity of the injury, the mode of communication varies.

In general, it is agreed that adverse events should be communicated to patients, but if a patient is not seriously harmed and is unaware of what has happened, or for near misses, a team assessment of the possible consequences of either choice should be made, based also on the indications of the company protocol.

Communication must be handled with great care, because all those who are involved in various ways have an altered emotional state: relatives are anxious and worried and the operators involved may show panic, a sense of guilt, uncertainty and anxiety; as well as being engaged in actions aimed at reducing the harmful effects (Bellandi, 2006).

It emerges from this analysis that there is a common thread between management, risk management and marketing for the healthcare enterprise. Thus, it was shown how clinical risk, if managed correctly, is not an expense for the company, but an opportunity.

In particular, there is an increasing willingness in healthcare systems to embark on a process of corporatisation, which opens the field to marketing orientation.

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The peculiarities, seen above, in the health system mean that marketing concepts cannot be overlooked without careful reflection on the needs and on the values.

The application of marketing logic should enable healthcare companies to have a clear vision of the path they want to take so that there is a feedback from the demand and from the fact that there should be freedom of choice towards the health offer, whether public or private.

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Chapter 12

Contemporary Issues on Agriculture and Health:

Financial Framework, Reforms, and Competition Policy

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ABSTRACT

Rights and restrictions, education and financial resources at both European and national levels represent the core points of attention in proposing useful considerations on the effects of the pandemic in the health sector. Looking at health as a single and isolated sector makes it difficult to focus on the specific transversal aspects that are extremely relevant in the context we live in. Thus, health has to be considered from a multidimensional perspective, which encompasses different aspects ranging from legal to economic and social issues. The chapter develops an analysis that, through a complementary approach, embraces different sectorial dimensions, considering the supranational scenario and the current measures the Italian government has set in place till now. Within this framework, over the years, safe health has been more and more identified as a direct consequence of a safe agricultural environment. Thus, the whole chapter emphasises the important link to be inevitably taken into consideration for the future: the nexus between agriculture and health.

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INTRODUCTION

Health as a Constitutional Right: An Introductory Overview by Gianclaudio Festa

The protection and defence of human health are among the fundamental tasks of a liberal democratic country, which combines the liberal principle of individual rights with the democratic one of people's sovereignty. To this end, the national healthcare system must be viewed not only with reference to strictly health-related activities, but under a wider perspective related to the general economy, education and competition policies, and the legal and political aspects of EU financial measures.

It follows that the introduction to this chapter must necessarily deal with the legal foundations of the principles and rights concerning health protection, in order to subsequently develop considerations on the transversal issues.

From a legal point of view, at European level, the Lisbon Treaty focuses on health in Title XIV denominated 'Public Health'. In particular, Art. 168 TFEU (ex. Art. 152 of the European Community Treaty) provides that 'A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities'.

Furthermore, the first paragraph underlines the system of powers characterising the role of the EU, whose responsibility is to complete national ones in such cases as the fight against major health scourges by promoting research into their causes, their transmission and their prevention, as well as health information and education. The monitoring, early warning and fighting of serious cross-border threats to health, and information and prevention for the reduction of drug-related health damages are other EU competences aimed at integrating national policies. The second paragraph of Art. 168 focuses mainly on the actions of member States, assumed to operate according to the principle of loyal cooperation in liaison with the EU Commission.

At national level, Italy has given the public value of health, for both the individual and the community, a place in its Constitution[1.]. In particular, the constitutional framework outlines a decentralised Italian health system with most administrative and organizational powers governed by regions and limited powers at national level. More specifically, the State sets objectives for eliminating geographical differences in social and health care conditions and determines Essential Levels of care to be guaranteed to all citizens (the core benefit package called 'LEAs').

Within this context, the safeguarding of people's health is basically related to psycho-physical integrity, the right to a safe environment, to receive health care and medical assistance, and to decide whether to accept medical care or not. Ensuring these conditions allows people to be integrated in society and led to the creation of the National Health Service (NHS) in 1978 aimed at creating an efficient and uniform health system.

In this regard, one of the main concepts of its functioning is universal coverage for all citizens.

The first part of Art. 32 of the Italian Constitution formally states the State's obligation to ensure health protection as a 'fundamental individual right' and, in parallel, a public collective interest shared by all members of the community. In line with this, the pandemic and the vaccination campaign offer a contemporary example which stresses this coexistence because the protection of individual rights permits consequently preserving society as a whole. As a result, the right to health is strictly related to the individual as such, so that it can be defined a fundamental and inviolable right attributed to a man or woman as an 'individual'. By implication, no one can transfer it, sell it or give it up. On this point Art. 2

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of the Italian Constitution highlights the concept of 'human personality', which implies the preservation of each individuality in line with the personalistic principle[2]. Furthermore, Art. 2 must be interpreted in combination with Art. 3, which emphasises the value of human dignity and equality before the law irrespective of gender, race, language, religion, political opinions and personal and social conditions.

Given their clear-cut meaning, the fundamental rights are foundations of the democratic structure of a State, whose nature would inevitably change without them, albeit a democracy can exist even if freedoms and rights may appear in contrast each other.

Thus, health is a subjective right and, at the same time, a social interest. In its first status it refers to the right to be protected as an individual, and to receive health services from the State as a citizen. In its second status it refers to the fact that the Italian State is required to ensure health protection as a collective interest, in so far as it is an instrument to promote human dignity. It turns out that all issues involving health concern both the individual as such, as well as in his relationships within the community, where other individual rights find their background.

Indeed, the Italian Constitution protects health among other individual rights such as, for instance, the freedom to express thoughts or the right to work. In particular, the pandemic has made fully apparent that the need to protect collective health with a set of national measures implies constraints on individual freedoms. The imposed lockdown for health-related reasons allowed the reduction of Covid cases, albeit the freedom to regularly circulate of each individual was deeply compressed. Thus, it becomes appropriate to investigate the balance between the individual right to health established in Art. 32 of the Italian Constitution and the individual right to freedom emphasised in Art. 13, which explicitly states 'personal freedom is inviolable'.

The adoption of measures such as prohibiting free movements for a long period is an instance that has highlighted the prevalence of the right to health over others constitutionally guaranteed. The legitimacy of imposing specific constraints such as the ones introduced by the Italian and other governments worldwide is in fact enshrined in the articles establishing the above rights.

Firstly, the law can limit individual freedom in relation to Art. 32, which refers specifically to the protection of health by the State. Secondly, Art.16, which concerns the rights of every citizen to reside and travel freely within national boundaries, admits restrictions by law for reasons related to public health and security. Thirdly, authorities may, for proven reasons of public safety, suspend the right of people to get together (Art. 17). Finally, in Italy, private initiative cannot be exercised if it is in contrast with social utility or in ways that can cause damage.

The importance of the right to health may also be observed in view of its relationship with the right to life, which is given legal force at supranational level in Art. 2 of the European Convention on Human Rights (the Convention)[3].

The first paragraph states formally that 'Everyone's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law'.

Art. 32 states further that the State must guarantee free treatment to indigents and that no one can be forced to be subjected to a certain medical treatment unless this is made compulsory by law.

However, the law can never breach the limits imposed by respect for the human person. Even in this case as explained above, the vaccine adhesion in the pandemic has recently given rise to significant debates on the counterbalance between individual rights and the interests of community. In particular, the core issue concerns how relevant it is to safeguard human beings through vaccination to protect the

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entire community and systemically avoid critical consequences such as, extreme pressure on intensive care units and the closing of schools, public services and private firms to restart as before.

The State must ensure the necessary conditions for accessing healthcare so that people's rights in this regard be satisfied by all means suitable for both general and specialist health needs. Thus, the constitutional provision emphasises the principle of equality, which is at the basis of the Italian healthcare system and its procedures. Ensuring treatment does not imply necessarily receiving it. While everyone has the right to refuse care, it is essential that people be correctly informed about their condition and possible medical treatments before deciding. Here arises the concept of 'informed consent' towards health operators, who must abstain from starting procedures on patients who decide to avoid medical treatment. In the end, the last concept embodied in the Article is that of physical integrity.

In a wider perspective it is the connection between the protection of health and agriculture that has nowadays gained topicality. Over the years it has become increasingly recognised by public opinion that a healthy life is a direct consequence of the combination of correct nutrition, healthy eating habits and adequate medical treatment. Nevertheless, the Italian Constitution, despite its recognition of the fundamental right to health, does not assert any specific right of the individual to food, and more particularly, to 'safe food'.

In spite of the absence of any mention to this particular right, Art. 10 of the Italian Constitution permits referral to other provisions of international law, specifically, indirectly pointing out the right to food in three important legal provisions: Art. 25 of the Universal Declaration of Human Rights (UDHR); Art.11 (paragraph 1) of the International Covenant on Economic, Social and Cultural Rights (ICESCR) and the Rome Declaration of 1996 (FAO, 1996)

According to Art. 25 of UDHR 'Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control'.

According to Art. 11 of ICESCR 'The States Parties to the present Covenant recognise the right of everyone to an adequate standard of living for himself and his family, including adequate food'. Art. 12 adds that 'The States Parties to the present Covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health', and that '1. The States Parties to the present Covenant recognise the right of everyone to an adequate standard of living for himself and his family, including adequate food, clothing and housing, and to the continuous improvement of living conditions. The States Parties will take appropriate steps to ensure the realization of this right, recognising to this effect the essential importance of international co-operation based on free consent'. The second paragraph specifies 'The States Parties to the present Covenant, recognising the fundamental right of everyone to be free from hunger, shall take, individually and through international co-operation, the measures, including specific programmes, which are needed:

1. To improve methods of production, conservation and distribution of food by making full use of technical and scientific knowledge, by disseminating knowledge of the principles of nutrition and by developing or reforming agrarian systems in such a way as to achieve the most efficient development and utilisation of natural resources;
2. Taking into account the problems of both food-importing and food-exporting countries, to ensure an equitable distribution of world food supplies in relation to need'.

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Moreover, the aforementioned Declaration emphasises ‘the right of everyone to have access to safe and nutritious food, consistent with the right to adequate food and the fundamental right of everyone to be free from hunger’, and, in particular, ‘the need to adopt policies conducive to investment in human resource development, research and infrastructure for achieving food security’. Thus, as the provision explicitly highlights, ‘we must encourage generation of employment and incomes, and promote equitable access to productive and financial resources’.

In conclusion, the above normative framework focuses on the link between health and agriculture and on the countries’ commitment to adopt policies necessarily addressed at different fields, such as, on the one hand, the system of ‘economic and financial resources’ and, on the other, the promotion of research and ‘human resources development’, where education plays a decisive role in society.

BACKGROUND

Food and agriculture contribute to improving the living standards of populations, implying due attention to the quality of products increasingly connected to the health sector.

Resources related to agriculture and health provide people with integrated skills, experiences and expertise as well as combined solutions towards higher level food securities for all communities, especially the poorest ones.

The chapter describes contemporary issues concerning agriculture and health with a look at the Italian scenario which shapes the background to the whole research, where food quality, the Mediterranean diet and agriculture represent well-known aspects which identify Italy.

The work provides an overview at both European and national level in order to design a detailed and integrated framework for a comprehensive understanding of the link between health and agriculture.

Many studies in literature have accentuated this relationship focusing, in particular, on the considerable impact of changing healthcare environments. These studies point at useful considerations related to systems where the agricultural and health sectors collaborate together, providing new models of “Health extension”.

As a result, shared outcomes from agriculture and health could play a crucial role in outlining a path towards wellbeing and a correct nutritional balance.

MAIN FOCUS OF THE CHAPTER

The work describes the main procedural and content profiles characterising the potential link between health and agriculture. Throughout the chapter, health is analysed from multiple perspectives, focalising on current relations between health and education, financial instruments, EU policies and national expenditure. Hereunto, the description provides a comprehensive view of health from specific points of observation assessed in light of the constitutional provision establishing the priority of the right to health over all others constitutional rights. The work intends to focus on the foundations of both sectors, health and agriculture, to design the core framework illustrating the connections between them. The core aspects are necessary to interpret the main current debates at European and national level and to draw some conclusions, which may result useful for all stakeholders interested in the contemporary and innovative aspects of the sectors considered.

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Issues, Controversies, Problems

Health and Agricultural Education: Considerations on Food Safety Following the Coronavirus Pandemic by Federica Corrente

In light of the current Covid-19 health emergency, new challenges are impacting global issues: health, the economy, agriculture and education are facing a completely new scenario. This experience will provide responses in terms of behaviors, policies and reforms in all the sectors involved. At first,it was necessary to manage the crisis and the immediate consequences of the pandemic, but now it is time to act as an opportunity for development (WFP, 2020)

The Coronavirus pandemic has undoubtedly changed the way we look at nutrition and food safety. (FAO, 2020a)

This section describes the role of agricultural education and policy measures to be implemented in the food sector in light of the effects of Covid-19. Agriculture is of the utmost importance as it is not only strictly related to health and safety, but also because it is connected to the world economy. This is why, investing in agricultural education and implementing opportune policies, can contribute to improving the quality of our daily lives and lay the grounds for a renovated model of agricultural education all over the world.

The most relevant measures are related to the introduction and application of healthy eating habits as a preventive measure and the adoption of new policy reforms to develop agricultural education from childhood onwards at school.

After an introduction to the basic principles of a healthy diet suggested by the WHO, to be implemented individually as a preventive measure against contracting infections and maintaining a healthy lifestyle, the section focuses on the recommendations issued by the EU Commission and national policy issues connected to agricultural education.

Current scientific knowledge enables preventive possibilities against the emergence of a great number of diseases. Over the last two years as the COVID-19 pandemic spread, there has been a continuous transmission of data and information regarding people infected, deaths, swab tests and the great commitment of doctors and nurses in intensive care services. This huge set of data and information has led people to become immediately more and more conscienious of diseases, encouraging their prevention medical knowledge, which begins with the adoption of correct and safe nutritional behaviours.

With the same emphasis, strict attention has been paid to prevention measures such as quarantine, lockdown, social distancing, face masks, hand washing up to the vaccine rush. The sadness of the pandemic landscape becomes even deeper when one realises that among the preventive measures encountered, it is sometimes difficult to discover what should be the first approach in preventing infection: keeping the immune system very active (FAO, 2020b).

It is equally well-known that SARS Cov-2 is most likely to affect immunosuppressed individuals such as the elderly, those suffering from one or more diseases such as obesity, diabetes, organ failure and cancer patients with tremendous virulence and danger (World Health Organization Team, 2020).

The causes of immunosuppression are innumerable including pollution, excessive and sometimes improper consumption of drugs, lifestyle habits and last but not least, incorrect eating habits. Adequate nutrition is an effective way out against most infectious diseases, be they intestinal, respiratory, circulatory or of any other kind. At the same time, malnutrition due to excesses or deficiencies may cause an increase

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in the incidence, severity and mortality of infectious diseases. This occurs not only in countries with limited resources since in richer countries malnutrition is frequently hidden within an incorrect lifestyle.

Nutrition is becoming increasingly poor due to pollution, intensive crops and farming, food refining and conservation and all this can lead to a depletion of nutritional substances.

Unfortunately, too many diseases and deaths are always recorded and this is closely related, directly or indirectly, to overeating and poor food choices. The food errors that a large part of the world'spopulation make every day vary but can be summarized as follows (WHO, 2020).

- Eating too much food (quantitative). A reduction in the quantity of food consumed would make it possible to postpone or avoid the onset of most chronic-degenerative diseases (diabetes, cardiovascular diseases, autoimmune diseases, infectious diseases and dementia): eating less may be the path to a healthy old age.
- Eating foods too rich in simple sugars. Excessive consumption of simple sugars (sucrose, fructose, therefore sweets of any kind) is one of the main causes of metabolic diseases (obesity, diabetes, dyslipidemia, hypertension) and immune diseases. Simple sugars are indeed the cause of low-grade chronic inflammation which, in addition to aggravating the aforementioned diseases, also leads to a reduction in taking healthy foods to satisfy nutritional needs adequately.
- Eating too much meat, especially red and processed meat. Red meat increases the risk of arterial hypertension, ischemic heart disease and stroke and, in addition, is an important factor in increasing cancer mortality. As for the effects of meat on the functioning of the immune system, it should be underlined that a greater intake of red and processed meat, at the expense of whole grains, is associated with higher inflammatory markers accelerating cognitive decline in old age.
- Eating too much "junk food", food with very low nutritional value, and the high consumption of toxic substances, including trans - fatty acids and/or refined sugars.

Food education is a global issue and can affect individuals at all ages, therefore it is extremely important to intervene with particular attention to the paediatric stage, because eating habits acquired during the first years of life will hardly be abandoned over future years. Adults have to teach children good eating habits: reducing the consumption of animal foods, reducing packaged foods and enriching the diet with foods of plant origin, especially fresh vegetables, whole grains, legumes, fresh and dried fruit.

In May 2018, the Health Assembly approved the 13th General Programme of Work (GPW13), which is guiding the work of WHO in the period 2019–2023 (WHO, 2018).

Moreover, to support Member States in taking the envisaged necessary action, the WHO has developed a roadmap for countries (the REPLACE action package) to help accelerate actions.

The habit of a healthy and conscious diet is a pleasure and an investment in health every day: bodies are almost always able to overcome attacks by viruses, bacteria, fungi or germs provided that they are kept in good health and adequately protected.

However, it is also true that diet evolves over time, according to both social and economic factors. These factors include income, food prices and availability, individual preferences and geographical and environmental factors. Promoting a healthy food environment requires the involvement of multiple stakeholders, as well as the government and the private sector. The effectiveness of governments in efforts to create a healthy food environment foresee the creation of coherent national policies and investment plans to encourage consumer demand for healthy foods and meals. It is extremely important, for instance, to develop school programmes that encourage children to adopt and maintain a healthy diet and educate

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children, teenagers and adults regarding nutrition and healthy dietary practices. It can also be useful to encourage culinary skills, including activities for children through schools.

The pandemic represents an opportunity to implement new measures in the food sector in order to face serious challenges, including education.

In response to the specific recommendations of the European Commission on Italy, Mission 4 of the NRRP (National Recovery and Resilience Plan) (Italian Government, 2021) intervenes through education and research. The NRRP, is the instrument set by the Italian Government to implement reforms and investments to overcame the crisis due to the pandemic. The Italian plan foreseen by the Recovery and Resilience Facility (RRF) is one of the two instruments set by the NextGenerationEu (NGEU), the European solution to the pandemic crisis, the other being the REACT-EU (Recovery Assistance for Cohesion and the Territories of Europe).

Italy is the primary beneficiary, in absolute terms, of these NGEU instruments. The RRF alone guarantees resources for €191.5b, to be used in the period 2021-2026, of which €68.9b are non-repayable grants.

The NRRP comprises a set of missions in accordance with the objectives set by the NGEU and the lines of actions apply to the sectors of digitalisation, innovation, competitiveness, culture and tourism, green revolution and ecological transition, infrastructure for sustainable mobility, education and research, inclusion and cohesion and health.

Mission 4 of the Plan refers to education and research. Among the possible measures to put in place there is the enhancement of educational services, from kindergartens to University. The "Education and Research" Mission is based on strategies focused on the improvement of teacher recruitment and training processes and the upgrading of school infrastructure.

In this light, a measure related to canteen services will provide around 1000 renovated launch facilities or new constructions by 2026, with the aim of gradually implementing full time school. The project will be carried out through local administrations. This is certainly an interesting area that deserves further insights, although details have not been defined yet.

The Mission also foresees the reform of recruitment and instruction of teachers, with the aim of increasing the expertise of school staff, particularly where food education is involved. The reform aims to meet European standards, building a qualified body of teachers trained with continuous professional and career development.

The national strategy of the 2017/2023 Schools Programme established by the Italian Ministry of Agricultural, Food and Forestry Policies also includes the so called "Frutta e Verdura nelle scuole" Programme (lit. 'Fruits and Vegetables in Schools') (Italian Ministry of Agricultural, Food and Forestry Policies, 2017).

The Programme is meant for pupils aged between six and eleven in primary schools. The aim is to encourage children to consume fruit and vegetables and to support them in healthy eating habits, as well as spreading educational messages on food waste and how to prevent this.

Here also, specific teacher training initiatives have been devised to promote food education issues and fun based--didactic initiatives aimed at facilitating the tasting and consumption of distributed foodstuffs. Children are involved through "Fruit Days", during which many types of products are distributed together to be consumed in as many different way possibles, or by visiting educational farms. All these activities are meant to promote a knowledge of food production processes.

Over the years, the Programme has involved an average of about 1m pupils and from the activation of the Programme to date the results show a growing propensity for families and children to consume fruit and vegetables.

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The reform aims to favor correct information to pupils at school regarding the principles of sustainability and organic agriculture. The goal is connected both to the necessity of promoting the consumption of organic and sustainable foods for the environment and reducing food waste.

Additionally, in this regard it is also important to refer to EU Regulation No 1308/2013 which establishes a common organisation of markets in agricultural products, defining aid schemes intended to improve the distribution of agricultural products and children's eating habits for those who regularly attend nurseries, pre-schools or primary or secondary-level educational institutions administered or recognised by the competent authorities in Member States (EU Regulation, 2013).

Financial Support for Agriculture and Health: Perspectives and Improvements in the European Programme 2021-27 by Elena di Paolo

The Coronavirus period has emphasised the role of health in society and, in particular, the need to constantly support the system of national institutions established with the aim of ensuring health-related services and medical care at optimal level.

The pandemic has proved worldwide that, in exceptional circumstances, all types of structures and institutions engaged in the health sector end up being inevitably subjected to unpredictable difficulties.

As of today, the pandemic crisis has highlighted health protection as a public interest of paramount importance and the exceptional experience has helped make people and institutions better prepared for future unexpected emergencies. In this context, from the beginning of COVID-19, several Member States have been required to find financial resources to face increased upcoming needs and solve historical gaps in their health systems, as occurred in Italy.

For this reason, it is deemed important to pay attention to how Europe will financially intervene through specific support directed at improving the two sectors of agriculture and health.

Never before has health been considered such a crucial and transversal subject for many sectors and become a fundamental issue of national policies especially with regard to the agricultural sphere.

Therefore, in view of the negative pandemic effects, EU Institutions and Member States have negotiated a set of measures regarding an amount of financial resources programmed to bridge the existent gaps in Italy and, more widely, in Europe.

To begin with, Member States basically use ESI Funds to support specific sectors such as agriculture, education and the environment, in addition to national public expenditure and over a programme cycle of seven years[4].

In this context, the Common Agricultural Policy (CAP) through its national Operative Programmes (OPs) represents the core system of financial resources devoted to supporting the agricultural sector and its specific aspects[5]. The structure of the CAP consists of two 'pillars' of measures that basically focus on income support schemes and specific investments in agriculture, the forestry sector, rural areas, the environment and climate. These pillars respectively rely on two specific funds: the European Agricultural Guarantee Fund (EAGF) and the European Agriculture Fund for Rural Development (EAFRD).

With regard to the current scenario 2021-27, the CAP mostly focuses on actions linking both the agricultural and health sectors that substantially involve the environment, climate change, food value chain and animal welfare. More specifically, the main areas of the new CAP include climate mitigation and adaption, protection of water quality, prevention of soil degradation, protection of biodiversity, reduction of pesticides and enhancement of animal welfare. In such areas, practices concern husbandry, organic

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farming, animal welfare plans, agro-ecology, agro-forestry, carbon farming, precision farming, nutrient farming, protection of water resources and soil and Greenhouse Gas (GHG) Emissions.

The system of financial resources and the EU long-term budget perspective are outlined in the recent Multiannual Financial Framework ("MFF"), finally approved at EU level on 10-11 December 2020, for the incoming seven-year programme period 2021-27 (Council Regulation, 2020).

The whole budget is divided into seven different lines of action ("headings"), where just over €356m of the total commitment appropriation will support the heading 'Natural resources and the environment' which notably concerns agricultural measures connected to the environmental context[6].

In fact, the latest approved MFF specifically focuses on the link between agriculture and environmental sustainability rather than on sustainable growth, as was the case in the previous funding period 2014-20, whose measures were grouped under the specific heading 'Sustainable growth: natural resources' (Council Regulation, 2013).

Further to this framework, the pandemic has inevitably reconfigured the previous general structure of EU funds 2014-20 in order to direct new additional financial resources to specific ad-hoc programmes, thereby leading to a review of current policies.

To begin with, NextGenerationEU and React EU are the main initiatives that have involved EU and national authorities in negotiations to assign the available financial resources[7] (EU Regulation, 2021).

In this context and to summarise, on 13 July 2021 the ECOFIN Council approved the Italian plan of reforms in order to sign grants and loan agreements for up to 13 percent pre-financing and to start receiving funds for implementing the related investments[8].

To reach the above approval, the EU Commission had previously pointed out the conditions and the qualitative and quantitative targets that Italy is required to comply with, over the next years (EU Commission, 2021a).

Indeed, during the forthcoming year, each Member State has prepared and submitted a detailed plan called the "National Recovery and Resilience Plan" (NRRP) concerning ways and methods to use and spend the amount of financial resources that Europe has set up as an answer to the pandemic[9].

In detail, the second policy area of the Italian NRRP called "Green revolution and ecological transition" is specifically devoted to ensuring a sustainable agricultural sector through actions of waste management, investments in renewable energies and incentives for the main food supply chains. More precisely, with regard to the specific measures on agriculture, the well-known "circular economy" represents the main focus of the Italian plan[10].

In this respect, the national and regional operative programmes of the ESI Funds and the NRRP have to be coherent with the main systemic European strategies forming part of the regulatory and normative system that each Member State is required to follow.

The delays caused by the pandemic have slowed down the real implementation of projects over the programme period 2021-27, leading to a priority in analysing the strategic framework at EU level for improving the recent national funding procedures.

In fact, the national operative programmes have to be in line with European strategies and initiatives, which include the well-known "Green Deal" and, most notably, the "Farm to Fork" strategy (F2F).

Both strategies have a longer time horizon (2050 and 2030) than the ordinary seven - year period that characterises a common EU programme cycle aimed at managing financial resources from ESI funds (2027)[11].

More specifically, the Green Deal is the systemic strategic framework which outlines a common direction among States in order to ensure a sustainable environment for people, the planet and the economy,

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whilst the F2F is the new strategy of the EU Commission that specifically concerns various aspects related to agriculture and sustainability ‘from the producer to the consumer’.

In May 2020, the EU Commission presented the “F2F” strategy, whose main target is to “build up” fair, healthy and environmentally-friendly food systems[12] (European Commission, 2020).

The range of actions of the F2F connects it strongly to other strategies such as the one that aims to protect nature and biodiversity[13].

Within this context, the Commission has oriented Member States to improve their national food systems and policies in order to create a harmonised framework in Europe towards a common idea of health. In detail, the Farm to Fork strategy is basically targeted at:

1. reducing by 50 percent the use of antimicrobials for farmed animals;
2. reducing chemical and hazardous pesticides;
3. reducing nutrient losses to the environment from both organic and mineral fertilizers by at least 50 percent;
4. identifying plans, practices and initiatives of conversion to “organic farming” for at least 25 percent of existing farmlands.

Thus, this strategy allows the Commission to outline an integrated path for each Member State to gradually limit the pollution of soil, water and air and to consequently ensure a healtier environment for human beings.

Among the main objectives, the EU F2F strategy promotes sustainable food consumption and facilitates the shift to a healthy and sustainable diet.

Therefore, the strategy must focus on improving consumer information to ensure the transparency of food products and guide consumers in understanding the actual food quality. Indeed, enhancing awareness by consumers on nutrients represents an essential part of the processes ‘from production to consumption’ and, in this respect, does not acquit producers of their responsibility. In fact, the role of the producer remains fundamental in the production chain both in the adoption of correct practices and the accurate and transparent reporting of them on the product label.

Within this framework, the Commission has started to stress the importance of correctly informing consumers in order to make people aware of their choices for a healthy balanced diet. For this reason, a particular focus has been placed on a specific aspect that links both the agricultural and health sectors: the front-of-pack nutrition labelling.

Subsequently, in line with the F2F and the main initiatives connecting health to agriculture, the EU Commission is expected to take a decision within 2022 on the best system summarising food product information for consumers.

Among the various systems proposed, a new labelling form called “Nutri-Score” (NS) has become one of the most debated at European and national level.

The NS was created by a team of French researchers who have designed a traffic light scheme for labelling comparable products, on the basis of many studies regarding nutrients[14].

This mechanism consists in different scores of product safeness signaled by different colours (light and dark green, yellow, orange and red) and alphabetical letters (from ‘a’ to ‘e’), for instant and easy comprehension by consumers. For instance, vegetables and fruits contribute to the highest final score of a product, while fats lead to the lowest one.

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Taking into account the above considerations, the foundations of this approach are directed at enhancing the value of health thanks to the adoption of an immediate graphic form.

Indeed, the more the details and information are formally "simplified" and easily comparable within the same category of products, the higher consumer awareness will be regarding what they buy for their proper nutrition. In this respect, the system would guide consumers towards a healthier quality of life with easy alerts of different colours and letters toward a diet based on a correct nutritional balance. To this end, the mechanism could imply firstly, a consumer propensity to buy less canned foods and, secondly, a decrease in diseases such as diabetes. From the market viewpoint, the idea behind the NS should guarantee fair competition within the same categories of producers, even if over different countries, by ensuring a common standardised assessment. Indeed, reducing dispersion and confusion for consumers due to the different ways of labelling by producers and among countries means starting to regulate the food market as a whole.

Hence, on reflection and besides the aforementioned improvements, a question arises: will this harmonised scheme of labelling definitely produce only benefits?

Several organisations representing firms and plants have highlighted some negative national consequences related to the NS mechanism, which may significantly risk discriminating against PDO ('Protected Designation of Origin') and PGI ('Protected Geographical Indication') products[15].

This critical aspect deserves careful consideration, especially in view of the negative impacts of Coronavirus on the food production chain and the long periods of closures that severely affected the well-known Ho.Re.Ca system[16].

In this respect, a common assessment aimed at formalising a standardised labelling that will focus on only the best nutrients in a product, may represent a threat to all the producers of specific characteristic foods of national traditions. As a result, a lot of traditional products may not be considered nutritionally suitable, in spite of their important identifying role in certain countries, for instance Parmesan cheese in Italy.

In this context, many Ministries and organisations stress the possible negative effects on food production chains representing national traditions and denoting 'territorial specificity (Codacons, 2019). They have highlighted the difference between labelling as a means of information on the one hand and, on the other, of influence, orientating consumer choices through a visual mechanism of symbols (letters and colours). In this regard, the "traffic light" signals of the NS mechanism may discourage consumers from buying specific foods that could be considered, however, part of a healthy diet if consumed in limited quantities. In line with this, many researchers and politicians have claimed that a food product cannot be considered safe or not a priori, because this depends on the specific diet in which the product is part of and on the amount of intake in an individual food plan[17]. This is the approach of a team of Italian referees acting at political level that promotes the well-known 'NutrInform Battery'(NIB)[18].

Hereunto, the idea is to coherently consider each product in view of its role in a specific diet plan, rather than merely in its specific nutritional values which have to be precisely declared on the front-of-pack labelling.

Thereby, the link between agriculture and health is enhanced through the application of the principle of transparency that prevails over the visual immediacy derived from a schematic drawing of colours and letters only.

To summarise, the above mentioned organisations and authorities have focused the attention on both the economic (the possible exit of certain operators from the global market) and health (incomplete nutritional knowledge by consumers resulting from a graphic labelling) sides of the issue.

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In contrast, a team of scientists has claimed that the economic laws (of return) ought not to prevail over science, which instead should drive the consumption choices for a safe diet. In line with this view, the mechanism of NS points at creating a final assessment able to make comparisons of products belonging to the same categories. The chromatic scheme should create awareness regarding the best product in a precise cluster of different producers[19].

Within this framework, it is deemed essential to emphasise that the F2F strategy is not compulsory for each State because it draws a direction aimed at enforcing the message to safeguard both health and agriculture. The strategy aims at designing a system of guidelines and even if the operative measures still have to be formally identified by each Member State, the overall strategic framework undoubtedly represents a big challenge for the future.

In conclusion, there are open questions that still need to find proper answers.

Both the aforementioned approaches propose two views that, although opposing, may both be shared.

In fact, the NS can represent an opportunity to make consumer awareness more complete and simpler than it is today, even if there are some issues concerning consumer communication that need to be carefully considered. For instance, are there mechanisms to orient people to correctly understand the key (colours and letters)? This point is extremely important for elderly people, since if they are not correctly informed on the meaning of the scores, they will not understand why a cheese shows a worse letter than a carbonated drink like Coca-Cola.

On the other hand, the NIB system interprets the value of a product in terms not only of its single components but also of its link to a diet plan. Thus, the methodology proposes an evolutionary approach and a more extended and open-minded assessment.

The underlying idea of the NIB is undoubtedly innovative and it is conducive in favoring the Mediterranean diet, which represents one of the traditional Italian assets.

Despite the preminence and high worldwide recognition, many other well-known nutritional plans and lifestyle food choices characterise the EU scenario such as vegetarian, "dissociated" or protein- based.

As a result, it might be appropriate to consider the NIB and NS system as approaches that are complementary rather than opposed.

A possible solution for the compulsory and harmonised labelling the EU Commission is supposed to approve by 2022, could be a combination of both. This would mean having an immediate framework of the elements of a single product and, at the same time, its assessment in a more systemic Mediterranean plan with the possible addition of more details on other types of diets too.

In conclusion, many aspects linking specific nutritional values and different types of diets inevitably affect both agriculture and health and will become crucial issues not only in the next programme period 2021-27 but also in the more long-term scenario of the strategic path towards 2030.

Spending Measures and Investments in the Italian Health Sector: Conclusive Remarks by Elena di Paolo and Giustino Lo Conte

Following the analysis of Section 3 'Financial support for agriculture and health: perspectives and improvements in the European Programme 2021-27', this paragraph intends to provide an insight on national public spending to cope with the pandemic in Italy.

Indeed, the Covid-19 outbreak has ignited many debates on how each country is facing the crisis and improving the national health system.

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To begin with, the pandemic has strongly stressed the right to health due to the massive increase in Covid cases that unexpectedly characterised Italy and most other countries since February 2020.

An exceptional health occurrence such as a pandemic implies for every public health system a greater effort in terms of human, financial and organizational resources due to the sudden unprecedented increase in requests and needs.

This brings to the fore the crucial relationship aimed at striking a balance between the need for long term fiscal sustanability and the protection of health, which has inevitably prevailed over other individual rights that were subjected to restrictions, such as the right to freely move during the pandemic.

The exceptional decision to temporarily suspend the 'Stability and Growth Pact' (SGP) using the 'General Escape Clause' (GEC) demostrates the high value attributed by Europe to health and sheds light on unprecedented financial interventions in all EU countries[20].

Through the Stability and Growth Pact, the 27 European countries aim to keep budget deficits below three percent of GDP and public debt below 60 percent of GDP. These rules were put on hold in March 2020 to avoid a severe economic downturn in the area of the Union as a whole and to recalibrate resources to new strategic objectives. In this respect, European institutions have been temporarily permitting Member States to adopt the necessary measures directly aimed at restoring the health sector without the restrictions of the aforementioned Pact. To this end, in the Spring 2021 European Economic Forecast, the EU Commission has pointed out that the GEC will continue to be applied in 2022 and 2023 (EU Commission, 2021b).

In the wake of a new 'flexibility' of Member States policies, it is important to analyse how the Italian government plans are designed to overcome the negative effects of Coronavirus and to what extent national measures are in line with EU requirements, in order to avoid missing out on current EU opportunities.

In this context, the Italian government has enacted a number of measures targeted at repairing the big gaps in national health structures from 2020 to 2021.

Hereby, it is essential to report a summary of the main decrees up to 2021 addressed at the health sector, which represents the central line of intervention, as well as the planned measures to boost the job market system and to increase liquid assets for workers, firms and families. In particular, the measures regard the health sector focus on the recruitment of new doctors and medical personnel, a higher number of hospital beds and the setting-up of *una tantum* benefits for certain categories of workers.

These measures have been enshrined in several decrees here listed in chronological order: 'Cura Italia' (17 March, 2020), 'Liquidità' (8 April 2020), 'Rilancio' (19 May 2020) and 'Ristori' (14 August 2020 and 28 October 2020), followed by 'Ristori Bis' (9 November 2020), 'Ristori Ter' (23 November 2020) and 'Ristori Quarter' (30 November 2020).

Moreover, besides these provisions directly covering the main urgencies, in the budget law for the year 2021, the Italian authorities approved huge investments targeted at the health system. In particular, the planned reforms focus on the employment of human resources to empower certain administrations.

The National Institute for Health, Migration and Poverty (INHMP) and the Italian Medicines Authority (AIFA) for example, are required to activate new permanent contracts and extend current fixed-term ones till the end of 2021. With regard to administrations encompassed in the National Health Sistem, additional human resources can be recruited from the list of participants in public selections who qualified even if not winners. Moreover, new appointments of people from professional registers for fixed-term contracts are also permitted.

Besides measures regarding employment, another set of norms establishes compensation totalling €850m. In this context, a new type of compensation has been assigned to permanent operators in the

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health sector, without any distinction of roles. Another type of benefit has been attributed to general practitioners and pediatricians who decide to avail of additional professional support in their specific range of family assistance. Other measures in 2021 concern an increase in financial resources by about €1m for swab tests and new contracts for doctors who have completed their training. In detail, for the National Vaccination Plan the government has planned to allocate about €650m for hiring 3000 doctors and 12000 nurses[21].

Moreover, a specific fund of €400m is earmarked for anti-COVID medicines and €70m for swab tests for doctors and nurses. A special provision in the 2021 budget law concerns the Value Added Tax (VAT) on rapid antigen testing, which has been fully removed for the fiscal year 2021. Moreover, the intervention plan pays special attention to safety levels in hospitals and other health structures, so that €2b will be allocated over a 15-year time period to renovate buildings and to bring them up to a cutting edge technology.

To summarise, the current budget law highlights many investments aimed at improving the national health sector for a total of €24b, in addition to €15b from NextGenerationEU resources (The 2021 Budget Law, 2021).

In this context, regional and local governments play a central role in implementing the vaccination plans and in decentralising the crisis response. Indeed, the powers constitutionally assigned to the regions calls on them to autonomously organise their local health systems, while the State aims at protecting health under a more systemic perspective, focusing on the definition of essential levels of treatments as a matter of social and civil rights guaranteed for the whole national community[22].

Now, although the pandemic has shed light on the need to improve the dialogue between State and regions, a proper balance of their respective responsabilities in the health field turns out to be difficult not only to ensure, but also to define[23].

So far, the regions have mainly acted following the sharing of the attribution of powers between them and the State (‘concurrent legislation’), albeit the current epidemic emergency brings the related health measures under the framework of the ‘International Prophylaxis’, which pertains to the State[24] (Cassese S., 2021).

The heterogeneous responses of the Italian regions to the crisis has delineated a fragmented framework of intervention which, without proper coordination, will not allow a homogeneous trend of improvement throughout the whole national community.

Consequently, an analysis of the current power structure in Italy becomes one of the priorities in the running scenario of reforms.

To conclude, the phase of planning identifies a set of measures actually targeted to fill historical gaps, which will necessarily require well designed systemic coordination of all authorities at central and regional level in the national system of action, in order to manage, in an efficient and effective way, the consistent amount of Italian financial resources.

CONCLUSION

Financial support, reforms and investments in the area of health encounter difficulties that require a high level of attention from national authorities in shaping a well-targeted action plan. In particular, the old gaps transversally affecting the medical and health sectors require a deep analysis of the whole national structure that is about to be created in light of the recent measures described above.

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Thereby, the current intervention plan, which emphasises the relationship between health and agriculture, will provide the opportunity to test the capabilities of authorities in managing financial resources, as well as demonstrating that a positive change of direction in Italy is not so far away.

SOLUTIONS AND RECOMMENDATIONS

The chapter identifies the front-of-pack labelling as one of the drivers to orientate people toward a correct dietary balance.

In view of the upcoming decision on the EU Commission agenda concerning the best nutrient profiling system, any kind of mechanism will become a means of transparency and a vehicle for conveying to consumers the importance of being educated in health safety.

Simplifying the label means finding the key for the consumer to develop autonomous understanding of the nutrients in each product.

In this regard and in addition to a safe diet, other lifestyle components contribute to health and well-being. Indeed, a healthy lifestyle includes other equally important additional habits such as avoiding smoking and alcohol intake, exercising regularly, getting adequate sleep and minimising stress.

FUTURE RESEARCH DIRECTIONS

Over the years, safe health has been increasingly considered a direct consequence of a safe agricultural environment. Appropriate innovative cultivation techniques oriented towards cutting edge technologies and the role of education leading to a correct balance represent some of the basic requirements for a proper long-term lifestyle.

The chapter represents a preliminary step to design a path for further studies aimed at protecting health from diseases by means of a safe diet. Furthermore and apart from rediscovering more appropriate lifestyle-related health issues, new and re-emerging infectious diseases may appear, thereby requiring advanced assessment, before they actually become a reality. Moreover, there is a need to improve healthcare and to consider it a priority for people who still live under poor conditions. The chapter outlines an innovative framework, which appears as an incubator of ideas and thoughts to construct new solutions for the future. In particular, taking into account all of the sections of the work, the link between agriculture and health will become an essential combination for dealing with a great variety of problems ordinarily faced by society, inducing professionals and researchers called to address these topics.

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*National Recovery and Resilience Plan (NRRP). (2021, May 5), retrieved from <https://*www.governo.it/sites/governo.it/files/PNRR.pdf>

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ENDNOTES

[1] Before such formal inclusion, the World Health Organization (WHO) had already recognised in 1946 the value of health, conceived as "*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity"*. In 1789 the American Constitution contained a broad reference to health which gave rise to the concept of 'general well-being', extremely innovative for that time.

[2] Constitutional Court ruling (1994, January 24), n. 13: "Among the rights constituting the untradable endowment of the human person, Art. 2 of the Constitution also recognises and guarantees the right to personal identity' …. 'Personal identity is therefore a good in itself, independent of personal and social conditions, personal merits and flaws, so that everyone has a right to the preservation of his individuality' ".

[3] Art. 2 of the Convention contains two substantial obligations: the general obligation to protect by law the right to life, and the prohibition of intentional deprivation of life, subject to a list of strictly defined exceptions.

[4] The principle of additionality is at the basis of the EU funding mechanism and it drives the correct way to spend the available financial resources of each Member State. This principle ensures that contributions from funds related to a Member State must not replace national public finance or equivalent structural expenditure.

[5] The Common Agricultural Policy (CAP) is the main EU policy devoted to the agricultural sector that was set in 1962. For further details on the CAP: <https://ec.europa.eu/info/food-farming-fisheries/key-policies/common-agricultural-policy_en >.

[6] In addition to the EAGF and EAFRD funds, the measures related to the heading "Natural Resources and the environment" may be also supported using the programme "LIFE" for the environment and the climate and the Just Transition Fund (JTF), which will support the changes leading to a thriving and socially fair climate-neutral economy. The total amount of heading 3 - Natural resources and the environment - and the main aspects that concern the assignments of resources are detailed in EU Regulation issued on 17 December 2020. Source: Council Regulation (EU, Euratom) 2020/2093 of 17 December 2020 laying down the Multiannual Financial Framework for the years 2021 to 2027, (2020, December 22), Official Journal of the European Union, Annex I.

[7] Regulation (EU) no 2021/241 fixes the main aspects regarding the NextGenerationEu. Ref. Reg. (EU) No 2021/241 of the European Parliament and of the Council of 12 February 2021 establishing the Recovery and Resilience Facility, available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R0241&from=IT>.

[8.] The first proposal of the Italian Recovery and Resilience Plan was sent to the Italian Parliament on 15 January 2021 and, afterwards, to the EU Commission on 30 April 2021.

[9] For an overview of the current NRRP, see: Sciortino, A. (2021, July 28). *PNNR e riflessioni sulla forma di governo italiana. Un ritorno all'indirizzo politico "normativo"?*. Federalismi.it, 18.

[10] The National Recovery and Resilience Plan presented by Italy envisages investments and a consistent reform package, with €191.5 billion in resources being allocated through the Recovery and Resilience Facility and €30.6 billion being funded through the Complementary Fund established by Italian Decree-Law No.59 of 6 May 2021. Source: Italian Government website at <https://www.governo.it/sites/governo.it/files/PNRR.pdf>.

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[11] 2027 is the formal deadline of the recent EU seven-year cycle that does not consider the years allotted to the activities to conclude the programme. For instance, the reimbursements of the beneficiaries referred to the EU programme period 2007-2013 were actually completed two years after the seventh year.

[12] EU Commission (2020). Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions a Farm to Fork Strategy for a fair, healthy and environmentally-friendly food system, COM(2020) 381 final. (2020, May 20), Brussels.

[13] The 2020 BS was adopted in 2011 by the EU Commission to face the decline of biodiversity and ecosystem in the EU by 2020. Differently, the other most recent strategy concerns the subsequent framework of protection till 2030. It is involved in the EU Green Deal and was formally published in May 2020 after a public consultation that started in January. Details about the EU BS can be red at: <https://ec.europa.eu/environment/strategy/biodiversity-strategy-2030_en>.

[14] The EREN (Equipe de Recherche en Epidemiologie Nutritionelle) has developed the current version of the NS system on the basis of the scale of nutritional values from the formal tables identified by the Food Standard Agency (FSA). In Northern Ireland, the FSA is responsible for nutrition labelling. Official website <https://www.food.gov.uk/business-guidance/nutrition-labelling>.

[15] With regard to the Italian context, for instance, Federalimentare (Italy) has explicitly declared its positions about the Nutri-Score system. For more insights on this issue: Federalimentare (2019, 26 June). *Federalimentare: Nutriscore fuorviante, penalizza il Made in Italy,* [press release], official web site, available at: <http://www.federalimentare.it/new2016/ms_comunicati_det.asp?ID=946> and Federalimentare. (2020, February 12). *Etichetta a batteria, Federalimentare: Battaglia unanime contro il Nutriscore*.[press release], official web site, available at: <http://www.federalimentare.it/new2016/ms_comunicati_det.asp?ID=976>

[16] In the Dutch, Italian and French languages the term Ho.Re.Ca. corresponds to the system of food service and hotel industries (Hotellerie-Restaurant-Café or Catering in some cases).

[17] During the Agrifish Council on 15 December 2020, the Italian Ministry T. Bellanova presented a document that was approved by representatives of several other countries such as Greece, Czech Republic, Latvia, Romania, Hungary and Cyprus. The report disagreed with the mechanism at the basis of Nutri-Score. More insights on this issue can be seen in the press release: OriGIn Italia, (2020, December 16). *Etichetta Nutriscore. Origin Italia: le indicazioni geografiche e le eccellenze dell'industria agroalimentare italiana dalla stessa parte Positiva posizione contrarietà ministra Bellanova a consiglio Agrifish*, OriGIn Italia. Ref. available at: <https://www.origin-italia.it/wp/wp-content/uploads/2020/12/20201216_OI_nutriscore-2.pdf>.

[18] For a comprehensive description of the NIB system see at the specific website: <https://www.nutrinformbattery.it/>.

[19] For more details see: Group of European scientists supporting the implementation of Nutri-Score in Europe (2021, March 16). *Call from European scientists to implement Nutri-Score in Europe, a simple and transparent front-of-pack food label with rigorous scientific support, intended to guide dietary choices and thus contribute to chronic disease prevention.* [Press release] retrieved from <https://www.ehesp.fr/wp-content/uploads/2021/03/Nutri-Score-Press-Release-March-16-2021.pdf>.

[20] The "General Escape Clause" is one of the two clauses of the Stability and Growth Pact (1997) that allows Member States to undertake appropriate budgetary measures in exceptional circumstances.

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The clause provides an extension of the deadline for Member States to correct their excessive deficits under the 'excessive deficit procedure', provided those Member States take effective action as recommended by the Council. The severity of the constraints and the need to use greater 'long-term flexibility' under the Pact have led the EU Commission to prefer to adopt this clause rather than the other one called 'The unusual event clause'. However, the latter could be allowable also, since the Coronavirus pandemic actually represents an occurrence outside the control of governments. Source: Communication from the Commission to the Council on the activation of the general escape clause of the Stability and Growth Pact, (2020, March 20), Brussels, COM(2020) 123 final. For more insights see: Commission's Communication to the Council on fiscal policy '*One year since the outbreak of COVID-19: fiscal policy response'*, (2021, March 3), COM(2021) 105 final and Domenicali C. (2020, June 17). *La Commissione europea e la flessibilità "temporale" nell'applicazione del Patto di Stabilità e Crescita,* Federalismi.it.

[21] The SARS-CoV-2 / COVID-19 Vaccination Strategic Plan to prevent infections by SARS-CoV-2 has been drawn up by the Ministry of Health, the Extraordinary Commissioner for the COVID-19 Emergencies, the Italian National Institute of Health (ISS, Rome), the National Agency for Regional Health Services (Agenas, Rome) and the Italian Medicines Authority (AIFA, Rome). The legislative reference regulating the plan is Law no 178/2020. The Decree issued by the Ministry of Health on 20 March 2021 and the Plan of the special Commissioner published the day after, have actually enacted the aforementioned strategic plan. This plan is based on two documents which are targeted, on the one hand, to fix the main details for preparing the vaccination strategy and, on the other, to issue recommendations concerning target groups, specific categories and priorities. Source: Law no.178/2020 (2020, December 30). *Bilancio di previsione dello Stato per l'anno finanziario 2021 e bilancio pluriennale per il triennio 2021-2023.* (20G00202), Official Gazette. For more details: <https://www.epicentro.iss.it/en/vaccines/covid-19-vaccination-plan>.

[22] The reference is Art.117, paragraph 2, lett.m) of the Italian Constitution which has introduced by Constitutional Law no 3 in 2001 a renewed framework of powers between the regions and the State.

[23] For critical insights on the dynamics that have characterised the relationship between the Italian regions and the State and the adopted measures related to the COVID emergency see: Marchese, C. (2021, January 27). *Il ruolo dello Stato a fronte dell'emergenza pandemica e le risposte elaborate in sede europea: le garanzia dei diritti ed il rilancio economico alla luce del rapporto tra condizionalità e solidarietà,* Rivista AIC, 1.

[24] The national power of "International Prophylaxis' is mentioned in Art. 117 lett q) of the Italian Constitution. For more details: Cassese S. (2021, February 26). *Cambiare la rotta. La lotta alla pandemia è competenza dello Stato*. Corriere della Sera.

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Chapter 13

Teledermatology and Telemedicine:

Expanding the Reach of Medical Consulting Beyond Physical Barriers

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ABSTRACT

Telemedicine is a new branch of medicine exploiting the new communication devices to expand medical services and consultation beyond physical limits. This new significant chapter in medicine will interest every medical area, taking advantage of digital devices that are becoming more complex, reducing the need for the patient's physical presence only to perform analysis or interventions. Teledermatology is a new expanding area in telemedicine, consisting of the ability to resolve skin-related health problems without the physical presence of the patients. Skin diseases represent a significant source of morbidity and a minor source of mortality worldwide. In this chapter, the authors analyze how telemedicine and teledermatology developed, their current use in medicine, and current studies and reviews already present in literature. Also, future possible prospects and developments of these techniques will be analyzed.

INTRODUCTION

Information and telecommunications technologies have radically revolutionized the daily activities of millions of people, contributing to the improvement of life quality and work in the most varied fields. One of the sectors that have drawn the most significant benefits, particularly from the synergy between information technology and biomedicine, is health. Thanks to these new technologies, it was possible to initiate a concrete process of renewal and rationalization aimed at overall improving the quality of the system itself (Hjelm NM.,2005).

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The World Health Organization has defined telemedicine as follows: “The delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communication technologies for diagnosis, treatment and prevention of diseases and injuries, research and evaluation, and for the continuing education of healthcare providers. All in the interest of advancing the health of individuals and their communities”. Various areas of medicine have been interested in this new method of visiting patients.

The birth of telemedicine fits into this context to conceive the activity of the doctor who, thanks to the help of technologies, manages to control and monitor patients without their physical presence; in this way, it is possible to optimize time and resources, as well as favoring weaker groups of patients, in particular the elderly, for whom it becomes problematic to move to perform hospital checks.

At present, it is not possible to give an unambiguous definition of the term telemedicine, especially in consideration of the fact that discipline is constantly evolving, parallel to the progress made by information technologies; A fairly comprehensive definition was provided by the experts of the

European Commission in 2008 for which telemedicine is ” ‘the provision of healthcare services, through the use of ICT, in situations where the health professional and the patient (or two health professionals) are not in the same location. It involves the secure transmission of medical data and information, through text, sound, images or other forms needed for the prevention, diagnosis, treatment, and follow-up of patients” (Nikus et al. 2011). In addition, in 1997 the World Health Organization also described telemedicine as “delivery health care, when distance is critical, from part of health workers; for this purpose, computer technologies are used and telecommunications for the exchange of correct information for the diagnosis, the therapy, the prevention of pathologies, for the permanent education of operators health and research and study in all sectors of interest for improving the state of health of the individual and the community “.

Ultimately, it is clear from all this that telemedicine always involves the provision of a health service and always places at the center the patient and the assistance he needs; It is therefore not a new medical specialty, but of a modality that uses the tools made available by new technologies to improve health performance while retaining the implications of any medical procedure from a professional point of view, ethical and legal. In this sense, implying the mediation of audiovisual communication systems in the doctor-patient relationship, telemedicine involves the complete computerization and integration of all hospital activities’ be they clinical but also administrative and managerial (Ekeland et al.2010).

However, telemedicine must not distort the physician figure and the relationship with the patient; it must contribute to maintaining the interpersonal relationship established in the therapeutic act intact. Therefore, attention to non-verbal language, considering the patient as a person rather than as a sick person, and interpersonal relationship must be guaranteed by the physician, especially when communicating a diagnosis or deciding on a therapy. However, it should be noted that telemedicine has a considerable value, especially from a psychological point of view for the patient and his family. A concrete example is given by the practice of the so-called homecare in which, thanks to remote assistance, it is possible to establish a direct connection between the patient and his family and the hospital that is treating him; continuous monitoring carried out remotely by medical personnel, it allows the sick person to feel safe even in his own home, with the advantage of enjoying the proximity of loved ones. This is an example of the “positive” application of technology to medicine; nevertheless, it is necessary to be vigilant in using these tools. (Sica et al.2010)The general issues that revolve around telemedicine do not concern only the medical field; there is, in fact, another delicate problem that affects a broader sector, namely that of information technology applications and their accessibility. If widespread diffusion use of new

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technologies in the field of medicine is the goal, it is necessary to guarantee the complete accessibility to IT tools for the most significant number of people possible. This lack of accessibility could lead to the risk of serious discrimination among those with easy access to these tools and those to whom economic or social reasons deny this access. Therefore, it is necessary to encourage training health professionals who will be involved in the application of telemedicine and train and inform users and render telemedicine as accessible as possible (Rutledge et al.2017).

HISTORY OF TELEMEDICINE

The idea behind telemedicine has its roots in a period where it was not yet possible to speak of telecommunications networks in the meaning we are used today; shortly after the invention of the telephone, in fact, the first tests of transmission of the "sounds" of heart and lungs took place, as physicians who could examine the state of the organs through "listening."

The first attempts at what we could consider an early telemedicine date back to the early 1900s. In 1906 Willem Einthoven, one of the fathers of electrocardiography, was the first to study an electrocardiogram transmitted over the telephone line; in 1920, in the United States, groups of doctors were hired for radio healthcare to the ships when they had medical emergencies; in 1955, the Nebraska Psychiatric Institute started experimentation, through a connection that used a closed television circuit to carry out consultations between specialists and for didactic purposes; the same system was also used to carry out group therapies (Hanach et al.2021).

In 1967, a diagnostic station was installed at Boston's Logan Airport, thanks to which the doctors who passed through the airport had the possibility of video transmit radiographic images of their patients directly at the Massachusetts General Hospital. In 1971 satellite transmission was used for the first time; experimentations concerned the state of Alaska, where satellites were installed in four different locations.

These devices allowed the transmission and reception of data on black and white televisions, while at Anchorages Alaska Native Medical Center, a television was installed in receiving mode. In this way, it is possible to verify how much and how an advanced and reliable communication system could improve medical care within a challenging area to reach. In the following years, telemedicine has played an important role too in international emergencies representing, in many cases, the means to overcome not only physical but also political, social, and economic distances; An example is the case of the devastating earthquake that struck Armenia in 1988 and which saw collaboration, precisely through telemedicine, between the United States and the Soviet Union (Bashur et al. 2016).

From the 1980s onwards, thanks to the digitization of communication systems, it was possible to integrate telecommunications with the computer allowing, in this way, the transmission of a more significant amount of data; simultaneous transmission of video, voice, and data became possible. Nevertheless, the real innovation of recent years is represented by the advent of the Internet, which paved the way for global communication; thanks to the network, it is now possible to record and send vast amounts of data, images, and audio to allow a sharing that overcomes the objective difficulty of distance. The change is undoubtedly revolutionary since it allows access to data to a virtually unlimited number of people simultaneously, with a radical reduction in costs compared to the past. Thanks to this one innovation, telemedicine has passed the experimentation phase to take root more and more in everyday life by modifying and improving the socio-sanitary system(Clark et al.2010). As for Italy, the first experiences of signal transmission biomedical were carried out in 1970 by the Faculty of Medicine of "La Sapienza

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University" of Rome, which launched experimentation for a prototype of Cardiotelephone. One of the first and most interesting experiments carried out was that of Marconi Foundation of Bologna, which, in 1976, initiated the practice of tele-electrocardiographic examinations through switched telephone lines, thanks to which the electrocardiogram could be performed at the patient's home, in the absence of the specialist, and directly detected by the hospital. Since then, Italy has shown to be at the forefront of design and experimentation innovative solutions for telemedicine; however, such solutions have not always had a concrete realization. The most widespread experiences are those relating to home care to patients suffering from particular pathologies (for example, diabetes) to counseling radiology for hospitals in particularly disadvantaged areas. Ultimately, it can be said that Italy is undoubtedly in the vanguard regarding scientific and technological skills (both in the medical field and computer science), and telemedicine has reached a good level of development; likewise, it is necessary to deal with the difficulties of its more widespread diffusion about the shortcomings, primarily related to the low investments in the sector, which prevent a definitive and lasting affirmation.(Sica et al.2010)

THE SPREAD OF TELEMEDICINE

Telemedicine constitutes a fundamental support to the clinical activity of doctors through the creation of digital files and the possibility of teleconsultations as well as administration, through the creation of systems for accounting, and the management of personnel and resources. The main sectors that have enjoyed the development and continuous affirmation of telemedicine are the diagnostic, the consultative, and the formative ones. In the diagnostic field, the application of telemedicine allows to carry out the remote diagnosis in real-time, creating a synergy between the caregiver and the expert on the subject: the first is concerned with transmitting electronically to the expert all the information relating to the patient, to allow him to integrate them and develop a complete diagnosis. In a consultative context, the possibility to hold "virtual" between doctors meetings becomes concrete, with the not insignificant advantage of not necessarily having to move patients and the documentation concerning them (with a consequent cost reduction); this also entails greater timeliness assistance, as well as the interaction between professionals with different skills, a decisive element in the elaboration of a diagnosis, and of a consequent therapy. In the training field, the tangible advantage is represented by the constant updating of health professionals, who can discuss and deepen particular clinical cases through a multidisciplinary comparison or the search for helpful information and bibliographies on a specific topic.

In the context of home care, the advantages are, clearly, more significant for the patient, who can benefit from adequate treatments in their own home instead of the hospital; this entails, first of all, an improvement in the psychological conditions of the patient who can, in this way, enjoy the closeness and support of family members (Ekeland et al.2010).

The spread of telemedicine is now a fact: the more frequent use of new technologies will bring undeniable benefits to health system management. In particular, there will be significant advantages for the elderly, as these technologies will simplify their lives by avoiding unnecessary movements for simple checks, allowing them to contact the doctor or a specialist unit at any time, with the certainty of being followed 24 hours a day. One of the difficulties faced with telemedicine, however, is the lack of knowledge of modern technologies by the older population: the use of touch screen mobile phones and the habit of using e-mail are not, to this day, particularly widespread, in the age groups to which telemedicine could be proposed. We, therefore, find ourselves having to analyze the pros and cons of

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this new methodology (Sica et al.2010). While technology simplifies medical procedures, on the other hand, it can generate in the patient a feeling of loneliness, as it comes to the lack of human relationship with the trusted doctor. In the increasingly frequent condition of isolation in which older adults live today, the doctor's visit constitutes an opportunity for novelty which ends up covering an amount of time much longer time than the actual visit. The elderly use to prepare in time for any event, and this keeps them busy and active for a long time, constituting a diversion, removing the boredom of everyday life (Ekeland et al.2010). Another field in which the lights and shadows of telemedicine are highlighted is that pediatric medicine where, for example, the transmission of the results of clinical analyzes by e-mail constitutes an undoubted advantage, especially for those patients who live far away from the centers of excellence to which they are necessarily aggregated. However, we do not have to forget that these little ones suffer from loneliness, as their clinical conditions tend to isolate them (Burke,2015). They may lack outdoor activities and contact with other children. Inside the hospital, on the other hand, it seems strange to say, the social activity carried out by doctors, psychologists, and various associations constitutes a very advantageous element. Once they arrive at the hospital for routine checks, children have the opportunity to meet other children with the same problems, have teachers at their disposal, and animators who can make their expectations more pleasant (Ellis and Russel, 2019).

Families also form natural self-help groups; they support each other by creating a very dense network of relationships and information exchange, which often are helpful in diagnosing the patient's condition.

It is, therefore, necessary to strive to make everything as intuitive and straightforward as possible to be able to convey to patients the certainty of being able, at any time and everywhere, to receive and transmit information through the many systems that technology puts and makes available to us (Scott Kruse et al.2018).

TRADITIONAL APPLICATIONS OF TELEMEDICINE

Among telemedicine's traditional clinical applications, we point out teleradiology, telepathology, teleconsultation, telecardiology, telemonitoring, teleassistance, and virtual hospitalization.

Teleradiology allows remote transmission and analysis of diagnostic images (X-ray, CT, MRI) acquired through a camera or scanned and transmitted in digital form (Hannah et al.2020). The purpose of the transmission may be, as already mentioned, to favor the comparison between doctors for the elaboration of a diagnosis or even create suitable supports for the training of specialized personnel. Images must be scanned directly into digital form and stored in DICOM1 format, in such a way as to allow an effective interchange between the equipment of the central system and those remotely located; the resolution of the images must also necessarily be suitable for their clinical use. The pictures managed in a teleradiology system can be classified in small and large matrix images based on the definition. The image file must include the data at the time of acquisition, patient identifiers (surname, first name, gender, date of birth, patient ID) and the methods of image generation (date and time of acquisition, examination, compression). Another criterion for establishing the validity and efficiency of a teleradiology system is transmission time: the transmission speed of the images is fundamental, in fact, for timely processing diagnosis and the consequent provision of adequate therapy. The transmission network must be equipped with self-test and self-monitoring that guarantee the arrival at the recipient of intact files regarding the image and associated data. On the workstation of the transmitting site, information about the successful sending of the image must be present or about any transmission problems that may have occurred.

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As for displaying images, you need to prepare a reporting workstation with dedicated display devices that use high-definition monitors. All the operations we have described require qualified personnel for an optimal realization. The radiologist in charge must maintain the central role by acquiring the technical knowledge necessary and, above all, managing and coordinating since the setting of the entire teleradiology process, with the primary objective of ensuring to users, first of all, and to all the professionals involved, the principal possible guarantees (Bashshur,et al. 2016). The compilation of the report, which has medico-legal value, remains indispensable, representing the final moment of the clinical, radiological act where the radiologist specialist responds, as far as possible, to all diagnostic questions posed by the prescribing doctor thus expressing his physician evaluation (Ekeland et al.2010).

Telepathology makes it possible to remotely observe and analyze samples of tissues in particular cases, allowing pathologists to examine them without being physically present in the hospital with timeliness essential for patient care. Histological preparation is carried out on-site in a peripheral hospital and subsequently remotely managed by specialists from a central hospital, thanks to an appropriate microscope: a typical case of application is the removal of tissue for histological examination during surgery (Farahani & Pantanowitz, 2015). Thanks to a cable connection, the operating room has the possibility to establish direct contact with the pathologist, and the histological slide to be examined is placed on a motorized microscope which is directly connected to the computer of the pathologist who carried out the examination. The pathologist can handle the microscope remotely in perfect autonomy, choosing the methods of analysis of the image, using all the tools in his possession to dissect it or enlarge it. In this way, it will be possible to quickly answer a surgeon who is waiting to decide on the most appropriate procedure for the operation to be performed (Lesher,& Shah,2018).

Teleconsultation is a system that uses the remote connection to ask a specialist's opinion in a particular sector through the exchange of data and images if you are faced with a particular case difficult to frame from a diagnostic and therapeutic point of view. Doctors can exchange clinical data, images X-rays, patient news, lab test results, and all that allows them to have a clinical picture as complete as possible for the formulation of a diagnosis and consequent therapy (Davarpanah et al. 2020).

The teleconsultation can take place strictly between doctors specialists and not, but it can also foresee the direct involvement of the patient. In the first case, the involved professionals share all material concerning the patient simultaneously and in real-time; in the second, instead, there is the need, from the doctors, to directly evaluate the patient that is involved for a direct and real-time evaluation of some particular attitudes or clinical aspects that necessarily require its presence. Ultimately, teleconsultation offers the possibility of a multidisciplinary approach which, by exploiting the different skills and professionalism, can lead to the optimal solution of a specific clinical case (Lupton & Maslen, 2017).

Telecardiology is based on a digital system consisting of an apparatus for transmission and managing and processing the layouts. The first consists of a numeric electrocardiograph with interpretative software capable of storing ECG traces. The main field of use of telecardiology is that of

Cardiological emergencies, in which timeliness is crucial for the intervention of the specialist and the development of an adequate therapy; just think that not all assistance centers can avail themselves of cardiological assistance in loco 24 hours a day, in addition to the fact that there are particular situations (medical guards, isolated units, private nursing homes) who can count on the sporadic presence of specialists, often difficult to trace, with consequent considerable delays in therapeutic intervention.

The telecardiology service is centered on a Cardiology center, where a cardiologist is present 24 hours a day to answer all requests for advice; the peripheral units, equipped with transmitting equipment, represent the service branches, widespread throughout the territory and guarantee users direct

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assistance. In addition to the management of cardiological emergencies, it is possible to carry out a constant control of the categories at risk and an effective prevention of all heart-related pathologies to the benefit, above all, of those who have no apparent symptoms or do not know they sick(Molinari et al.2018). Telemonitoring is a modality by which assistance is sought in decentralized structures compared to hospitals, preserving an adequate, if not higher, quality standard of the service offered. This type of assistance is essentially based on the efficiency of communication at a distance between clients and service centers: only in this case is it possible to guarantee a remote intervention that is as effective as possible in the resolution of cases that arise from time to time. The monitoring process consists of three fundamental moments: collection and sending of clinically significant signals by the patients to the assistance centers; acquisition, analysis, and evaluation of this data by the assistance centers; implementation of interventions in different ways according to the cases. Here are some of the possible examples of telemonitoring: cardiac telemonitoring: cardiac activity is continuously recorded thanks to portable equipment; subsequently, the data comes sent, through the network, to a center where they are analyzed and processed. From this analysis, information on the patient's cardiac activity is essential for the timely processing of diagnosis and therapy.

Telemonitoring of dialysis: clinical data, together with statistical data (obtained with automated management systems of the entire dialysis center such as medical records, programming cards, statistical processing) come addressed to a specialized management center that takes care of their processing, as well as general control of operations; wherever there were problems during a home dialysis session, even in relation with an equipment malfunction, it is possible to intervene timely.

Telemonitoring of diabetics: the pharmacological treatment of diabetes is essentially based on the administration of oral antidiabetic agents and/or insulin; the efficacy of therapy is assessed by monitoring the blood glucose, which is an additional parameter for personalizing therapy itself. Automatic systems allow insulin infusion continuously, starting from the glycemic rate, regulating its delivery speed; these devices can store in a memory the glucose value with the relative time indication. These values can then be sent to a remote specialized center, using a computer and a telecommunication system, along with any comments entered directly by the patient; the medical staff, in this way, remotely follow the patient.

Perinatal telemonitoring: allows monitoring of the fetal heartbeat and uterine contractions; It is possible to periodically check the data collected through scheduled calls, allowing immediate intervention in case of fetal distress or incipient birth (van den Heuvel et al. 2018).

Teleservice is to be considered a tool for integrating house services if coordinated with other social and health services in the area. In fact, the home service, privileging material interventions towards assisted, is inadequate due to the chronic shortage of staff compared to the mass of users in need of assistance, which is expressed, in the end, for the benefit only of a small part of the population. Teleservice, therefore, includes a set of services aimed at a large catchment area, with the purpose to optimally define what we have defined as homecare.

An indispensable premise for the realization of this service is the creation of a remote assistance center capable of implementing every possible initiative so that the subject can heal himself while remaining in his own environment, aware of receiving adequate assistance (Andrès et al. 2019).

The virtual hospitalization follows this same path. The hospital has integrated human and instrumental resources, which can also be used in reducing access times; no guarantee of a quality of performance is always obtainable otherwise. However, hospital admission presents some primary defects: the cost of hospitalization, the cost from lack of work activity, and psychological-affective problems related to hospitalization (Sica et al.2010).

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Home telemonitoring reduces hospitalization and improves the quality of life, integrating with post-hospital home care. Therefore, technologies offer an opportunity that also allows for improvement in the assistance quality: the virtual hospitalization at home. Part of hospital admissions can be accomplished "virtually" by assisting the patient electronically at his home or at the place of work. Technological innovation offers the opportunity to improve the quality of care, offering the patient the virtual hospital at their own domicile. This solution allows an improvement in quality assistance because treatment continuity is ensured even when the patient is unable to reach the hospital (physical impossibility, work, family accompaniment), further decreasing the social costs, both for the patient if a worker and for the family members, and reduce the inconvenience due to the movement of sick and disabled people. The main areas of interest for the first application of virtual hospitalization are oncology, surgery, and chronic diseases (e.g., heart disease, diabetes, etc.). The subjects involved in the delivery of the care performed during the virtual hospitalization are, first of all, the patient (object of treatment); the person in charge of the treatment (a doctor, a team of doctors) who follows the whole patient care process; the one who materially provides the cure (the responsible for the treatment, a specialist doctor, a nurse, sometimes the patient himself, a relative of the patient) who carries out the diagnostic and therapeutic activities and rehabilitation; the specialist doctor (a doctor, a team of doctors) who provides its skills in evaluating the results of the diagnostic tests, in the definition of the diagnostic and therapeutic protocol.

TELEMEDICINE DURING COVID TIMES

The SarsCov2 virus pandemic has given an enormous acceleration to the spread of telemedicine in territorial assistance.

In times of Covid-19, many patients will undoubtedly have benefited from telemedicine, avoiding reaching primary care clinics, with a high risk of overcrowding. However, like other home monitoring tools, access to telemedicine seems not to be available to all patients, leading to inequality in care and significant health discrepancies (Chowdhury et al. 2021). On this topic, the studies published so far report contrasting results. The cross-sectional study by Alexander et al., conducted in different areas of the United States, reported similar access to telemedicine services between African Americans and Caucasians. Controversially, the results of the study by Thronson et al., suggest a history of differential access to virtual health care. Specifically, the authors report low rates of telemedicine in clinics that care for homeless patients and those with little knowledge of the English language. The most common barrier to access is represented by the absence of the needed technology at the patient's home. These observations were also reported by Nouri et al, who showed in their study how patients with low socio-economic status accessed significantly less to telemedicine. The lowest rates of access to virtual visits were observed in African American patients, in older people, in people with little knowledge of English and without insurance (Combi et al.2016).

An essential element that must be considered to understand the results of telemedicine studies better is represented by the type of visits. Although the term 'telemedicine is often used in a generic way to describe the treatments performed, whether by telephone or with audiovisual technology, it is essential to highlight how these two modalities have very different implications (Baker, & Stanley,2018). The centers that provide Medicare and Medicaid services specify that to make a virtual visit, an interactive audio-video telecommunications system must be used. It appears evident that, in this definition, visits made only by telephone are not included. Therefore, patients who do not have an internet connection

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are excluded from the opportunity to be visited remotely; the only possibility remains for them to go personally to the clinic, with all the risks and expenses that this could entail. The selection of patients to be visited remotely must then be made after a careful assessment and will be agreed with the patient himself, carefully analyzing the risks and benefits of the virtual visit, without forgetting to provide as much patient-centered assistance as possible (Hare, et al 2020). Therefore, it will be necessary to aim for a hybrid model, in which the increase of remote visits can preserve a safer physical space for patients unable to take advantage of telemedicine. A significant policy change is needed to achieve this, considering that access to digital services is essential not only for health care but also for education, housing, employment, and other social services, such as food delivery in communities with covid-19 outbreaks. Health systems, local governments, telecommunications companies, schools, and philanthropic organizations must all work together to counter this unfair access to resources by providing broadband connections and compatible devices via the internet to the most disadvantaged patients.

TELEDERMATOLOGY: CURRENT USES AND FUTURE PERSPECTIVES

Telemedicine is one of the recent advances in modern telemedicine, allowing dermatologists to diagnose and cure patients remotely. This technology has been successfully used for consultations, follow-ups visits, and medication prescriptions. However, teledermatology does not allow for appropriate care in all skin conditions, as videos and photos may not be sufficient to reach a correct diagnosis. Some areas are traditionally more prone not to have a physician always present near the patients during consultations (such as radiology or nuclear medicine). Other branches are becoming more and more reliant on this new technique during the Covid pandemic (such as internal medicine, pneumology, etc.….). One in four people who consult a general practitioner or a family medicine practice do so for illnesses related to the skin and its appendages, such as hair and nails. Among all skin diseases, melanoma is one of the leading causes of mortality, and basal cell carcinoma is the primary cause of morbidity, with an increasing incidence. It is estimated that 3 out of 4 cutaneous neoplasms are basal cell carcinomas. The progressive aging of the population, excessive exposure to radiation, ultraviolet light, and immunosuppressive treatments are some of the various factors contributing to this phenomenon’s growth. Telemedicine in dermatology is similar to an outpatient visit, except that a mobile phone, tablet, or PC can be used to communicate with a dermatologist in the comfort and safety of home.

This visit modality will probably gradually become part of our lives even if a live doctor-patient relationship is always preferred and preferable. Various cutaneous diseases can be diagnosed and managed with this new technique, as all inflammatory dermatoses are usually chronic conditions not necessitating particular invasive procedures.

Teledermatology may be practically divided into two sub-branches: store-and-forward and synchronous teledermatology. Store-and-forward refers to the practice of sending images of skin lesions to dermatologists for evaluation. Synchronous teledermatology refers to live-stream virtual appointments.

Various studies suggest that physicians using store-and-forward teledermatology may obtain more accurate diagnoses than routine visits due to the possibility of second and third opinions(Lee et al. 2018). A comprehensive study in 2011 in the US delineated many of the potential uses and drawbacks of teledermatology. Digital programs were introduced to fit the demand for skincare. There are, however, several problems related to teledermatology. Traditionally, one of the critical barriers was the visit cost, which some patients considered too high, given the physical absence of the doctor in the location, although

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after COVID-19 this is a problem no more, given the need of using a teledermatology system. Other problems related to teledermatology and telemedicine, in general, are network connectivity, which may be a problem in remote areas with no or slow internet connection, the presence of technological devices, as smartphone and computer devices may be expensive and not available for everyone and communication issues, as it may be harder to communicate with patients without the physical presence(McKoy et al.2016) . Teledermatology may be used as an effective tool to manage common dermatological conditions such as acne, atopic dermatitis, bullous diseases, cutaneous infections, connective tissue disorders, wounds, vitiligo, psoriasis, and ulcers (Beer et al.2021).

Atopic Dermatitis

Atopic dermatitis (AD) is a pruritic, chronic and inflammatory skin disease, with an usual onset in the pediatric age. Several drugs are used in the treatment of this skin disease(Dattola et al.2019,Nettis et al.2020) . Telemedicine has been consistently shown to be effective in managing atopic dermatitis. In 2015, a research group compared telemedicine with face visits in a randomized clinical trial of 156 adults and children affected by atopic dermatitis. Each patient performed a live visit as the initial one. After that, half attended follow-ups in person with a dermatologist every two months for a year.

The other half regularly send pictures of their skin to a dermatologist prescribing treatments remotely. The researchers measured eczema's severity among all the patients at the beginning of the study and each follow-up visit using standardized scoring systems. Results showed no statistical difference between groups. Further subsequent studies showed no difference in atopic dermatitis outcome (Armstrong et al.2015)

Acne

Telemedicine has also been used to diagnose and monitor acne patients. In a randomized controlled trial evaluating isotretinoin therapy in 69 patients affected by severe acne, follow-up was performed either with face-to-face visits at 4-week intervals or telemedicine appointments every two weeks for twenty-four weeks, with no difference in patient's cosmetic outcome (Khosraviet al.2020)

Skin Tumors

Teledermatology has also been proposed in the management of pigmented and non-pigmented cutaneous lesions, with the use in loco of a dermoscopic device by a non-specialized healthcare provider that may send the images to a trained dermatologist in order to have dermoscopic diagnosis. This sub-branch of teledermatology, called teledermoscopy, is a growing area that allows the diagnosis of complex cutaneous malignancies without the presence in loco of a dermatologist, reducing the cost for both the patients and the physician and allowing the presence of a complex consultation with the presence in loco of a small dermatoscope.

In Italy and all around the world, various healthcare-associated facilities, such as pharmacies, aesthetic studies, etc., propose this kind of service in order to speed up the teledermatology and telemedicine brings to the plate the considerable advantage of not having a physician and the patient in the same place, reducing the costs of mobility, and expanding the reach for medical consultations, where some kind of medical assistance may not be traditionally present.

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Many patients in the world have no access to dermatological consultations, and skin cancers and cutaneous inflammatory conditions are becoming more frequent. The human eye easily sees skin disorders in the majority of cases, so imaging technologies can accurately capture them. The average waiting time for a dermatologist varies from 20 to 70 days, and also patients reporting changes in growth or in the color of a melanocytic lesion, which may be considered the first sign of melanoma, may found difficulties in having a dermatologic visit in a short time.

Psoriasis

Psoriasis is an inflammatory and chronic skin disorder associated with physical and psychological burden impairing patients' quality of life (Dattola et al.2020, Dattola et al.2020, Passante et al.2020). In the last decade, biologic drugs have widely changed treatment of moderate-severe psoriasis and other conditions, such as inflammatory bowel disorders, their number is increasing overtime (Iannone et al.2020, Roberti et al.2020). To monitor condition and the administration of systemic and biologic drugs, also psoriasis can benefit from telemedicine, with studies proposing this method of the patient-physician relationship as early as 2010. Following studies increased the number of patients involved, with a 2018 study involving almost 300 participants, confirming previous results (Armstrong et al.2018).

Despite its successful implementation in various dermatologic conditions, teledermatology had contradictory results in managing melanocytic lesions, particularly when involving skin cancers, although patients reported a high satisfaction rate, especially younger people. However, current recommendations indicate that potentially malignant lesions should require a face-to-face visit due to the lack of evidence of teledermatology. Teledermoscopy, which involves using a dermatoscope in the diagnosis of melanocytic nevi, seems to increase the diagnostic accuracy of the typical teledermatologic visit (Uppal et al.2021).

TELEDERMATOLOGY: FIRST STUDIES

Teledermoscopy is a branch of teledermatology, and recently, several studies have demonstrated its effectiveness in the remote diagnosis of skin pigmented lesions. In 1999, a teledermoscopic study via the internet between the centers of L'Aquila (Italy) and Graz (Austria), demonstrated an excellent level of concordance between the diagnosis made directly on the patient (L'Aquila) and the diagnosis on images in television (Graz, Austria).

In 2000, a subsequent multicenter international study conducted by the same group confirmed the previous results, highlighting the importance of remote diagnosis only by dermatologists who are truly experts in dermoscopy (Piccolo et al.2000)

Teledermoscopy is a promising technique for melanoma screening and pigmented skin lesion diagnosis and management. The feasibility of teledermatology and teledermoscopy has recently been tested. These new treatment methods can become a tool easily applicable by all dermatologists and open the door to new flexible triage systems for the identification of skin cancer in general and melanoma in particular. The improvement of virtual imaging systems for teledermatology has made it possible to avoid the limitations imposed by conventional photography. Finally, web consultations in the field of dermatology are a relatively new tool, and also many other possibilities may also be offered to doctors, such as continuing education in medicine, availability of atlases and online databases and specific web applications.

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TELEDERMATOLOGY IN COVID TIMES

Teledermatology has become the principal method to perform follow up visits and a common method for first visits during COVID times due to low costs, increased efficiency, greater flexibility, and high satisfaction rates of both patients and physicians, allowing dermatologists to provide dermatological care remotely, reducing the risk of COVID-19 to spread in inpatient settings. In addition to minimizing the spread of COVID-19, teledermatology has improved access to clinical care, as the number of dermatologists, especially in rural areas, may be deficient, down to 2 dermatologists per 100.000 residents, expanding medical care (Rismiller et al.2020).

THE FUTURE OF TELEMEDICINE

The development and diffusion of medical informatics and telemedicine seemed to have made substantial changes to the way of conceiving the different professional figures involved in the health system; the development of instrumentation more and more sophisticated could give rise to the “fear” of a progressive and irreversible replacement of professionals with machines or robots perfectly able to carry out their work or, in the specific case of telemedicine, of a clear and definitive separation between doctors and patients, both hidden behind a computer. In reality, health workers are always “present,” in constant contact with their clients, to analyze their state of health, develop a correct diagnosis and decide on the most appropriate therapy to follow. In this scenario so technologically advanced, therefore, the doctors and all the operators involved in health care not only are not replaced in any way by the machines, but they will be hit by specific and, perhaps, more significant responsibility towards patients; the changes will concern, in fact, both the different professionals involved and the methods of approach with the assisted ones. Concerning this aspect, for example, it is necessary to pay constant attention to the patient’s attitude towards this new type of assistance; it will be necessary to infuse it with an ever-increasing trust so that he is perfectly aware and safe at all times, even though he lacks direct human contact with the health professionals.

Therefore, there is the need to train professional figures capable of transmitting safety to the sick and offer them adequate support in an environment that, having become “virtual, ” risks initiating complex depersonalization processes with potentially devastating psychological consequences. Changes will also affect professionals even in the strictest sense. In addition, new professional figures will have to be added to those more closely related to the medical field. It will be necessary to train technical personnel capable of providing technical information for the socio-health system, capable of acting as an effective interface with the system of suppliers of products and services, capable of participating and providing valid contributions to both the design and renovation of health structures, both in the management and in the maintenance of the technological apparatus (Sica et al.2010).

In addition to the increasingly specialized technical staff, experts will be involved in Psychology to improve the quality of communication and to understand the needs of the sick; in Sociology, to carry out monitoring on the territory and elaborate the network of interventions; in Economics, to quantify expenses and rationally manage resources. As for the nursing and paramedical staff, it will be necessary to train employees to familiarize them with the new technological equipment and make them more and more active in the psychologic support process to the patient. Information service personnel should also have the skills to understand the patients’ real needs and provide them with the knowledge requests,

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acting as a valid point of reference. With this in mind, services capable of offering information will increasingly be thought of as always complete and reliable, representing a valid help for the patient, both from a functional and practical point of view(Lupton & Maslen, 2017).

CONCLUSION

Examining the technological progress in the field of medicine always emerges one of the main objectives of medical activity is strengthened: improvement of the quality of life. In fact, telematic applications can bring countless advantages, all referable to the goal of making people's lives better, from all points of view such as:

- Cancellation of space-time distances;
- Timeliness of diagnoses and, consequently, of therapies;
- Cost reduction;
- Possibility for the patient to be followed by highly specialized teams;
- Possibility to increase and improve the level of knowledge of all health workers.

Telemedicine, therefore, designed to improve the quality of life must be considered ethically valid because it is oriented towards the patient who is considered, first of all, a person. It is not an alternative to traditional medicine, but it becomes a valid support, thanks to the enormous contribution and facilitations it offers to the work of the doctor and of every subject involved.

In health workers, there is generally a solid will to expand their skills in the field of telemedicine as it is unanimously recognized that new technologies, and more generally telemedicine, will have an ever more significant socio-economic impact in our society in the medium and long term. However, there is no lack of doubts and distrust that may be easily overcomed through a more appropriate cultural approach, which contribute to bringing telemedicine into daily clinical practice; such an approach can be achieved through a continuous training process and qualification of health personnel. In parallel, these same experiences have shown that there are various types of defects, related to technological problems (in the past telephone lines not satisfactory, today the lack of adequate standards, etc.), to the shortcomings of the industrial world (such as the insufficiency of the sales network, the lack of knowledge of products), the shortcomings of public structures (the slowness of bureaucracy, late payments, etc.), the shortcomings of the health directorates (low investments to introduce technologies, non-evidence of benefits, etc.), cultural problems (a certain conservatism of the medical profession, mistrust of operators, inadequate training, etc.). To obviate such defects, the research system must take into account several aspects:

- -from the point of view of research it is necessary to start projects and experiments that lead to the creation of innovative applications but that hold always taking into account the real needs of users;
- -from the point of view of the formulation of scenarios, studies on evolution must be initiated of the sector, to have valid points of reference for the choices and priorities;
- -from the point of view of infrastructures, it is necessary to prepare the mechanisms for an even more effective participation of health workers and of patients (and their associations) to the construction of a network of technologies and skills (think, for example, of a transplant network);

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- -from the point of view of training and professional updating is necessary to always maintain a high standard of the cultural level of the operators in the telemedicine sector. This implies that in the future scenarios of telemedicine, reference should be made to all the following subjects:
    - Users of health services;
    - Health care providers (doctors, nurses, etc.) and at the level hospital, both distributed throughout the territory and cooperating with the hospital (doctor basic or private, polyclinics, analysis laboratories);
    - Operators in the field of prevention and health education;
    - Training facilities for health personnel (universities, nursing schools,etc.), in particular in relation to hospital training;
    - The control and planning bodies (Ministry of Health, Regional Epidemiological Observatories, Higher Institute of Health, etc.)

Telemedicine, therefore, acts as a support for the reorganization of the Health System contributing, in addition to the aforementioned cost reduction, also to the reduction of the inefficiencies of the structures in which personnel deficiencies occur; as a support to the activity of health professionals, becoming a guarantee of patient's care continuity, thanks to cooperation between different structures located throughout the area; as support to citizens who acquire the possibility to participate more actively in the choice of their own care and greater responsibility towards health(Sica et al.2010).

However, if the application of telemedicine will not come adequately accompanied by a comprehensive review of the health organizations involved, this application will risk turning into an additional cost and resulting in clinical failure.

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Chapter 14

Health Protection and Policies in the Pontificate of Francis

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ABSTRACT

The chapter, through a study of the Encyclicals, Apostolic Exhortations, speeches, and messages of Pope Francis, as well as some documents of the Roman Curia, highlights how the issue of health protection and policies in support of this human right are central to Francis' teaching. The protection must not be a mere statement of principle but the concrete realization of the right to health in a broad way, involving not only the physical well-being of the human person but also requires the protection of the environment of which every man is an integral part.

INTRODUCTION

The *tweet* launched by Pope Francis on 25 October 2018 on the occasion of the Global Conference on Primary Health Care is emblematic and encapsulates the meaning of his entire Magisterium on the issue of health, which the Pope defines as not a consumer good, but a universal right. Francis also highlighted the risk that *"The business model in healthcare, if adopted indiscriminately, instead of optimizing available resources, risks producing human waste"*. Thus, in his programmatic apostolic exhortation, *Evangelii gaudium*, he had vigorously urged rulers and financial power to ensure that there is health care for all citizens. In other words, *"quando la persona malata non viene messa al centro e considerata nella sua dignità, si ingenerano atteggiamenti che possono portare addirittura a speculare sulle disgrazie altrui. E questo è molto grave!" (When the sick person is not placed at the centre and his or her dignity is not considered, attitudes are generated that can even lead to speculation on the misfortunes of others. And this is very serious)* (10 February 2017), the Pope had said. In this lies the basic motive inspiring the Magisterium of Francis, which finds its most recent reference in the Angelus, recited at the Gemelli

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Hospital, last 11 July, in which he launched a strong appeal for the accessibility of a good health service, accessible to all, reminding individuals and States of the importance of effective, free and universal health care: *"In these days of hospitalization, I experienced once again how important is good healthcare that is accessible to all, as there is in Italy and in other countries. Free healthcare, that assures good service, accessible to everyone. This precious benefit must not be lost. It needs to be kept! And for this everyone needs to be committed, because it helps everyone and requires everyone's contribution. In the Church too it happens that at times some healthcare institution, due to poor management, does not do well economically, and the first thought that comes to mind is to sell it. But vocation in the Church, is not to have money; it is to offer service, and service is always freely given. Do not forget this: saving free institutions"*. Of course, even on this issue, while highlighting in the course of this contribution the peculiarities that the Magisterium of Francis offers, it is not difficult to bring out a clear continuity of thought and direction with the Magisterium of the previous Popes, where the theme of health is often linked to that of disease and suffering.

St John Paul II with his Apostolic Letter *Salvifici Doloris* on the Christian meaning of human suffering, of 11 February 1984, and with the establishment of the Pontifical Council for the Pastoral Care of Health Care Workers, we have the first systematic treatment of the theme of human suffering and health, understood in an integral perspective (Taliercio, 2005). In fact, after having described the world of human suffering (chap. II) with its different faces - physical, psychic and moral suffering - and their interdependence, the Pope enters into the fundamental theme: the question of meaning which the mystery of suffering poses (chap. III) in order to suggest how this precious experience of life can be corroborated and made fruitful, in the conviction that there is no direct connection between sin and suffering as a punishment for guilt, as a certain erroneous theology would have us believe. The fundamental answer to such a great mystery is not an idea, a thought of an intellectual nature, but a Person and his experience: Jesus Christ, the Son of God, the One who conquered suffering with Love (chap. IV), taking upon himself the pain of the world and experiencing Himself the drama of suffering to the point of experiencing God's abandonment, in order to redeem man (Moriconi, 2011; Zanotti, 2020). And the man who suffers is a sharer in the sufferings of Christ (chap. V) and can make even his suffering fruitful if he becomes capable of looking at Christ crucified and accepting the "Gospel of suffering" with love and courage in the mysterious, but always loving, design of divine Providence (chap. VI). Like Christ the Good Samaritan, the Church is at the side of people who suffer (Chapter VII).

Also fundamental is the institution of World Day of the Sick by John Paul II on 13 May 1992, for 11 February each year, the feast of Our Lady of Lourdes. The aims of the World Day of the Sick are: to make the people of God, Catholic health care instructions and civil society aware of the need to ensure the best possible care for the sick; to help the sick to appreciate suffering on a human and supernatural level; to involve dioceses, Christian communities and religious families in the health care ministry; to encourage the increasingly valuable commitment of voluntary work; to recall the importance of the spiritual and moral formation of health care workers; to make people understand better the importance of religious assistance alongside the sick (Arice, 2016).

In his magisterial interventions Benedict XVI too has often reflected on the theme of evil, pain, and suffering, emphasising the difficulties but always with a look of great hope for all, and above all recalling the question of meaning posed by the theme of suffering and the decisive and definitive 'answer' found in Christ and his Paschal Mystery. This is what he has done in his encyclicals, particularly in the first two. In the Encyclical *Deus Caritas est* of 25 December 2005, in a rich and comprehensive treatment of charity as an essential dimension of being a Christian, he proposes useful reflections in particular

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for those working in the field of health and care who, having been reached by the love of God in Christ Jesus, are called to be witnesses of his love, with gratuitousness, generosity and competence (Bartolini et al, 2006; Minambres, 2007; Fiorita, 2016). To those who are then engaged in the world of care and who sometimes feel that they are more substitutes for a work that should be done by the public than subjects of evangelisation in their work, the pope reminds us that charity is not a kind of social assistance activity for the Church but belongs to her nature, it is an inalienable expression of her very essence and, consequently, the Church's charitable organisations constitute her *opus proprium*, a task congenial to her, in which she does not collaborate collaterally, but acts as a directly responsible subject, doing what corresponds to her nature (Dalla Torre, 1979; MInambres, 2008). The second encyclical *Spe Salvi* of 30 November 2007 focuses on the theme of health linked to that of suffering, in numbers 35 to 40, in the section bearing the title 'Acting and suffering as places of learning hope'. This is the great Hope, the true and only answer to the question of meaning in the serious trials of life.

THE ENCYCLICALS

A 'global' vision of the right to health emerges in all its centrality in Francis' Encyclical Laudato si' (24 May 2013), which clearly shows that the protection of health 'passes through' the protection of the environment and that there can be no protection of the former without an awareness of the effective protection of the latter (Palladino, 2017). The Pope recalls that there are forms of pollution that affect people on a daily basis and that exposure to air pollutants has a wide range of effects on health, particularly among the poorest, causing millions of premature deaths: *"People take sick, for example, from breathing high levels of smoke from fuels used in cooking or heating. There is also pollution that affects everyone, caused by transport, industrial fumes, substances which contribute to the acidification of soil and water, fertilizers, insecticides, fungicides, herbicides and agrotoxins in general. Technology, which, linked to business interests, is presented as the only way of solving these problems, in fact proves incapable of seeing the mysterious network of relations between things and so sometimes solves one problem only to create others"* (n. 20). Attention is given to the issue of pollution produced by waste, including hazardous waste present in various environments (many of which are non-biodegradable: household and commercial waste, demolition debris, clinical, electronic or industrial waste, highly toxic and radioactive waste), so that the earth seems to be increasingly turning into a huge rubbish dump with bio-accumulation effects in the organisms of the inhabitants and with serious consequences for people's health (De Gregorio, 2016). Even in these cases, notes Francis: *"Frequently no measures are taken until after people's health has been irreversibly affected"* (n. 21). Many cities have become unlivable from a health point of view, not only because of pollution from toxic emissions, but also because of urban chaos, transport problems and visual and noise pollution: *"We were not meant to be inundated by cement, asphalt, glass and metal, and deprived of physical contact with nature"* (n. 44). The theme is taken up again in reference to 'reproductive health' policies, where instead of solving the problems of the poor and thinking of a different world, they simply propose a reduction in the birth rate. The Holy Father states that: *"it must nonetheless be recognized that demographic growth is fully compatible with an integral and shared development"* and blaming population growth - and not the extreme and selective consumerism of some - is a way of not addressing the problems (n. 50). The issue is also explored in the dimension of 'institutional' health: *"If everything is related, then the health of a society's institutions has consequences for the environment and the quality of human life. "Every violation of solidarity and*

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civic friendship harms the environment".[116] In this sense, social ecology is necessarily institutional, and gradually extends to the whole of society, from the primary social group, the family, to the wider local, national and international communities. Within each social stratum, and between them, institutions develop to regulate human relationships. Anything which weakens those institutions has negative consequences, such as injustice, violence and loss of freedom" (n. 142).

In the Encyclical Letter *Fratelli tutti* (3 October 2020), Pope Francis writes in no. 15 that this Encyclical Letter [...] is an addition to the Church's social Magisterium. In reality, integral ecology makes him make a real paradigm shift, broadening and deepening his gaze on the basis of the solicitations that come from reality. It is an exciting new step in the dynamic that has always marked the path of the Church's social doctrine (Spadaro, 2020; Costa et al, 2020). The Encyclical, from the point of view of a broad protection of the human person, highlights (n. 89) how we are still far from a globalisation of the most essential human rights and invites world politics not to neglect to place among its main and inalienable objectives the effective elimination of hunger. The Pope links the issue of health to that of food, pointing out that when financial speculation conditions the price of food, treating it as just another commodity, millions of people suffer and die of hunger: *"So many times, while we immerse ourselves in semantic or ideological discussions, we still let there be brothers and sisters dying of hunger and thirst, homelessness or without access to health care"*. Pope Francis challenges us to take a new leap: we are not only members of the same society or the same human family, but having been created by the same Father, all beings of the universe are united by invisible bonds and form a kind of universal family, a sublime communion that impels us to a sacred, loving and humble respect (n. 189).

APOSTOLIC EXHORTATIONS AND "MOTU PROPRIO"

The issues concerning the right to health are raised in the apostolic exhortations in line with what has already been highlighted in the encyclicals.

In the already mentioned Apostolic Exhortation *Evangelii gaudium* (24 November 2013), Pope Francis points out that humanity is living a historical turning point that can be seen in the progress that is being made in various fields, praising the successes that contribute to the well-being of people, in the field of education, communication and also health (Zanzucchi, 2014). At the same time, however, it is impossible to forget that the majority of men and women in the world live in daily precariousness, with disastrous consequences, with the increase in certain diseases and the increasingly real risk that fear and despair will take hold of the hearts of many people (n. 52). The theme is taken up again in the document, addressing the concern for the "health" of the institutions of civil society and the risk of seeing religion relegated to the secret intimacy of individuals, without any influence on social and national life (Di Iorio, 2015; Fuccillo, 2019; Serra, 2020). Instead, the Pope calls for concrete commitment, for a deep desire to change the world, to transmit values, to leave something better after passing through the earth: *"All Christians, their pastors included, are called to show concern for the building of a better world. This is essential, for the Church's social thought is primarily positive: it offers proposals, it works for change and in this sense it constantly points to the hope born of the loving heart of Jesus Christ"* (n. 183). Finally, the theme is addressed in the context of combating hunger and misery, for all those people *"without land, without shelter, without bread, without health"* and violated in their rights. Seeing their misery, hearing their cries and knowing their suffering, we are shocked to learn that there is enough food for all and that hunger is due to the poor distribution of goods and income (n. 191).

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The theme is explored in greater depth, focusing on the problem of so-called "reproductive health" in the apostolic exhortation on love in the family, *Amoris Laetitia*, (19 March 2016). Francis recalls that the demographic decline, due to an anti-natalist mentality and promoted by global reproductive health policies, not only leads to a situation in which the succession of generations is no longer assured, but also risks leading over time to economic impoverishment and a loss of hope in the future (Milani, 2020). It is true that the right conscience of spouses, when they have been very generous in the transmission of life, can guide them to the decision to limit the number of children for sufficiently serious reasons, but *always* "*for the sake of this dignity of conscience, the Church strongly rejects the forced State intervention in favour of contraception, sterilization and even abortion"* (n. 42). The theme returns, in the dimensions already mentioned, also in the Apostolic Exhortation *Querida Amazonia* (2 February 2020), both in terms of the health of the institutions of Amazonia (Berlingò, 2021), crushed by a culture that poisons the State and its institutions, permeating all social strata, including the indigenous communities (n. 23 and 24), and - in the concept of the "dignity of conscience" - in the concept of the "dignity of the Church" (n. 24). 23 and 24) as well as - in a related concept - on the more general state of "health" of the Amazon that affects the planetary balance, a cry that reaches everyone, so that the interest of a few powerful companies is not put above the good of the Amazon and, therefore, of all humanity (n. 48).

An "integral" development of man, which includes the environment in which man lives (Catta, 2015), understood in the broadest sense, also in consideration of the need to ensure justice, peace and the safeguarding of creation is at the basis of Francis' decision to establish, with the motu proprio *In tutto il suo essere*, the Dicastery for Promoting Integral Human Development in order to implement the Holy See's solicitude also in the specific area of health policies and pastoral care. The Dicastery is competent in matters concerning migration, the needy, the sick and the excluded, the marginalised and the victims of armed conflicts and natural disasters, prisoners, the unemployed and the victims of all forms of slavery and torture. The Commission for Health Care Workers has also been set up within the Dicastery.

Thus, also the new Statute of the Pontifical Academy for Life of 18 October 2016 establishes in art. 6 that the scientific and interdisciplinary activity of the Pontifical Academy for Life shall maintain a close connection with the bodies and institutions through which the Church is present in the world of biomedical sciences, health and health organisations, offering its collaboration to doctors and researchers, including non-Catholic and non-Christian ones, who recognise, as the essential moral foundation of medical science and art, the dignity of man and the inviolability of human life, from conception to natural death, as they are proposed by the Magisterium of the Church.

PONTIFICAL MESSAGES AND SPEECHES

The theme of health has also been taken up several times by Francis in numerous speeches, demonstrating how relevant it is and how close to his heart it is. Focusing on some of the more recent speeches, it is possible, first of all, to recall what Pope Francis said on the occasion of the annual international conference promoted by the then Pontifical Council for Health Pastoral Care (19 November 2015), tracing, starting from the Encyclical *Evangelium vitae*, the constituent elements of the so-called "culture of *salus*": welcome, compassion, understanding and forgiveness. These are attitudes that the Encyclical calls "positive requirements" of the commandment regarding the inviolability of life, and which still today must distinguish the health ministry: they *"range from caring for the life of one's brother (whether a blood brother, someone belonging to the same people, or a foreigner living in the land of Israel) to showing*

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concern for the stranger, even to the point of loving one's enemy" (n. 41). This closeness to the other, to the point of feeling him or her as someone who belongs to me, overcomes - explains Francis - every barrier of nationality, social extraction, religion, and also overcomes that culture in the negative sense according to which, both in rich and poor countries, human beings are accepted or rejected according to utilitarian criteria, in particular of social or economic utility. Again, Francis relates this need to protect health to the assumption of imperative responsibilities towards creation and the 'common home', which belongs to all and is entrusted to the care of all, even for generations to come, as he recalled in *Laudato si'*, inviting us to reflect on how the environmental factor, in its aspects most closely linked to the physical, psychic, spiritual and social health of the person, can also contribute to a new development of the culture of salus, understood also in an integral sense.

In his address to the leaders of the Order of Physicians of Spain and Latin America on 9 June 2016, Francis recalls how true compassion does not marginalise anyone, does not humiliate the person, does not exclude them, and even less does it consider their disappearance as something good. True compassion takes charge, against the triumph of selfishness, of that 'culture of discarding' (Pallottino, 2021) that rejects and despises people who do not meet certain standards of health, beauty and usefulness: *"Health is one of the most precious gifts that everyone desires. In the biblical tradition the close relationship between salvation and health has always been emphasized, as well as their reciprocal and numerous implications. I like to recall the title by which the Fathers of the Church traditionally designated Christ and his salvific works. Christus medicus, Christ the physician. He is the Good Shepherd who looks after the injured sheep and comforts the sick one (cf. Ezek 34:16); He is the Good Samaritan who does not pass by the injured person lying by the roadside, but who, moved to compassion, takes care of and assists him (cf. Lk 10:33-34). The Christian medical tradition has always been inspired by the Parable of the Good Samaritan. It is identifying oneself with the love of the Son of God, who "went about doing good and healing all that were oppressed" (Acts 10:38). How much good it does medical practice to think and feel that the sick person is our neighbour, that he or she is of our same flesh and our same blood, and who in his or her lacerated body reflects the mystery of the flesh of Christ himself! "As you did it to one of the least of these my brethren, you did it to me" (Mt 25:40)".*

In his address to the participants at the meeting promoted by the Charity and Health Commission of the Italian Bishops' Conference on 10 February 2017, the Pope also recalls how the degree of protection of human dignity is directly proportional and connected to the degree of health care. In fact, if there is one sector in which the culture of discarding makes its painful consequences evident, it is precisely the health sector. When the sick person is not placed at the centre and considered in his or her dignity, attitudes are generated which can even lead to speculation on the misfortunes of others. The Pope invites us to be vigilant, especially when the patients are elderly people whose health is severely compromised, if they suffer from serious illnesses that are costly to treat, or are particularly difficult, such as the psychiatrically ill. The business model in healthcare, if adopted indiscriminately, instead of optimising available resources, risks producing human waste. Optimising resources means, on the other hand, using them ethically and with solidarity, and not penalising the most vulnerable (Elefante, 2014; Leozappa, 2019). First place must be given to the inviolable dignity of every human being from the moment of conception until their last breath. It is not only money that should guide political and administrative choices, which are called upon to safeguard the right to health, enshrined in the Italian Constitution and other European and international documents (Dalla Torre, 1995; Alicino, 2011; Toscano, 2018), nor the choices of those who manage healthcare facilities.

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On 8 January 2018, addressing the Diplomatic Corps, Francis affirmed that defending the right to life and physical integrity means, among other things, protecting the right to health of the person and his or her family members, a right that has taken on implications that go beyond the original intentions of the Universal Declaration of Human Rights, which aimed to affirm the right of everyone to have the necessary medical care and social services. In this sense, it hopes that, in the relevant international contexts, efforts will be made to promote, first and foremost, easy access for all to health care and treatment, adopting policies that can guarantee, at affordable prices, the supply of medicines essential for the survival of the poor, without neglecting research and development of treatments which, although not economically relevant to the market, are crucial to saving lives.

Even more incisive on the subject are the words he spoke during his Address to the participants at the IV International Conference on Regenerative Medicine promoted by the Pontifical Council for Culture on 28 April 2018. The Pope recalls how we are increasingly aware that many ills could be avoided if there were greater attention to the lifestyle assumed. It is necessary, for the Pope, first and foremost to "prevent", that is, to have a far-sighted gaze towards the human being and the environment in which he lives; to think of a culture of balance in which all the essential factors - education, physical activity, diet, protection of the environment, observance of the "health codes" derived from religious practices, early and targeted diagnostics, and others - help to live better and with fewer health risks. This, Francis reminds us, is particularly important when thinking of children and young people, who are increasingly exposed to the risks of diseases linked to the radical changes of modern civilisation. Just think of the impact on human health of smoking, alcohol or toxic substances released into the air, water and soil. But this requires global and constant action that cannot be delegated to social and governmental institutions, but demands the commitment of everyone. There is therefore an urgent need to disseminate greater awareness among everyone of the need for a culture of prevention as the first step towards health protection. If we want to prepare the future by ensuring the good of every human person, we must act - concludes Francis - with a sensitivity that is all the greater the more powerful the means at our disposal. This is our responsibility towards each other and towards all living beings. There is therefore a need to reflect on human health in a broader context, considering it not only in relation to scientific research, but also to the ability to preserve and protect the environment and the need to think of everyone, especially those who experience social and cultural hardships that make both the state of health and access to care precarious (Petrini, 2020).

Finally, it is worth mentioning the recent Message addressed by the Pontiff to the National Conference on Mental Health on 14 June 2021, in which Francis hopes that on the one hand the health system for the protection of mental illness will be strengthened, including through support for organisations engaged in scientific research into these pathologies, and on the other hand that associations and voluntary work will be promoted which work alongside the sick and their families, within a framework of integral care for the person. Caring for others is not just a skilled job but a real mission, which is fully realised when scientific knowledge meets the fullness of humanity and is translated into the tenderness that knows how to approach and take others to heart, so as to ensure that the culture of community prevails over the mentality of discarding, according to which greater care and attention is given to those who bring productive benefits to society, forgetting that those who suffer allow the irrepressible beauty of human dignity to shine forth in their wounded lives (Angelelli, Cantelmi & Siracusano, 2018).

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MESSAGES FOR THE WORLD DAY OF THE SICK

It is in 2016 that, for the first time, Francis explicitly addresses the theme of health in a Message for the World Day of the Sick. Commenting on the New Testament episode of Cana in Galilee, he recalls how in that place the distinctive traits of Jesus and his mission emerge, as the One who comes to the aid of those in difficulty and need. And in fact, in his messianic ministry, he will heal many from illness, infirmity and evil spirits, he will give sight to the blind, he will make the lame walk, he will restore health and dignity to lepers, he will raise the dead, and he will announce the good news to the poor. Thus Mary's request, during the wedding banquet, suggested by the Holy Spirit to her maternal heart, brings out not only the messianic power of Jesus, but also his mercy. In the solicitude in the lives of so many people who stand beside the sick and know how to grasp their needs, even the most imperceptible ones, because they look at them with eyes full of love. For those who suffer because of illness, health is asked for in the first place. But, Francis recalls, love animated by faith makes them ask for something greater than physical health: a peace, a serenity of life that starts from the heart and is a gift of God, fruit of the Holy Spirit that the Father never denies to those who ask Him with trust. Also in 2017, Francis returned to the theme of health, believing that the World Day of the Sick could represent precisely the opportunity to find new impetus to contribute to the spread of a culture respectful of life, health and the environment; a renewed impulse to fight for respect for the integrity and dignity of people, including through a correct approach to bioethical issues, the protection of the weakest and care for the environment. In his 2018 Message, the Pope also recalls the Church's commitment, in those countries where health care systems are insufficient or non-existent, to work to offer people as much as possible for health care, to eliminate infant mortality and eradicate some widespread diseases, encouraging Catholic hospitals to avoid the risk of corporatism, which all over the world tries to make health care part of the market, eventually discarding the poor. This is a theme that will be taken up again in 2019 with a call to Catholic healthcare institutions not to fall into corporatism, but to safeguard the care of the person rather than profit: *"We know that health is relational, it depends on interaction with others and needs trust, friendship and solidarity, it is a good that can only be enjoyed 'to the full' if it is shared. The joy of free gift is the Christian's health indicator"* (CEI, 2020). Finally, in his Message of 2021, addressing those suffering the effects of the coronavirus pandemic, Francis emphasises how the experience of coronavirus disease makes one feel vulnerable and, at the same time, innately in need of the other (Santoro, 2020). The condition of creaturality has become even sharper. In fact, when one is ill, uncertainty, fear, and sometimes dismay pervade one's mind and heart; one finds oneself in a situation of powerlessness, because our health does not depend on our own abilities or on our 'struggling'. In addition, there is the institutional reflection that the pandemic has brought to light so many inadequacies in the health systems and deficiencies in the care of the sick. The elderly, the weakest and most vulnerable have not always been guaranteed access to care, and this has not always been done equitably. This depends on political choices, the way resources are administered and the commitment of those in positions of responsibility. Investing resources in the care and assistance of sick people, - says Francis - is a priority linked to the principle that health is a primary common good.

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THE NEW CHARTER FOR HEALTH CARE WORKERS

In February 2017, the New Charter for Health Care Workers was presented in the Vatican, updated 22 years after the publication of the first text (1995). The new document is above all a valuable compendium of doctrine and practice, a text which has therefore been revised and updated in such a way that the themes already addressed in the 1995 Charter are illustrated in more accessible and up-to-date language and contain an update in terms of science and content more generally accompanied by a review of the theological notes of the document (Honings, 1995). From a doctrinal point of view, the New Charter for Health Care Workers reaffirms the sacredness of life and its unavailability as a gift from God. Health care workers are ministers of life insofar as they are its servants, and they are called to love it and accompany it in the existential journey of generating - living - dying, the trinomial theme of the New Charter's Index. The achievements of biomedical research and the new socio-healthcare realities which have emerged since 1994, as well as the aforementioned pronouncements of the Magisterium of the Catholic Church which have been issued in the field of life sciences and health care, have made it necessary to revise and update the Charter of Health Care Workers. However, the Charter has retained its original structure as a tool for the serious preparation and ongoing ethical training of health care workers in order to maintain their due professional competence. First of all, the initial attention was paid to considering a broader spectrum of people involved in the biomedical field: besides the classic health professionals (medical, nursing and auxiliary staff), other figures working in the world of health in various capacities were also considered, such as biologists, pharmacists, community health workers, administrators, legislators in the field of health, operators in the public and private sectors. Some of the new articles are about them, and they are required to have a special responsibility in carrying out their service. All these workers carry out their daily practice in an interpersonal relationship, characterised by the trust of a person marked by suffering and illness, who turns to the science and conscience of a health professional who comes to assist and cure him or her. The Charter is intended to support the ethical fidelity of the health care worker in the choices and behaviours in which the service to life takes shape, and this fidelity is outlined by following the stages of human existence: generating, living, dying, as moments of ethical-pastoral reflection.

In the section on ‘generating’, the criteria for treating infertility have been better specified, as has the reference to natural methods not only for regulating fertility but also as methods of achieving pregnancy. There is also an article on the freezing of ovarian tissue (art. 38), an ethically sustainable response in the case of cancer therapies that may alter a woman's fertility. New attempts at human generation in the laboratory are also taken into consideration (Art. 39): between human and animal gametes, gestation of human embryos in animal or artificial wombs, asexual reproduction of human beings by twin fission, cloning, parthenogenesis or other similar techniques. All these procedures are contrary to the human dignity of the embryo and procreation, and are therefore morally unacceptable. Among the prenatal diagnoses, which are acceptable under certain conditions, pre-implantation diagnosis (Art. 36) is stigmatised as an expression of a eugenic mentality that legitimises selective abortion to prevent the birth of children suffering from various diseases.

The section on “living” confirms the position on abortion as always, with new articles on embryo reduction, interception, contraception, anencephalic foetuses, ectopic pregnancies and protection of the right to life (Art. 51-59). Attention is also paid to the issue of prevention and vaccines, which has been the subject of recent public debate (arts.69-70). The reference to gene therapy and regenerative medicine is topical from a scientific point of view (Art. 80-82). On a social level, the Charter dwells on the issue

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of the population's access to medicines and available technologies (Art. 91), an access that still today, especially in developing countries - especially in those characterised by political instability or scarce economic resources - is not guaranteed to large swathes of the population, especially in the case of the so-called 'rare' and 'neglected' diseases, to which the concept of 'orphan drugs' is applied (Art. 92). And health professionals and their professional associations are asked to promote awareness among institutions, welfare bodies and the health industry so that the right to health protection is extended to the entire population in order to achieve health justice, safeguarding the sustainability of both research and health systems. There are also new references to the involvement in experimentation of minors or adults unable to decide, on vulnerable subjects, on women of childbearing age in emergency situations. Lastly, this section highlights the role of clinical ethics consultancy (Art. 140), which can help to identify conflicts and ethical doubts which individual healthcare workers, patients and family members may experience in clinical practice, thus facilitating their resolution with shared diagnostic and therapeutic choices at the patient's bedside, within the value framework of medicine and ethics.

The section on 'dying' considers the attitude towards the sick person in the terminal phase of the illness, which is the place where the professionalism and ethical responsibilities of healthcare professionals are verified (Art. 145). In this context, a very topical aspect of the Charter - which has been the subject of much debate in the Italian Parliament in recent days - is the reference to the patient's expressing his or her wishes in advance (Art. 150) as to the treatment he or she may wish to undergo in the event that, in the course of his or her illness or as a result of sudden trauma, he or she is no longer able to express consent. The Charter states that the patient's reasonable wishes and legitimate interests must always be respected, but the doctor is not a mere executor, retaining the right and duty to refrain from expressing wishes that differ from his conscience. Equally important is the issue of nutrition and hydration, including artificially administered nutrition and hydration (Art. 152). They are considered to be among the basic treatments due to the dying person, when they are not too burdensome or of any benefit. Their unjustified suspension may have the meaning of a real euthanasia act, but it is compulsory, insofar as and as long as it proves to achieve its own purpose, which is to provide hydration and nourishment to the patient. The ethicality of deep palliative sedation in the phases close to the moment of death is confirmed, implemented according to correct ethical protocols and subject to continuous monitoring. In the background of this section is the protection of the dignity of dying (Art. 149) in the sense of respecting the sick person in the final phase of life, excluding both anticipating death (euthanasia) and prolonging it with so-called 'therapeutic obstinacy' (Flick, 2011). The Charter certainly cannot be exhaustive with regard to all the problems and issues arising in the field of health and illness, but it has been drawn up with the aim of offering the clearest possible guidelines for the ethical problems which have to be addressed in the world of health in general, in harmony with the teachings of Christ and the Magisterium of the Church. The good of the human person and of society is at the heart of the New Charter for Health Care Workers. Indeed, the Church has always perceived service to the sick as "an integral part of her mission", associating "the preaching of the Good News with the care and treatment of the sick". The vast world of services to human suffering 'concerns the good of the human person and of society' itself.

On this subject it is also worth mentioning the recent Letter of the Congregation for the Doctrine of the Faith *Samaritanus bonus* on the care of persons in the critical and terminal phases of life of 22 September 2020 (Ruggieri, 2020). The letter is a 45-page text that contains precise indications on euthanasia, therapeutic obstinacy, basic care such as nutrition and hydration, analgesic therapies, conscientious objection, the role of the family, pastoral accompaniment and the training of health care workers, and in its conclusions notes that "the greatest misery consists in the lack of hope in the face of death". The

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Letter is addressed to the Catholic people in all its forms - legislators, judges, jurists, doctors, nurses, pharmacists, teachers, catechists, priests, parents and the simple faithful - and follows in the wake of numerous previous documents and the Magisterium of the Popes from Pius XII onwards on the subject of "assisted dying" (above all *Evangelium Vitae*, the declaration *Iura et Bona*, the Charter of Health Care Workers, the Instruction *Dignitas personae* and the declaration on artificial nutrition and hydration, and the more recent *Joint Declaration of the Abrahamic monotheistic religions on end-of-life issues*); all the more significant at a time when euthanasia is being widely and uncritically legalised in the name of a misunderstood conception of humanity, medicine and law. The Letter is structured in V paragraphs: Caring for one's neighbour; the living experience of the suffering Christ and the proclamation of hope; the heart that sees of the Samaritan: human life is a sacred and inviolable gift; the cultural obstacles that obscure the sacred value of all life; the teaching of the Magisterium: an articulate paragraph that dwells on issues that are all of great importance: therapeutic abandonment, basic care, palliative care, the role of the family, hospice, vegetative state, conscientious objection, accompaniment, discernment and training (Navarro Valls & Martinez Torron, 1995; Turchi, 2009, 2010). An exhaustive document, characterised by clarity of exposition. The problems and emerging issues touch on and explore theological, anthropological, sociological, juridical, ethical, pastoral and medical questions. Caring for others and their health - as clearly emerges from reading the document - is not only an ethical question but is 'giving to each his own', a legal duty in the strict sense of recognising that each person has his or her due, by virtue of his or her own vulnerability, since in the care relationship there is always a demand for justice in the full recognition of the other. This is an issue that also involves the disciplines of ecclesiastical law and denominational rights. This is in the conviction that the bioethical debate is the fertile ground in which to sow the seeds of intercultural dialogue so that the fruits of people oriented towards meeting, or at least the goodwill to meet, are produced. In the field of bioethics, an articulated system of relations between the political community and ethical-religious groups is increasingly being tried out, and scholars of the religious fact can make a valid contribution to biojuridics because they have always studied how to support and enhance this dynamic relationship of complementarity/distinction between religion and politics, ethics and law, conscience and society, individuality and pluralism, in order to achieve greater areas of freedom and thus to make man more of a person and society more civilized (Dalla Torre, 1993; Sgreccia, 2007; Freni, 2014; Tham, Kwan & Garcia, 2017). This brings us to the heart of the central issue of laicity, or rather of the system of relations between the legal system and ethical demands; a healthy laicity is not opposed to ethics or religiosity; laicity is not an ethic opposed to others or a culture opposed to others, but is the seat of dialogue and respect, the structure of that particular form of State we call pluralist democracy, which does not allow itself to be tempted to use positive law to impose ethics or to translate social practice or the feelings of the majority into norms.

HEALTH AND THE CATHOLIC CHURCH'S COMMITMENT IN TIMES OF PANDEMIC

Finally, it is impossible not to emphasise the Church's commitment to health protection in times of pandemic. Elsewhere it has been stressed that the Catholic Church and other religious denominations, in Italy - as in other parts of the world - have shown a great sense of responsibility by accentuating the limitations imposed by States on the possibility of exercising the right to collective religious freedom and, therefore, to hold public religious functions and rites, with the shared objective of averting the spread

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of the Covid-19 epidemic (Palumbo, 2021). The difficult balancing act between the right to health and the right to religious freedom has been widely discussed by scholars and, although reasonable critical positions have emerged, it is important to recognise that religious denominations, and the Catholic Church in particular, have demonstrated an ability to adapt, while claiming, after the lockdown phase, the right balance between public health needs and the right of the faithful to return to participate in religious services and rites in their presence (Santoro & Fusco, 2020; Fuccillo, Abu Salem & Decimo, 2020; D'Arienzo, 2020; Marcaccio, 2021).

During this phase, the Pope made several significant interventions on the subject of health. The images of the extraordinary moment of prayer in time of pandemic held by Pope Francis in an empty St Peter's Square on 27 March 2020 are still vivid. Invoking the Lady to give health to bodies, Francis pointed out that the "storm" of the pandemic had unmasked the vulnerability of human beings and left uncovered those false and superfluous securities with which people have built projects, habits and priorities: *"In this storm, the façade of those stereotypes with which we camouflaged our egos, always worrying about our image, has fallen away, uncovering once more that (blessed) common belonging, of which we cannot be deprived: our belonging as brothers and sisters"*.

In his video message on 25 September 2020, on the occasion of the 75th session of the United Nations General Assembly, Francis recalled that the pandemic highlighted the urgent need to promote public health and to realise the right of every person to basic health care. In that context, he renewed his appeal to policymakers and the private sector to take appropriate measures to ensure access to vaccines against Covid-19 and the essential technologies needed to care for the sick, giving priority to the poorest, the most vulnerable, those who are generally discriminated against because they have neither power nor economic resources. In his video message of 19 November 2020, Francis states that *"La pandemia ha fatto vedere il meglio e il peggio dei nostri popoli e il meglio e il peggio di ogni persona. Ora più che mai è necessario riprendere coscienza della nostra appartenenza comune. Il virus ci ricorda che il modo migliore di prenderci cura di noi è imparando a prenderci cura e a proteggere quanti abbiamo accanto: coscienza di quartiere, coscienza di popolo, coscienza di regione, coscienza di casa comune" (The pandemic has shown the best and worst of our peoples and the best and worst of each person. Now, more than ever, we need to become aware of our common belonging. The virus reminds us that the best way to take care of ourselves is by learning to care for and protect those around us: neighbourhood consciousness, people consciousness, region consciousness, common home consciousness)*. In his discourse to the members of the diplomatic corps accredited to the Holy See on 8 February 2021, Francis recalled how, from the very beginning of the health crisis, it was evident that the pandemic would have a major impact on everyone's lifestyle, shattering comfort and established certainties. We were shown the face of a world sick not only because of the virus, but also in the environment, in economic and political processes, and even more so in human relationships. The risks and consequences of a way of life dominated by selfishness and a culture of waste have been highlighted, and now - says Francis - we are faced with an alternative: to continue on the road travelled so far or to embark on a new journey. The pandemic has brought humanity face to face with two inescapable dimensions of human existence: illness and death. Precisely because of this, it recalls the value of life, of every single human life and its dignity, at every moment of its earthly journey. The pandemic has underlined the centrality of the right to care, which every human being is entitled to; and in this sense - says the Pope - it is indispensable that those with political and governmental responsibilities should work to promote, first of all, universal access to basic health care, also encouraging the creation of local medical centres and health facilities that meet

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the real needs of the population, as well as the availability of therapies and medicines. It cannot be the logic of profit that guides such a delicate field as health care and treatment.

In the context of the pandemic, Pope Francis asked the Dicastery for Promoting Integral Human Development to create a Commission, in collaboration with other Dicasteries of the Roman Curia and other organisations, to express the Church's concern and care for the entire human family in the face of the COVID-19 pandemic. The Commission was a qualified and rapid response to the pandemic. Inspired by the teachings of the encyclicals *Laudato Si'* and *Fratelli Tutti*, the Commission responds to the Pope's call to 'prepare the future' through science, theological reflection and deep collaboration, giving priority to the least of these. Drawing on the wealth of expertise of local communities, global platforms and participating academic experts, the Commission seeks not only to alleviate the suffering caused by the emergency, but also to initiate a process of transformation of hearts, minds and social structures, towards a new model of development that prepares a better future for all. Within the Commission there is a specific Taskforce working on health. Among the main challenges identified are inadequately equipped health systems and unequal access to health care, as well as the challenge of worsening mental health, the increase in addictions, domestic violence and suicide. On the topic of psychological health, the Dicastery published in November 2020 the grant "*Accompanying people in psychological distress in the context of the Covid-19 pandemic*". The grant stems from the realisation that the global epidemic of COVID-19 has challenged our physical resilience and revealed the fragility of our bodies. It has also affected the psychological balance of many people. Concern about a mysterious, unknown disease and an elusive future has activated the fear of death - and the fear of loneliness or abandonment - for many. The experience of mourning for loved ones or friends, without the possibility of funeral rites, was all the more powerful for those suffering from mental frailty. Consequently, a team from the Dicastery for Promoting Integral Human Development proposed an in-depth reflection to those involved in accompanying particularly vulnerable people: the elderly, migrants, seafarers, the unemployed and homeless, people in detention, without forgetting those who give their skills, their strengths and sometimes even their lives to care for others.

CONCLUSION

The *excursus* of the sources just mentioned highlights the founding characteristics of the Magisterium of Pope Francis with regard to the protection of health, as a broad, indeed global right.

The Encyclicals, the Apostolic Exhortations, the speeches and messages as well as the documents of some of the offices of the Roman Curia, show that Francis has indeed not hesitated to address the issue of health, whenever possible, and unequivocally highlight the centrality of the protection of human health, a universal right, due to each man as such, good, physical and mental defence, relief of suffering in respect of life and human dignity.

This protection must not be a mere statement of principle but the concrete realisation of the right to health in a broad sense, involving not only the physical wellbeing of the human person but requiring the protection of the environment of which we are an integral part. Care for Creation is also care for man himself and his integral health. This is why it is necessary that the harmonisation of the right to health protection and the right to justice be ensured by a fair distribution of health structures and financial resources, according to the principles of solidarity and subsidiarity. Fairer and more just health care can be built on these two principles. For a fairer and healthier world it is necessary to acquire - as emerges

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from the Magisterium of Francis - a different view of human health and care that takes into account the physical, psychological, intellectual, social, cultural and spiritual dimension of the person. Acquiring this holistic view allows us to understand that providing everyone with the necessary health care is an act of justice, i.e., giving back to the person what is in his or her right. Even before the pandemic, Francis had pointed out that we are all brother systems, all in the same boat, responsible for each other, that our well-being and health also depend on the responsible behaviour of all. The pandemic, in particular, has taught us that health is a common good so that by protecting one's own health, one protects the health of others and the community as a whole. Greater equity in health protection in the world can only be achieved through a renewed moral commitment from countries with greater resources to those most in need. It is thus desirable to achieve universal health coverage for all individuals and communities.

The commitment of the Catholic Church and, most recently, of the Magisterium of Francis has recently received important recognition with the recent adoption by the WHO of the Resolution entitled *'Participation of the Holy See in the World Health Organization'* presented by Italy, which formalises the participation of the Holy See in the work of the World Health Organization as a non-member observer State. A decision that certainly reflects the relationship that the Holy See has had with this Organisation since 1953, and testifies to the commitment of the family of nations in addressing, through dialogue and international solidarity, the global health challenges that afflict humanity, a fundamental aspect of the progress of the 2030 Agenda for Sustainable Development (Alleanza per lo Sviluppo sostenibile, 2021). Strong and resilient health systems are indeed a key element in achieving the Sustainable Development Goals, which aim above all to ensure healthy lives and promote well-being for all, at all ages.

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Chapter 15

The Condition of Vulnerability in the Educational Context:

Ethical Considerations and Juridical Perspectives

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ABSTRACT

The chapter compares the Hippocratic-inspired model of care, based on philanthropia, with the functionalist model, which instead leads to an essentially clinical-therapeutic approach. The reflections are set against the background of the recent school legislation which sanctioned the transition from the school of integration to the school of inclusion, with particular reference to the problems of vulnerable individuals and the solutions proposed in favor of the latter, by the International Classification of Functioning, Disability, and Health. Starting from this, the authors urge the legislator to enhance the dimension of dialogue "with the other" in order to arrive at future legislation leading to the achievement of full protection of the dignity of the human person, considered in all its dimensions.

INTRODUCTION

The issue of vulnerability in the school / educational context has been the focus of numerous regulatory interventions in the last few decades. Specifically, the succession of laws introduced has seen an evolution in the regulation of this issue which, from initially differentiating between non-vulnerable pupils and pupils with vulnerability (or with disabilities), has shifted to the integration of the vulnerable, finally reaching their full inclusion in the school context.

Considering this regulatory path, it should not be forgotten that the high degree of inclusion achieved by pupils with vulnerabilities has specifically found an essential reference point in the specialized sup-

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port teacher. The importance of this particular teacher figure has been appreciated all the more in the pandemic period we are experiencing today, in which educational poverty and school dropout are accentuated for all pupils, and even more so for those with vulnerability. Starting from this, however, it must be acknowledged that the inclusion achieved today cannot be entrusted only to the support teacher who is in close contact with the vulnerable pupil: it is the ethical duty of every teacher in a class, of the school and of those who direct it.

Hence the reflections that will be presented here will delve into the ethical dimension of the teacher-learner relationship, which in our opinion is analogous to the relational dimension of care established between those who have the ability to provide support or care, and those who, on the other hand, need to receive such support and care.

SEN: BETWEEN THE SKILLS PROFILE OF THE INCLUSIVE TEACHER AND THE SUPPORT TEACHER

In view of the above, it can therefore be said that, since the effectiveness of the support teachers' intervention is directly proportional to the extent to which the context is enabling (a statement that finds its conceptual foundation in the relational dimension of care and in the ethics of skills), it follows that their skills must be in tune with an inclusive context also made up of curricular teachers whose skill profile corresponds to that of an inclusive teacher.

Below we will take into account the content of an article entitled Bisogni Educativi Speciali (BES) e normativa scolastica, postilla critica by Antonella Valenti, who reflects on the relational dimension of the teacher / pupil relationship mentioned above and who makes an in-depth critique of the school regulations on SEN (Valenti, 2014).

According to Valenti, who is Coordinator and Head of the Centro Studi 'Bisogni Educativi Speciali e Autismo' of the Dipartimento di Studi Umanistici dell'Università della Calabria, the SEN legislation does not place sufficient emphasis on the educational relationship as it should be understood, that is, first and foremost as an instance of dialectical meeting between people involved in educational dialogue. According to the author, this is "a perspective that – with reference to Buber – evokes a meeting between an I and a thou, as a dialogic relation or pre-structure on the basis of which one can speak in terms of the relation between teacher and pupil. A thou, the pupil, with singularity, individuality, particularity, diversity with special educational needs. On the other hand – continues Valenti - alongside the a priori dialogicity – the pre-structure that always precedes any pedagogical statement – we must place a paradigm that today is indispensable and at the same time unwavering: the paradigm of care […] [understood as, nda] the sense of responsibility constituting the essence or the a priori of every educational act" (ivi, p. 95).

In this sense, as the author herself also clarifies, the paradigm of care is not "a specific paradigm of special educational needs in teaching, but the fact that the pedagogical system would have no meaning beyond the idea of care, if by this we mean the sense of responsibility constituting the essence or the a priori of every educational act" (Ibidem). And for the sake of completeness, it must be remembered that here the author also cites the thought of some authors who have made significant contributions to the theme (Boffo, 2006; Cambi, 2010; Foucault, 2010; 2011).

This sense of responsibility, Valenti continues, is the essence of every educational act and is found in dialogue, of which the reference point and yardstick of every pedagogical effort lies in the uniqueness of the pupil. This uniqueness of the individual pupil derives from his/her specific life experiences,"from

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expectations but also demands, anxieties and worries, hopes and dreams. The human being, as an entity and at the same time a being, a rightly privileged entity – in the Heideggerian sense – therefore capable of understanding and interpretation, is not merely a body and physicality. It is an entity capable of questioning and self-questioning, capable of meaning and requiring meaning. Education, however it is defined, whether it targets specific needs or is general, takes place within this giving and searching for meaning. It follows that both dialog and care are prerequisites to be met by acknowledging the complexity of the pupil's uniqueness" (Valenti, 2014, p. 95).

Valenti then commends Morin for emphasizing that the human being is physical, biological, psychic, cultural, social and historical at the same time and she does so by stating that when the human relational dimension of the educational act is not considered "it can happen that teachers are asked for 'other' skills to satisfy needs that are considered 'new', but that in fact have always featured in the long pedagogical debate" (ivi, p. 96). It follows that focusing on teaching methodology alone does not allow the educational function of the teacher to be valorized with equal dignity. This is because:"While schooling deals with facts and figures, education refers to the need to promote processes of personal growth, teaching to understand and responsibly manage the 'human condition'" (ibidem). These are aspects that, in our opinion, in some ways bring Valenti's thought closer to the ethics of care, which finds in Virginia Held one of its greatest exponents (Held, 1997; 2006). In other words, they bring it closer to the concept of integral care for the individual, respectful of human nature considered in all its dimensions and, as we argue here, not only oriented towards the learning of facts.

Furthermore, the human condition just mentioned by Valenti does not merely require knowledge, but "instead presupposes dialog, empathy, the ability to discuss and, last but not least: to listen. It is therefore necessary to rethink the educational relationship, to recognize it as an indispensable a priori, fundamental both on the theoretical-pedagogical level and on that of the assessment of teaching. This rethinking is also needed because the current school legislation does not seem effective when it should in fact be looking at initial and in-service training for teachers and school heads and at self-directed learning for all pupils, without exception" (Valenti, p. 96).

It is in this sense, therefore, that it would be appropriate to rethink the skills of the inclusive teacher in general, as well as of the specialized support teacher in particular, and to address future school legislation to achieve this purpose.

AND SCHOOL LEGISLATION

In this regard, Valenti herself also makes observations about the school legislation which is supposed to regulate the aspects mentioned so far. We will start from these for the continuation of the argument put forward here.

Valenti's reflection focuses primarily on understanding "what has been done and which direction has been taken so as to ask ourselves what still remains to be done [because, considering the breadth of the perspective, nda] […] special education itself needs to engage in dialog with other scientific and research fields: from pedagogy and general didactics to neuroscience through to phenomenology also in a pedagogical key.

Starting above all from the latter, it will be easy to replace the abstract with the concrete, impersonal order with interpersonal order, school law with school life and sociality, with the authentic, immediate

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teacher-pupil relationship which in relation to orders, directives, circulars and ministerial notices, is certainly the condition, the beginning and not the derivative" (ibidem).

The author therefore suggests a precise horizon for paideia, which does not coincide with mere episteme or with empirical research alone: it coincides, instead, as she also points out with reference to Borrelli's Preface to one of her volumes (Borrelli, 2012) with a more authentic sense of education, the one that belongs above all to "the plane of the affective/emotional dimension of education, making the teacher-pupil bond unique because it opens up to the humanus of humanitas" (Valenti, p. 96). This openness to the humanus is considered fundamental here. It could be said that teachers and school administrators should first of all be pedagogues, emotionally and affectively involved in the process of student care (according to the Hippocratic model of care, that is, according to a model that looks at the patient's every existential need and not only at those strictly of a medical nature) and not mere technicians and bureaucrats who apply a functionalist, aseptic model that is not emotionally relational.

The author further specifies this by asking who the Other / Others are for the teachers. She replies that "Their closest interlocutors are the pupils in flesh and blood. Staying faithful, also terminologically, to the teaching of Lévinas, clearly visible between the lines [Valenti believes that, nda] the Other in front of I the teacher, is the pupil with the singularity of his/her Face" (ivi, p. 97).

Valenti's reference here is specifically to Levinassian existential-phenomenological philosophy and to the importance that this theory attributes to vulnerability and the Face,"so close to the face of a person who in school life experiences a state of distress or difficulty, whether or not related to their being 'different', of every student who «continuously or in certain periods, may manifest Special Educational Needs: either for physical, biological, physiological reasons or also for psychological, social reasons»" (ibidem). The definition quoted by the author above is also a reference to the Ministerial Directive 27 December 2012 – Strumenti d'intervento per alunni con bisogni educativi speciali e organizzazione territoriale per l'inclusione scolastica.

In the light of what has been reported so far, how should we therefore interpret the Directive on BES mentioned above in the considerations referred to Lévinas? The risk that can be glimpsed in Valenti's statements on this issue is related to pedagogy making a cowardly capitulation before economic-juridical needs, which the political decision-maker might endorse.

In this regard, the author asks: "If following the tradition, the value and force of the recent law on SEN seek to be equal to Laws 118/1971, 517/1977, 104/1992 and to Sentences 215/1987 and 80/2010 of the Constitutional Court, then how can they be expressed in all their significance?" (ivi, p. 99). And, considering that the Direttive mentioned earlier refers to Law n.53/2003, she, in part answering the first question, acknowledges that: "The direction is that of the global taking charge of all students with SEN, better than all those that a Class Council is able to identify as such." (ibidem).

For the sake of completeness, and in addition to the normative references just mentioned with Valenti, here it can also be remembered that the process of legislation that sanctioned the transition from a school of integration to one of inclusion finds its precedents in the field of international law where many of the principles were affirmed, and then actually implemented in the national law of nations. In this regard, it is worth remembering the Declaration on the Rights of Disabled Persons, UN, December 9, 1975 and the Convention on the Rights of Persons with Disabilities (CRPD), with Optional Protocol, of 13 December 2006 ratified in Italy by Law 3 March 2009, n.18 "Ratifica ed esecuzione della Convenzione delle Nazioni Unite sui diritti delle persone con disabilità, con Protocollo opzionale, fatta a New York il 13 dicembre 2006 e istituzione dell'Osservatorio nazionale sulla condizione delle persone con disabilità".

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It should also be remembered that, in application of part of the principles enshrined in the two international documents just mentioned, Law n. 104/1992 mentioned above had sanctioned a turning point, since, recognizing the centrality of the disabled, it had indicated "for the first time among the aims of the Republic the promotion of full integration of the handicapped person in school by means of measures designed to fully implement the right to study, with special reference to teaching and technical equipment, curricula, specialized languages, testing and evaluation both during the year and at the final state exams, as well as the availability of specifically qualified teaching and non-teaching staff" (Maci, 2020, p. 25) .

And it should be remembered that, with specific reference to the school context, subsequently, the Legislative Decree n. 66/2017 "Norme per la promozione dell'inclusione scolastica degli studenti con disabilità, a norma dell'art. 1, commi 180 e 181, lettera c), della legge 13 luglio 2015, n. 107" revised many of the provisions in L. 104/92 of this decree (also to remain in line with the comparison proposed in these pages between the figure of the doctor and that of the inclusive teacher, where both are conceptually included within the category of care, in the broad sense) and notice for example, what is envisaged by Capo III "Procedure di certificazione e documentazione per l'inclusione scolastica", art. 5 "Commissioni mediche. Modifiche alla legge 5 febbraio 1992, n. 104". In this article in paragraph 2, there is both a change in the composition of the medical boards referred to in the Law of 15 October 1990, n. 295 and the replacement of the instruments of Functional Diagnosis and of Dynamic Functional Profile with the new tool of the Functioning Profile, which at a detailed level then takes the form of Individual Project and Individualized Educational Plan (PEI). More closely related to the central theme of this paper is Chapter V "Formazione iniziale dei docenti per il sostegno didattico nella scuola dell'infanzia e nella scuola primaria", which in art. 12 "Corso di specializzazione per le attività di sostegno didattico nella scuola dell'infanzia e nella scuola primaria", introduces provisions regarding the specific discipline of the programming and delivery activities of the specialization course in pedagogy and special didactics for educational support activities and school inclusion.

More recently, the provisions of Legislative Decree 66/2017 mentioned above have been further modified by the "Inclusion Decree", that is, Leg.Decree n. 96 of 7 August 2019 "Disposizioni integrative e correttive al decreto legislativo 13 aprile 2017, n. 66", laying down "Norme per la promozione dell'inclusione scolastica degli studenti con disabilita', a norma dell'articolo 1, commi 180 e 181, lettera c), della legge 13 luglio 2015, n. 107".

Among the many innovations introduced by Legislative Decree 96/19, we wish to highlight here, for example, those relating to art. 4, which in paragraph 1, letter b) lays down, among other things, that the "medical boards as per Law n.295 of 15 October 1990, n. 295, are composed of a medical examiner, in the role of president, and two doctors, one of whom is a specialist in Pediatrics or Infantile Neuropsychiatry and the other a specialist in the pathology related to the condition of the specific individual. Such boards include a specialist assistant or social worker, or a psychologist working for state facilities". This therefore specifies, even more than the previous decree, the professional skills required in the medical field, for the purpose of a more correct assessment of disability in children and adolescents to achieve the best possible school inclusion. The same article also provides for the involvement of the pupil's family and also "as far as possible in the respect for the right to self-determination of pupils with disabilitites, with the participation of the school head or of a specialized support teacher from the school where the pupil or student is enrolled". Finally, it is useful to recall here that in the same decree, in art. 8 "Modificazioni all'articolo 9 del decreto legislativo 13 aprile 2017, n. 66" we find the creation of *Territorial Inclusion Groups* (GIT), composed of teaching staff experienced in the field of inclusion, aimed at giving support to schools for the drafting of the IEP (Individualized Educational Plan). This

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is “in accordance with the bio-psycho-social approach underlying the ICF classification, in the optimal use of the numerous supports available, envisaged in each school’s Inclusion Plan, in the enhancement of educational co-responsibility and of the activities of inclusive teaching”.

THE IMPORTANCE OF THE UNIVERSITY TRAINING COURSE FOR TEACHERS SPECIALIZED IN SUPPORTING VULNERABLE PUPILS

Alongside the central theme of this paper, it now seems useful, also in light of the provisions of the legislation mentioned above, to examine more specifically the importance of university training for teachers specialized in supporting vulnerable pupils. Without claiming to give the reader an exhaustive analysis, but simply with the intent of providing a guide for in-depth study, we will then offer our reflections, especially applicable to the narrower field of Special Educational Needs.

In this regard, it must be premised that the question of teacher training is governed by the 2012 Directive mentioned above, which expressly refers to the need to train teaching staff as well as school managers. Such training must be carried out at higher education level, through the university system. On this, Valenti again suggests that, alongside the Masters and specific specialization courses provided by universities, designed to increase the skills that can lead to the highest possible degree of inclusion and education of vulnerable students (a vulnerability which, as will be clear by now, we see as a general conceptual category applicable to all types of pupils with special educational needs and / or in any case with disabilities),“it is to be hoped that the same effort might be devoted to the issues of the third area, of economic, social, cultural and linguistic disadvantage. In that case it would be useful to provide courses in emotional/affective and empathetic/relational literacy, because an authentic, positive relationship between the self and others hinges on one’s capacity for empathy, the ability to put oneself in the other person’s shoes, to understand their state of mind and their feelings. But understanding the other person, helping them to recognize and manage their emotions, requires genuine self-understanding: self-awareness and self-management of their emotions by the teachers themselves” (Valenti, pp. 100-101).

But the skills of curricular teachers aimed at inclusive training for pupils with SEN are skills that are naturally also included in the skills profile of the support teacher. For this reason, appropriate emotional / affective and empathic / relational literacy courses must also be part of the training of the specialized support teacher.

Emotional literacy lessons, therefore, capable of completing the training process of the educational community that enables pupils with SEN to express their abilities to the utmost. Valenti (p. 101) considers this educational community fundamental for integration and inclusion, also citing Paparella, in the hope that the educational community will be able to find “resources, energies and efforts to devote to overcoming distress and disadvantage and to guarantee equal opportunities, above all in training, education and in the choice of a life plan” (Paparella, 2009, p. 12).

Consequently, it does not seem unreasonable to say that even though the ICF wants to introduce a new way of interpreting the meaning of SEN (with particular reference to pupils who, due to physical or mental impairments, need the help of the specialized support teacher to be included in the context of the school and beyond), if one accepts Valenti’s conclusions, it is unlikely that this result can be achieved, due to its being limited only to the bio-psycho-social model.

With what has been said so far, however, we do not want to deny the usefulness of the ICF. This tool remains, in fact, fundamental for the transition from integration to inclusion. According to Lascioli, who

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also cites D'Alonzo (2016), in fact, "the use of the conceptual apparatus of the ICF appears fundamental, being the instrument par excellence for the analysis and interpretation of a problem in functioning, as indicated by the measure we have seen in Chap. 2 (Ministerial directive of 27 December 2012, C.M. n.8/2013, Miur note of 27 June 2013, n. 1551). […] The concept of SEN gives rise to an 'inclusive conception' of special education that can be summed up in the following cardinal points: firstly, the presence of pupils with SEN in a school poses a problem of non discrimination, which requires solutions that lead both to avoiding any form of labeling of pupils, and to reorganizing the education system in order to avoid any form of exclusion. Secondly, using an inclusive logic to deal with the presence of SEN conditions means knowing how to intervene in learning contexts by making the necessary changes to them so that every student can experience 'good functioning' in learning (Universal Design for Learning). Lastly, teaching must be conceived in flexible forms according to the principles of differentiation, individualization and personalization, with the aim of ensuring that all pupils have the conditions to be able to experience their own scholastic success" (Lascioli & Pasqualotto, 2019, pp. 71-72).

In conclusion, what we want to affirm here is that the ICF must certainly be seen as an aid for inclusive teachers, which helps them to focus on the needs of the pupil with SEN, but we also want to affirm that together with this instrument the teacher will also have to use philanthropia. Only in this way, in fact, will he be able to consider vulnerable pupils in all the dimensions of their human nature.

IS IT POSSIBLE TO CONTINUE TO CONSIDER LAW AS A VALUE IN THE CONTEXT OF OUR CULTURE?

On reflection, however, the question that arises is whether, with reference to "care for the other" in a broad sense, it is correct today to still seek a reference to the values within our culture. This is especially the case when the scientist model seems to be the one that dominates in theoretical reflection, at least if we consider the references made to the ICF in this paper. It is a scientist model that also seems to dominate in the field of law, both for the issue of the inclusion of vulnerable pupils that we are dealing with here, and for many of the current issues of bioethics. But dealing with the latter is outside the scope of this paper. However, to stay with the topic we are tackling here, it must be said, with greater depth, that the scientific paradigm seems to dominate if we consider that often the legislation on school inclusion has favored the acceptance of the contents of the ICF model. Starting from this and returning to the question posed earlier about the correctness of continuing to look for a reference to values in our culture, if we stop at the field of law, we must accept that it coincides with the similar question that Enrico Opocher asked himself in the conclusion of his famous Lezioni di Filosofia del diritto about whether or not to speak "of law as a value in the context of our culture" (Opocher, 1983, p. 267). The reference to values here must inevitably be more or less directly considered with reference to the classical values of the concept of man that Aristotle gave us, and which then, starting with the Stoics, crossed the Middle Ages and with different adaptations was considered by later thinkers, according to the meaning they attributed to reason. Hence the correctness of considering the Aristotelian concept of man as a traditional concept of man.

These questions will not receive an answer here, and anyway it certainly could not be a definitive answer. However, just to underline an aspect that is considered fundamental, in our view Opocher's question is undoubtedly an acknowledgment of an aversion to metaphysics in the classical sense, already felt and known at that time, and even more so today in the postmodern era. That aversion today leads to

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the disowning of any function for values, as well as the rejection of "the very legitimacy of the value of conscience in life" (Ibidem).

It has been said above that the aversion to metaphysics was already known at the time when Opocher was writing his Lezioni di Filosofia del diritto because,it is well known that many authors over the centuries have been critical of metaphysics. Looking at the twentieth century, for example, we can recall the anti-metaphysical positions of Alf Ross, as was also stated in a recent work on the role of legal politics and on the opportunity for the legislator to consider social reality, precisely in the light of Ross's thinking. Social reality has, in some ways, inspired the legislator also for the rules issued on the subject of the inclusion of vulnerable pupils: think of the normative provision of the figure of the specialized support teacher, a professional figure that has become indispensable in a society like ours in which the parents of a vulnerable boy / girl often both need to work to ensure the satisfaction of the needs of the family unit, and consequently have less time available to monitor the school progress of their child. Incidentally, Ross entrusts his arguments refuting metaphysics essentially to four articles, collected today in Democrazia, potere e diritto (Ross, 2016), which collects articles that Ross published in Danish newspapers over about twenty years, up to the mid-seventies. The Ross articles cited specifically are: So read Marcuse!; Herald of left-wing fascism; Homage to Fanny Hill; I believe. Reading these four articles gives a good understanding of Ross's position on the indemonstrability and irrelevance of metaphysics. This position stands as one of the fundamental points as far as the scientific character of Ross's legal realism is concerned (Tarantino, 2021). But to stay with Scandinavian legal realism, reference must be made to the thought of another thinker belonging to the Uppsala School: Hägerström. Of the latter author, we will just mention his pressure for a cogent critique of metaphysical positions which can be found summarized in his well-known paraphrase Praeterea censeo metaphysicam esse delendam (Metaphysics must be destroyed). It can reasonably be said that from that statement onwards there was a strengthening of the positions critical of metaphysics. This critical position for some decades now has been increasingly put forward under the aegis of a reigning scientism, in a shiftfrom a humanistic civilization and culture towards a technological - or worse, technocratic - civilization and culture. This is the result of reason being used no longer as an instrument for governing passions and instincts, for the creation of correct social and relational relationships, but increasingly as a means that must ultimately lead to the production of technology, of scientific instruments that enhance the human condition, from which, however, man himself often ends up being dependent or submissive. And the empowered individual, the first product of this scientific and technocratic model which leaves little room for values, will easily end up being preferred, with little doubt, to a student who, on the other hand, has any degree of vulnerability or disability.

However, if we consider the process that over the years has led to the inclusion of vulnerable pupils, in certain respects one cannot say that the ethical dimension of the relationship of support/care for others (therefore involving reference to a system of values) has been completely abandoned and replaced by an aseptic, scientist model for the inclusion of the vulnerable. Such a model only takes into account the human being's biological dimension and overlooks the other dimensions making up human nature. An overall vision of this process towards the full inclusion of vulnerable pupils offers hope, especially in relation to the possible future improvements that the legislator could bring to it. In our opinion, this hope rests on the possibility of completely rediscovering the usefulness of the role of values to guide human actions, capable of leading individuals towards mutual respect. This can be glimpsed if we look at the overall process which, from the differentiation of vulnerable pupils, passing through integration, has finally led them to a good degree of inclusion. This comes despite the concern about the current crisis

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of values in society mentioned above. This crisis is no longer confined to small groups of individuals (possibly sharing particular intellectual beliefs or ideological convictions), as often occurred in the past, but is spread horizontally throughout “liquid” postmodern society (Bauman, 2017). The main outcome of this values crisis is the replacement of ethics with legality and the shifting of the values issue from the domain of each individual’s morals and conscience into that of public ethics, which however is oriented by the political and cultural beliefs of the rulers of the time, and increasingly also by whoever is capable of using the media to influence (not always virtuously) the behavior of the majority of citizens. Profound reflection on these statements, while certainly of interest in the legal-philosophical issues it would tackle, would also be very vast, and at the same time would risk losing sight of the theme of inclusion which must be the focus of our attention. To explore the question further would therefore be beyond the scope of this paper.

CONCLUSION

Wishing now to conclude these reflections, if we consider what has been said so far, there will be no difficulty in recognizing that, despite the usefulness mentioned by Lascioli, the ICF in its exclusively technical use risks slipping towards the functionalist paradigm of care. This paradigm, by rejecting the ethical dimension described above, but also the affective / emotional dimension suggested by Valenti, does not seem capable sic et simpliciter of accepting the needs of the human person considered as a totality, not only in the technically detectable dimensions, but all the constitutive elements in ontological terms. Incidentally, it is also difficult to “typically” frame all the needs of a subject within general categories. In fact, with regard to individual needs, there is often space for novelty, indeterminacy and “a-typicality” (Dovigo, 2008, pp.18-19).

The conclusions reached so far suggest that it can certainly be considered both useful and necessary to provide training courses, for example, on the use of the ICF as a reference point for developing technical tools such as the operating profile, the IEP and the Life Plan for the Disabled, but that it is of fundamental importance to hold training courses on emotional skills (certainly closer to the Hippocratic model of care as it is widely understood). In fact, in line with what Valenti said, teachers who undertake the training course for the specialization in support for the disabled, in their profession will face many difficulties related to the context, the vulnerable pupil and the class group at the same time. It is often overlooked that teachers will inevitably be called upon in their daily professional life to manage first and foremost their emotions (Dato, 2017) and their own personal condition of fragility, and that only later, once this emotional condition is overcome, will they be able to implement all the strategies listed in the IEP.

At the same time, however, it is necessary to get personally involved, first on a human level and then professionally, in the face of an always open challenge. This raises various questions whose answers will probably arrive over time, but are based on the long-term perspective. of an inclusive present that looks to a future of greater well-being for the pupil’s existential condition, as well as for that of the teacher.

Moreover, the teacher’s skills should by law be perfected through the provision of additional complementary instruments for the inclusion of vulnerable pupils, so that the care for their vulnerability will increasingly coincide with respect for their intrinsic dignity (Becchi, 2009; Tarantino, 2018; Vincenti, 2009; Viola, 2006; Waldron, 2012). The latter, incidentally, is achieved when the individual is empowered to fully realize his or her potentialities, also by exercising social skills (Luhmann & De Giorgi, 2003)). This dignity, as has been authoritatively recalled, can in fact be distinguished according to a theory of

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gifts and a theory of performance. The former is related to "the attempts to explain the dignity of man as the particular quality or property with which the individual is endowed by nature or by his creator [...] Unlike the theory of endowments, the other view conceives the dignity of man as a product of his actions, as the performance of human subjectivity: in this conception man earns his dignity insofar as he autonomously determines his own behavior, managing to constitute an "identity" for himself" (Hoffmann, 1999, p. 626). But the theory of endowment and the theory of performance cannot be seen as being in conflict with each other, since, on reflection, both are founded on the principle of autonomy of the single individual.

It is to be hoped that all the help that the inclusive teacher is able to give must be aimed precisely at developing the autonomy of the vulnerable pupil.

NOTES

The translation from Italian of the parts quoted in the text in quotation marks was carried out by the authors of this paper.

Even within the conceptual unity of the contribution, the paragraphs titled: "... AND SCHOOL LEGISLATION", "THE IMPORTANCE OF THE UNIVERSITY TRAINING COURSE FOR TEACHERS SPECIALIZED IN SUPPORTING VULNERABLE PUPILS", "IS IT POSSIBLE TO CONTINUE TO CONSIDER LAW AS A VALUE IN THE CONTEXT OF OUR CULTURE?", "CONCLUSION" they must be attributed to Giovanni Tarantino; the paragraphs titled: "INTRODUCTION", "SEN: BETWEEN THE SKILLS PROFILE OF THE INCLUSIVE TEACHER AND THE SUPPORT TEACHER ..." they must be attributed to Maria Sponziello.

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KEY TERMS AND DEFINITIONS

Autonomy: Ability to govern itself, with its own laws.

Care: Moral attitude that aims at the physical and spiritual support of an individual.

Dignity: Moral superiority that comes to man from the possession of reason.

Education: The action of providing, especially for children, the moral and cultural principles belonging to a specific social group.

ICF: International Classification of Functioning, Disability and Health, drawn up by the WHO (World Health Organization).

Value: What must be the object of choice or preference. Philosophically it is understood in a generalized sense, referring to any object of choice or preference.

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Vulnerability: Condition of fragility of an individual, due to which, for example, he can receive damage or discrimination.

ENDNOTES

[1] In the school context, the functionalist model of reference is that of the ICF (International Classification of Functioning, Disability and Health) drawn up by the WHO (World Health Organization).

[2] In Italy, in the past, pupils with vulnerabilities were relegated to "differential classes", defined by the CM of 11 March 1953 1771/12 as classes that "welcome nervous, late, unstable pupils, who reveal the inability to adapt to the discipline common and normal teaching methods and rhythms and can reach a better level only if the teaching is imparted to them in particular ways and forms ". Differential classes which, as is well known, saw their overcoming only starting from the Law of 30 March 1971, n. 118.

[3] The revolutionary significance that Law 104/92 had in Italy is proven by the fact that the provisions contained therein have definitively overcome the definitions of pupils in conditions of vulnerability that were in antithesis with today's concept of inclusion. These definitions were, for example, those present in art. 12 of Law no. 1859 of 31 December 1962 "Establishment and organization of the state middle school", in which vulnerable pupils were defined as "school maladjusted"; or those contained in Legislative Decree N. 1518 of 22 December 1967, which qualified them as pupils "hypodotected, intellectually not serious, environmental maladjusted or with behavioral anomalies".

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Chapter 16

How Does 24-Hour Shift-Working Affect Intensive Care Unit Nurses?

A Qualitative Descriptive Study

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ABSTRACT

The purpose of this study is to describe intensive care nurses' perceptions and experiences of shift working and reveal how to cope with its effects. Data were collected through an individual semi-structured interview guide and transcribed verbatim by using a qualitative descriptive design. Interviews were done with 11 Turkish intensive care unit nurses. As a result of the analyses, four main themes were obtained: 1) the effects of shift working on nurses' lifestyle, 2) the effects of shift-working on nurses' working life, 3) the effects of shift working on nurses' patient care practices, and 4) the strategies used by nurses to cope with the effects of shift-working. The positive and negative consequences of the multifaceted effects of shift-working perceived by nurses should be taken into consideration, and individuals or a group of nurses who have been searching for strategies to cope with and overcome these effects should be supported.

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INTRODUCTION

In the Turkish health system, the hospitals are categorized into three as state, university, and private hospitals. The total number of employed nurses is 303.201 (Annual Health Statistics, 2018). According to these numbers, we can calculate that there are 301 nurses per 100.000 people. This ratio is 1179 for the USA, 841 for EU, 938 for OECD countries (OECD Health Data, 2019). As it can be seen from these statistics, while the majority of nurses in healthcare services in Turkey work in shifts (Özvurmaz & Öncü, 2018), 21% - 30% of the total employment in Europe and the United States of America (USA) (Boivin & Boudreau, 2014; Parent-Thiron et al., 2015), and 40% of healthcare employment in European Union (EU) work in shifts. The shift-working can be classified as shift schedules that differs from traditional daytime work schedule such as fixed night shifts, early morning shifts, late afternoon/evening shifts and rotating shifts (West, 2008; Cheng & Drake, 2018).

In Turkey, most of the studies examining the effect of the shift-working on nurses have been conducted cross-sectionally. Based on the self-reports of nurses working in shifts, these studies mostly investigated the relationship among sleep quality, life quality (Bumin, Tatlı, Cemali, Kara, & Akyürek, 2019; Gök, Peköz, & Aslan, 2017; Karakaş, Gönültaş, & Okanlı, 2017), job performance and occupational accidents as well as the mental status of nurses (Selvi, Özdemir, Özdemir, Aydın, & Beşiroğlu, 2010; Sönmez et al., 2010). Another study found that work schedules and night shifts lead to increased family conflicts and decreased life/job satisfaction (Yıldırım & Aycan, 2008). Besides, few studies focused on ICU nurses have investigated the relationship between ICU nurses' job index, nursing work environment and burnout (Kökçü & Terzi, 2018); also, they have investigated the relationship between burnout levels, sleep quality (Şentürk, 2014) and job satisfaction (Özden, Karagözoğlu, & Yıldırım, 2013). Therefore, in the context of Turkey, there is a gap in evaluating the effects of shift-working on ICU nurses from a holistic approach and identifying the strategies that they prefer to cope with these effects of shift-working. The study aims to define the experiences of ICU nurses working in 24-hour shifts in Turkey. Besides, the coping strategies that nurses apply to mitigate the negative effects of the shift-working is another aim of the current study.

BACKGROUND

Shift-working is an obligatory lifestyle for many nurses including the intensive care unit (ICU) nurses due to the 24-hour continuous patient care necessity in the hospitals (Jensen, Larsen, & Thomsen, 2018), and the current shift requirement causes several negative effects on nurses' health. Physiologically and mentally, the shift-working causes several short period symptoms like fatigue (Barker & Nussbaum, 2011); eating disorders (Dias & Dawson, 2020); circadian cycle disorders due to sleep loss and a decrease in sleep quality; and lower risk of alert (West, 2001; Crew, 2006); and also, it causes several long term problems such as frequent headaches and tension headaches (Bjorvatn, Pallesen, Moen, Waage, & Kristoffersen, 2018); an increase in obesity risk (Saulle, Bernardi, Chiarini, Backhaus, & La Torre, 2018); shift-working disorders such as shift-related insomnia, and/or excessive sleepiness (Vanttola, Puttonen, Karhula, Oksanen, & Harma, 2020); cardiovascular diseases (West et al., 2007; Knutsson & Boggild, 2000); weight loss (Nasrabadi, Seif, Latifi, Rasoolzadeh, & Emami, 2009); lower fertility and higher miscarriage rates (Costa, 2010). Psychologically, shift-working negatively affects the cognitive functions by increasing the level of global cognitive impairment (Kaliyeperumal, Elango, Alagesan,

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& Santhanakrishanan, 2017) and decreasing the global cognitive performance level (Marquié, Tucker, Folkard, Gentil, & Ansiau, 2014). Besides, psychologically, nurses working in rotational or fixed night shifts are affected twice as much (Alsharari, 2019); (Panczyk et al., 2017; Yüzügüllü, Aytaç, & Akbaba, 2018). The job satisfaction and the quality of life of the ICU nurses decreases due to the increase in exhaustion (Kavlu & Pınar, 2009); and the increase in their shift periods (Stimpfel, Lake, Barton, Gorman, & Aiken, 2013)

The effects of shift-working on family life and social life creates a fragmented appearance. While some studies focus on the positive aspects of shift-working on family and social life (Crew, 2006; Gifkins, Loudoun, & Johnston, 2017); most of the studies state that shift-working will have negative effects on family and social life (Jensen et al., 2018; Yıldırım & Aycan, 2008) and these people working in shifts spend less time with their families (Barnes, 2011). In Saudi Arabia, 90.9% of nurses work in shifts think that shift-working negatively affects their social life, and they also add that the reason for these negative effects stem from the cultural beliefs and religion (Alsharari, 2009). Because in family-oriented cultures like Saudi Arabia, shift-working and being away from home at night creates a negative socio-cultural image of themselves as well as their family members and the public (Nasrabadi et al., 2009). Furthermore, Vitale, Varrone-Ganesh, & Vu (2015) discovers that the lack of family support increases the negative effects of night shifts on the nurses.

Many systematic and comprehensive studies conducted in recent years have been focusing on the effects of shift-working on the personal and professional outcomes of nurses. Dall'Ora, Ball, Recio-Saucedo, & Griffiths (2016) aimed to evaluate the effects of shift-workings on the performance of the employees and their well-being and they revealed that the shifts over 12 hours and above have negative effects on all the performance and well-being scores of the employees. Min, Min, & Hong (2019) systematically evaluated how working schedules affect the fatigue of the nurses working in shifts in hospitals and they concluded that increased working hours raised the fatigue and the number of injuries and decreased the job performance at the same time. Another systematic research discussing the relationship between negative effects and the shift length revelaed that nurses working in 12-hour shifts or above make more mistakes (occupational accident) (Clendon & Gibbons, 2015).

In the literature, besides empirical and systematic studies, qualitative studies about the shift-working of healthcare employees or nurses were also conducted. Thomson, Schneider, & Hare-Duke (2017) evaluated the perception of healthcare employees about the effects of a 12-hour shift on their performance and patient care. Gifkins et al. (2017) compared the shift-working practices of both experienced and inexperienced nurses working in either short or long shifts. Da Silva, de Assunção Ferreira, & Apostolidis (2016) examined the effects of "elapsed time since graduation" and "work shift" variables on social representations (a cognitive process) of permanent nurses who serve in ICUs and proved the effect of shift-working on the daily care of the patients in ICUs.

The coping activities that can mitigate the negative effects of the way of nurses working in shifts, are discussed in two categories: problem-focused (focusing on the management of the problem such as time management strategies) and emotion-focused (strategies such as regulating the emotional reactions, conscious awareness, relief/relaxation and receiving help from co-workers or friends) (Lazarus & Folkman, 1984; Lim, Bogossian, & Ahern, 2010). The nurses can mitigate the problems in their working life with emotion-focused coping strategies like religion and positive framing, and problem-focused coping strategies like instrumental support and planning (Fathi & Simamora, 2019).

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THE METHODOLOGY OF THE STUDY

Design

We used the qualitative research method to enable a detailed and comprehensive study about the experiences of nurses' work in shifts. Qualitative studies are useful to explore and understand the inner world of people. Actually, the individuals' experiences of a phenomenon form the basis of their own reality. Therefore, you can use individuals' experiences and lives to define a phenomenon based on their own perspective (Jahromi, Moattari, & Sharif, 2013).

Participants

Our study group consists of 11 nurses working in the ICU units of the hospitals in 24-hour shifts. The inclusion criteria of the nurses forming the study group was determined as being an intensive care nurse and working in 24-hour shifts. Intensive care units were chosen as the sample of the study because it was considered as the unit with the highest shift-working experience. The opinion of the head nurse was also taken about the shift-working system. We decided on the participants by using a snowball sampling method. The snowball sampling method is preferred not because it is simple to apply but because its strategies are eligible for this study (Yin, 2011). The first participant was a person who met the inclusion criteria and was reached through the personal and professional relationships of the researchers. In the later stages, the nurses, who met the inclusion criteria until the data saturation, were included in the study group. Using the snowball sampling method also reduces the risk of bias in samples with homogeneous characteristics (intensive care nurses and 24-hour shifts) (Naderifar, Goli, & Ghaljaie, 2017). We reached the participants via the personal relationships of the researchers. The thematic saturation principle was adopted in determining the size of the study group (Bengtsson, 2016: 10) and it was assumed that the data reached saturation when new themes and categories could not be created, and the participants used similar statements. The demographic information of the participants is listed in Table 1.

All 11 nurses who participated in this study are female. The ages of these nurses are between 26 and 47 years. The time they spent in nursing is between 7 and 28 years. The period they worked in shifts is between 3 and 20 years.

Data Collection

30-60 minutes-long face-to-face interviews were held with the participants in March 2020 by using semi-structured interview forms, and these interviews were recorded in audio by the primary researcher and then transcribed by other researchers. In the interviews, the nurses were asked to describe unforgettable shift-working experiences and their feelings or emotional state at that moment. In addition, in the interviews, the nurses were also asked to give detailed information about three situations: The objective description of the events in the environment where this shift-working occurred, the reasons for their feelings at the moment of the event, and the consequences of the event for the nurses. The participants determined the interview time and places, and they informed the researchers with a phone call. We interviewed some of the nurses in the ICU while we interviewed the others in a café. Face-to-face interviews were held with all the participants once, and the participant's confirmation was obtained by making a phone call for the themes that emerged in the analysis results.

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Table 1. Demographic information of the participants

Participant	Gender	Age	Years in Nursing	Years in Working in Shift	Education
Participant 1	Female	45	26 years	20 years	Bachelor's Degree
Participant 2	Female	26	7 years	7 years	Bachelor's Degree
Participant 3	Female	42	19 years	3 years	Associate's Degree
Participant 4	Female	42	13 years	13 years	Bachelor's Degree
Participant 5	Female	45	28 years	15 years	Bachelor's Degree
Participant 6	Female	45	27 years	19 years	Bachelor's Degree
Participant 7	Female	47	22 years	20 years	Bachelor's Degree
Participant 8	Female	41	16 years	10 years	Associate's Degree
Participant 9	Female	44	25 years	15 years	Associate's Degree
Participant 10	Female	43	19 years	15 years	Bachelor's Degree
Participant 11	Female	42	12 years	10 years	Bachelor's Degree

Ethical Considerations

We asked for the verbal and written consent of the participants before the interview. We explained the objective and the scope of the research to the participants and stated that participation was totally voluntary, and they had the right to quit at any phase they want. We coded the participants and changed their specific personal information to conceal their personal identity and information they gave (Like P1, P2,). Isparta University of Applied Sciences Ethical Committee approved this study with their decision numbered 2020/20 (1).

Data Analysis

We transferred the interview transcripts to the Maxqda 18 data analysis software (Verbi Software, 2018) and the primary investigator conducted the first analysis. The other investigators who were not present in the interviews listened to the interview records and read the transcripts to conduct their analysis. We analyzed the data with inductive content analysis. Inductive content analysis was carried out in 3 stages: open coding, categorization and abstraction (Elo & Kyngas, 2008). Open coding was done in the first stage. At this stage, the words, phrases, sentences, and paragraphs that make sense in the documents were defined as codes, coding pages were created and codes thought to be related were collected and they were brought together randomly than, similar coding pages were brought together and the codes were defined in categories. In the second stage, the categories were classified. At this stage, categories were compared and the categories that were thought to be related were brought together and gathered under themes as top categories. In the last stage (abstraction), main themes were created by naming the themes with content-specific statements. The objective of this analysis is to identify the themes by studying the transcripts (Powell, 2013: 2175). Four researchers started the analysis independently with systematic coding of the data. The analyzed patterns were identified as either a word or a paragraph. The researchers compared the coding tree diagram obtained through verbal material in the meetings, restructured them

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several times and continued these meetings until they reached a consensus. Then we compiled the similar and related codes together to construct them under the main themes and the subthemes. The main and the subthemes were formed by using the raw data and with the help of related literature (Liamputtong, 2009), and they were discussed until reaching a consensus among all the researchers. We considered reaching theoretical saturation after we were not able to deduct any new themes or concepts from the verbal material. After that, we commented on the relationships between main themes and subthemes and we discussed them in the concept of literature. Since the native language of the researchers is Turkish (participants also speak the same language), data analysis was conducted in Turkish. The language was translated into English while the findings were being presented.

Trustworthiness

We conformed to credibility, transferability, dependability and verifiability criteria to provide trustworthiness (Lincoln & Guba, 1986). To provide the trustworthiness, we directly reflected the participant statements and shared the main theme and the subthemes with some participants for approval. The credibility of the study was enhanced by describing the data collection and analysis process in detail and computerized analysis. In order to conform to credibility criteria, we continued to discuss the findings until reaching a consensus among the researchers. We referred to related literature and discussed the findings to reflect the facts to the maximum extent and to provide verifiability.

FINDINGS

Table 2 shows the four main themes and their sub-themes that were obtained as a result of the analysis of the interview transcripts.

The Effects of Shift Working on Nurses’ Lifestyles

The effects of shift-working on a lifestyle was the most dominant theme in the analysis of interview transcripts.

This theme consists of health, family life, time management, socio-cultural and economic subthemes. The subtheme of health consists of psychosomatic effects like exhaustion, tension, impatience, insomnia, stress and nervousness, and the nurses also mentioned some somatic effects like circadian rhythm disorder, leg and foot pain, joint pain, fatigue, and weakness. Some of the participants stated that the insomnia that they were suffering became chronic and they also had difficulties in falling asleep out of the working environment.

In some period, I visited a psychiatrist. I can’t fall asleep. I can’t go to sleep even until 4 a.m. in the morning and I generally have a shift the next day. (P2)

I feel so tired after the shifts that I can’t feel even my feet. (P10)

The subtheme “family life” includes some complaints as well. They frequently complain that they can’t spare enough time for their family and especially for their children and this deficiency causes the

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Table 2. The effects of 24-hour shift-working and coping strategies

Themes	Sub Themes	Theme Content
Effects on Lifestyle	Health	Includes nurses' statements about the impacts on their physical and psychological health and their effects on their lives.
	Family Life	Includes nurses' inability to take care of their family members and the negative statements of this situation.
	Time Management	Includes nurses' statements about the inability to spare enough time for themselves, housework, and other activities and their negative feelings.
	Social / Cultural / Economic	Includes nurses' statements about the inability to participate in social events, religious and national meetings, meetings with friends, and the negative effects of these, as well as the extra financial benefits of shift-working.
Effects on Working Life	Communication with Management	Includes nurses' statements about the inability to contact the management level when they need in the 24-hour shift-working and the inability to solve the problems quickly.
	Limited Access to Resources	Includes nurses' statements about the inability to reach experts in 24-hour shift-working, and complete urgent official works, and the negative aspects of these.
	Increased Workload	Includes nurses' statements about the lack of personnel support such as patient caregivers and medical secretaries in the 24-hour shift-working. They have to do many tasks that are not included in the job description of nurses.
	Relationship with Co-workers	Includes nurses' statements about the buddy system, which is understood as a very important coping strategy at the same time. In addition, it includes explanations about the effects of working in 24-hour shift, such as stress and insomnia which disrupt the relationships with colleagues.
	Perceived Control in Shift Planning	Includes nurses' statements about taking into account nurses' requests while shift plans are being made and the positive results of this.
Effects on Patient Care Practices	The Nerve Control	Includes nurses' statements about the negative reflections of the stress brought by 24-hour shift-working on patients.
	Malpractices	Includes nurses' statements about medical errors that occur because of fatigue and insomnia due to the shift-working.
	Comprehensive Information About the Patient	Includes nurses' statements about how 24-hour shift-working facilitates the patient follow-up.
	Emotional Bonding	Includes nurses' statements about how 24-hour shift-working facilitates emotional bonding with the patient.
Coping Strategies	Rest	Includes nurses' common statements about resting to cope with the physical effects of 24-hour shift-working.
	Co-workers Support	Includes nurses' statements about the buddy system.
	Family Support	Includes nurses' statements about the support of spouses, children and parents.
	Appreciation	Includes nurses' statements about how appreciation, such as thanks from patients' relatives and the management, help nurses to cope with negative situations.
	Being Away from Work	Includes nurses' statements about the relief of being away from work.

feeling of guilt and broken family bonds. The Turkish culture conveys major roles to the mothers which causes deep emotional reactions when the nurses were interviewed about their family life. Sometimes they could hardly speak and we realized that this issue was their sore point.

I am trying to compensate with my tolerance for the time and energy that I have stolen from them (P7)

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The thing is that the family bonds break at some point. You can hardly follow your child's growing, what he lives and everything else. You can realize everything late such as a problem that they have at school. (P1)

The adverse effects of the subtheme "time management" can be listed as being useless after shift times to complete the housework and personal tasks due to fatigue and time constraints.

After all, you don't want to do anything in the first day…I don't even want to go outside because I feel so tired. The second day, I complete the unfinished tasks and the tasks given during my shift. (P10)

Furthermore, some participants consider the low number of duty days in a month as an advantage, and they state that no other job has this advantage.

Let me tell you a positive aspect of it; firstly, we have only 7 shifts in a month. In which job can you complete your monthly work in 7 duty days? This is nearly impossible. (P2)

Under the subtheme "socio-cultural and economic" title, we put some complaints together. The nurses stated that they have difficulties in exercising, shopping and building social relations like meeting with friends. The national and religious days (these days are holidays in Turkey) carry a special value in Turkish and Islamic culture and relatives traditionally come together even if they live in different cities. The nurses feel angry and upset because they keep working in these days and this issue is listed under this subtheme. But there are also some positive effects under this subtheme that nurses mention about the shift-working and these ones are the relatively high salaries and the overtime payments.

Since I work in busy services, I can't think of choosing an activity for myself, having leisure time and shopping during my shift and going downtown after the shift. I don't have any power to do anything. (P3)

The longest periods that people can behave relaxed are annual leaves, religious holidays, national holidays and weekends. People working in normal schedules can plan short trips with their families and they can have some free time together. But that is not true for us. (P6)

But since my income is not enough for my expenditures in these days, I frequently need to work overtime. (P4)

The Effects of Shift-Working on Nurses' Work Lives

Under this theme, the effects of shift-working expressed by nurses on the work environment are included. Accordingly, subthemes of the theme were defined as; communicating with the management, limited access to resources, increased workload, perceived control in shift planning and the relationship with co-workers.

Considering the effects on business life mostly the nurses made comparisons between the night shifts and day shifts which are very remarkable. Since participants work in 24-hour shifts, they work both day and night. Therefore, they can make a comparison between day shifts and night shifts. The difficulties in night shifts when compared to day shifts are listed as the communicating with the management, reaching

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the specialists, accessing the resources and the increase in bureaucratic workload (which is not normally in their job description) due to a lack of medical secretaries.

Night shift is more disadvantageous. It is also true for the administration perspective. If the patient causes trouble, have a problem or argue with you, you can't call the administration for help at that time of the night. (P5)

Now we have foreign patients…However, after normal business hours, we are having problems in payment, cash desk, data automation or ELISA sampling…Since they are not solved, they hamper our job. (P7)

There are times that we do the jobs of admin personnel, secretaries and doctors. Nurses have extra jobs here in addition to their own jobs. The burden on them is so big. (P1)

There was the time that 5 patients arrived at the same time. They came from the polyclinic for hospitalization. It took half an hour to fill a file. (P8)

nurses emphasize the importance of colleague support when they can't reach the specialists and managers, or they have limited access to resources. Nurses frequently mentioned the buddy system process for this theme. We observed that buddy system is an important component of this profession either serving as a coping strategy or facilitating the job tasks of shift-working.

Buddy system means helping each other. For example, if my patient is catheterized and worsened, she helps me in this situation. (P4)

For example, a patient who was in a very bad condition arrived at 6 a.m. He had complicated issues. He had a renal failure, a lung failure, and a heart failure. The unit was overcrowded. We were two people there and we couldn't handle it. So, I called a friend of mine from cardiovascular and surgery services by using my informal and bilateral relations. She was not obliged to come. At that time the patient was catheterized...My friends arrived and thankfully helped me out. (P8)

Besides, some participants stated that 24-hour shift-working sometimes caused tensions between co-workers, and it grows the impatience due to sleeplessness, fatigue, and stress.

We have a minimum of 9 people in shifts. If it increases to 11 or 12 people, they start teasing each other. Why? Because they are always sleepless. (P1)

The perception of control over shift scheduling is another theme that nurses mentioned. Nurses stated that their opinions and private cases are considered when the shift schedule is determined. The nurses perceive this application as a mitigating factor for the negative effects of shift-working.

Now, let's say that we can make one request at least. I requested the end of the month so; I can go to Eskisehir and rest in that day. I can spend time with my daughter and work for 3-4 days. (P11)

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The Effects on Patient Care Practices

Under this theme, the effects of shift-working on patient care are defined. Subthemes of the theme are the nerve control, malpractices, ordinary care, comprehensive information about the patient and emotional bonding.

Some nurses stated that the 24-hour shift-working affects the quality of patient care. Even though they try to be careful, fatigue, sleeplessness, and tensions lead to some medical errors. They also told that they could get angry with the patients even if they were unconscious. They talked about their experiences of this issue. Besides, they told that they could provide a better service but they served at an average level due to the fatigue.

One of my friends gave food to a patient who was supposed not to be fed. This caused bleeding. Why did that happen? She was working shifts every other day. She was confused and accidentally fed that patient. (P1)

If you are awake between 12:00 a.m. and 4 a.m., you start raising your voice…I think it was after midnight and we had a patient with apoplexy. We couldn't even give a sedative to him. I remember raising my voice. Actually, it resulted from the working hours. (P2)

Although you try your best, if the shift comes one after the other day…Actually, you only save the day. You have no positive or negative effects on the patient. I am not really sure if we have a negative effect on the patients or not. But we save the day. Was the patient stable? Did you handover the patient? If yes, you are OK. (P11)

Despite these adverse effects, some nurses state that caring for the same patient for 24 hours provides continuous communication and interaction which leads to know the patient better and have more information about his disease. Besides, long periods of interaction with the patient enable them to build an emotional bond and empathy. This situation gives the nurse the feeling of playing a role in the patient's healing which also increases the level of job satisfaction.

You don't know the patient. You are not aware of the incidents of the day shift. For example, when a doctor visits the unit after 4 o'clock for consultation and asks questions about the patient, it seems that you don't know anything. But if you work in 24-hour shifts, you will know everything about the patient and feel more relaxed. (P4)

After a while, you feel like living together. I mean it looks better to the patients. It builds trust to the nurse. The patients tell that they are happy to be together until the morning. (P9)

Coping With the Shift

Under this theme, coping strategies used by nurses to deal with the negativity of shift-working are defined. Accordingly, these strategies are rest, co-workers support, family support, being away from the job, self-motivation and appreciation.

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We collected the statements about the coping strategies against the negative effects of 24-hour shift-working under the main theme of "coping with the shift". According to these statements, nurses mostly complain about resting. The nurses stated that a quality rest after the shifts reduces the negative effects of the shift. We can easily understand this if we consider that somatic health problems are defined as a leading subtheme of the personal effects of the subtheme. Besides, co-worker support is also another leading and common coping strategy. The nurses frequently mentioned about the buddy system that are special to ICUs. In this context, nurses see the presence of the buddy system as an effect on the professional occupational environments of shift-working and also use this structure, which is an occupational environment element, to deal with the negative effects of shift-working. For this reason, the buddy system was also defined under both themes.

My buddy is the most important component of the shift for me. She both supports me and chats with me as having the same troubles. She eases the fatigue and stress of the shift. (P10)

Additional coping strategies are family support, being away from the job and being awarded. Some nurses consider the patient appreciation as an award while some others consider it as being officially awarded.

When I sleep from the morning to the night, I consider it as breathing. (P4)

When I go away from the ICU for a while, I return more relaxed and patient. Patience vanishes at some point (P2)

Thanks to God my spouse always helps me. It is all his responsibility to ferry me to and from the job. I don't drive and he never complains about such things. At least, I don't waste time in commuting. (P5)

Sometimes so many troubles happen especially in the night shifts that keep you busy and you need an award. I don't know why but it eases the fatigue when I am hailed. (P11)

SOLUTIONS AND RECOMMENDATIONS

One of the leading findings of the study about ICU nurses is the effects of 24-hour shift-working on nurses' health. In particular, psychosomatic effects such as exhaustion, tension, impatience, sleep deprivation, stress, nervousness; and somatic effects such as disturbed sleep, foot and leg pain, joint pain, fatigue, asthenia have come to the fore. There are also findings in this direction in the studies of Yüzügüllü et al. (2018), Kavlu & Pınar (2009), Dall'ora et al. (2016), Min et al. (2019), and Özden et al. (2013). Considering its effect on family life and in accordance with the results of this study, it was stated that shift-working increases the time allocated to the family and therefore, it has positive effects in some studies in the literature (Crew, 2006; Gifkins et al., 2017). Similar to the findings of Yıldırım & Aycan (2008), Barnes (2011), and Jensen et al. (2018), negative effects such as guilt caused by not spending enough time with the family, rupture of family bonds, and conflict have also been found in this study. This result may be thought to stem from the big role of the mother in Turkish family culture. On the other hand, another finding is that shift-working also affects the time management of nurses. As

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Crew (2006) stated, the loss of the first day after the shift causes time pressure to establish business and social relations. On the other hand, gaining non-working days due to the shift-working was expressed as a positive effect by nurses (Nasrabadi et al. 2009; Alsharari, 2019). Accordingly, nurses have difficulties in establishing social relations. In addition, the economically positive effects of the shift stated by Crew (2006) were also reported by ICU nurses in this study.

It has been determined that ICU nurses use several strategies such as resting, co-worker support, the buddy system, a family support, being awarded and being away from job for a while to cope with the negativity experienced. The leading strategies in this study are resting, a co-worker support, and the buddy system. The findings of the study in this direction were similar to the findings of many previous studies (Gifkins et al., 2017; Savic et al., 2019; Thomson et al., 2017). When we consider that one of the leading themes in the personal effects of the shift is somatic health effects, the strategic use of resting can be understood better. In addition, a buddy is a responsible person who gives support in the care of the patients and also, he or she is a person to whom the patient can be safely delivered when it is not possible to be around the patient for any reason. The buddies have information about each other's patients. This situation is perceived as a reassuring behavior by the nurse who is in charge of the patient and it is used as an important informal coping strategy. It can be said that there are some factors such as critical care of ICU nurses to patients between life and death, professional environmental characteristics of them like ethical issues related to death (Alameddine, Dainty, Deber, & Sibbald, 2009), training of nurses in a collective cultural context (Hofstede, 2001). Nurses tend to have a dependent self-construct in accordance with this context that provides a basis for the buddy system. Interdependent self-construct involves a person seeing himself as part of a broad social relationship and it makes a large reference to the thoughts, feelings, and actions of other people with whom the person communicates (Markus & Kitayama, 1991). In response to their stressful and exhausting duties; ICU nurses have used more emotion-focused and approach-focused coping strategies and less problem-focused and evasive strategies (Lee, Tzeng, & Chinag, 2019; Lim et al., 2010) ICU nurses and unregistered health care assistants reported that (Gifkins et al., 2017), they are appreciated by their managers and patients and this situation highlights the personal motivation (Thomson et al., 2017), which represents cognitive coping that adopts a positive and necessary attitude towards shift-working (Savic et al, 2019); and they can go away from work by listening to music, watching TV and concentrating on things like mobile phones (Epstein, Soderström, Jirwe, Tucker, & Dahlgren, 2019).

It was found that the shift-working of ICU nurses has an effect on the professional environment of nurses. Accordingly, the factors such as increased the workload in night shifts, limited access to resources, or difficulty in access to the management are perceived differences in the professional environment between day and night shift. Indeed, a similar difference between night and day shifts was found in the study conducted by Da Silva et al. (2016) which suggests that the nurses highlight the care processes, institutional structure and workload resulting from the number of employees, and in Powell's study (2013) which states that they have difficulties in reaching specialists and providing material. In addition, the increase in communication with friends (buddy system) was seen as the positive effect of the shift on the professional environment. However, shift-related sleep deprivation, fatigue and stress may have negative effects on their relationships with their colleagues and as Thomson et al. (2017) stated, long periods of shift have a negative impact on employee fatigue. As a result, shift-working leads to less tolerance to colleagues and professionalism turns into exhaustion.

Generally, units in the hospital that are not very related to each other and have different educational background experience and expertise share the same floor, while the units with similar tasks and spe-

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cialties are located far from each other and this situation affects the shift negatively. Because nurses get help in difficult times from the nearest units. Such a structure makes it difficult for nurses to get support and it can be stressful for them. Knowing that they are close to their co-workers who are well-educated about the expertise that they need makes them feel more comfortable. In many studies, it has been stated that the control over shifts is a factor that shapes the effect of these shifts (Thomson et al., 2017), and it will reduce the difficulties of working in shifts if nurses have the opportunity to plan their own shifting schedules (Gifkins et al., 2017; Jensen et al., 2018). The effect of 24-hour shift on patient care among the ICU nurses was evaluated from two aspects: patient care quality, and continuous interaction and communication. In the interviews, the nurses stated that the poor quality of patient care that is because of the fatigue and sleep deprivation causes negative effects such as tension, medical. In contrast, they stated that continuous interaction and communication have positive effects such as obtaining detailed information about the patient, providing a sense of completing the care service, and establishing an emotional bond with the patient. The presence of positive and negative effects on patient care obtained from the study show similarities with the findings of previous studies. In these studies, negative effects were found as follows: longer and extended shifts increase medical errors (Clendon & Gibbons, 2015; Min et al., 2019); and they increase the risk of making mistakes as a result of a lack of sleep (Crew, 2006); and they also cause the poor treatment quality and forgotten treatment (Dall'Ora et al., 2016). Nurses' exhaustion reduces their tolerance to the patient and it causes them to approach their work routinely and triggers professionalism (Thomson et al., 2017). In contrast, ICU nurses (Ose, Tjønnås, Kaspersen, & Færevik, 2019) reported that 12-hour shifts or more have had positive effects on establishing emotional and natural relationships with patients due to the continuity of patient care and the completion of patient care-related tasks. And nurses also stated that they can watch their patients longer and uninterruptedly, and they have a sense of accomplishment by completing the task.

Practical Implications

Within the scope of the findings of this research, the close positioning of units that are interdependent in terms of organizational structure design can be suggested. Besides, spreading the application of the buddy system which is explained before as one of the effects of the shift on the professional environment and one of the informal coping strategies in all units and turning it into a formal form can be considered as another suggestion. In order to provide work-family balance, the implementation of a working system where nurses will increase their control power over the shift planning may be suggested.

FUTURE RESEARCH DIRECTIONS

This study reveals the effects of shift-working and the strategies to cope with these effects from the perspective of nurses. It is recommended that future studies investigate the effects of shift-working from the perspectives of spouses and children. However, a comparative research can also be conducted on nurses working with different shift systems at other units outside the ICU.

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LIMITATIONS

The findings should be considered under several limitations. Although there are many female nurses on a national scale, there are also male nurses. However, there were no male nurses in the study group. Another limitation of the research is the criterion taken into consideration in the formation of the working group. The research took into account only the experience of ICU nurses working in 24-hour shifts.

CONCLUSION

This study based on the experience of nurses working in ICUs in Turkey with a 24-hour shift reveals how nurses are affected by this kind of shift-working, and nurses' coping strategies to ease the negative effects of their shift-working. Interviews with nurses have shown that nurses handle shift-working in terms of themselves, their professional environment, and patient care.

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KEY TERMS AND DEFINITIONS

Buddy System in Nursing: The execution of nursing service by pairing an experienced nurse with an inexperienced nurse.

Coping With Shift: Coping strategies used by nurses to deal with the negativity of shift-working.

Intensive Care Unit: The unit where all the methods used to temporarily replace these functions of organs or organ systems that have partially or completely lost their functions and to treat the main causes of the disease are applied.

Patient Care: The service given to those who need care after an operation or surgery due to any health problem, who are bedridden, elderly or who cannot take care of themselves.

Shift Working: The work in the workplace by dividing the workers into two or three groups, in a way that the starting and exit times are consecutive.

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Chapter 17

The Efficiency of Nations in the Struggle Against the COVID-19 Pandemic

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ABSTRACT

This chapter aims to investigate the efficiency of nations in their struggle against the COVID-19 analysing data from June and December 2020 with a novel three-stage methodology. In the first stage, 107 nations were clustered into highly competitive, competitive, and non-competitive countries using their Global Competitiveness Index scores (World Economic Forum) to evaluate comparable countries in the second stage with the Data Envelopment Analysis. In the third stage, the relationship between countries' efficiency and performance in 66 variables published in the United Nations Human Development Report was investigated along with the long-debated aspect of a nation's political governance regime using Tobit regression. The worst performing highly competitive nations were USA and UK, competitive nations were Chile and Peru, and non-competitive nations were Brazil and Mozambique. Air pollution, international inbound tourists, urban population significantly reduced while domestic credit and gross national income per capita significantly increased efficiency, but the political regime did not affect it.

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INTRODUCTION

The COVID-19 crisis has caused unprecedented suffering across the world. Millions have become infected, and hundreds of thousands have lost their lives. Nations mobilised their health workers and infrastructure to curb the spread of the disease and cure the infected. A global pandemic has severe worldwide impacts influencing economic and living conditions of nations. It reduces the Gross National Product (GNP), restricts the life expectancies, and even prevents the students from getting an adequate education. On the last day of 2019, Chinese officials warned the World Health Organization (WHO) of pneumonia cases with an unknown cause in Wuhan City, Hubei, China. The International Committee on Taxonomy of Viruses announced the name of the new virus as the Severe Acute Respiratory Syndrome CoronaVirus 2 (SARS-CoV-2). On 11 February 2020, the WHO announced "COVID-19" as the name of this disease and declared the outbreak of COVID-19 a global pandemic on 11 March 2020 (WHO, n.d.).

COVID-19 is currently one of the most significant healthcare problems worldwide. As of 18 December 2020, the total confirmed number of cases is 75,371,570, and the death toll is 1,670,455 (Worldometer, 2022). There are still 107,229 people in serious or critical condition. The countries have not been able to stop the growth of the pandemic within their boundaries. In fact, Huang et al. (2020) use a novel deep neural network framework to forecast the COVID-19 outbreak in Germany, Italy, and Spain and show that there is a disproportionate burden across countries, suggesting that important factors positively or negatively influence the countries' attempts to respond to this pandemic.

This research aims to identify the efficiency of nations against the COVID-19 pandemic and determine the factors that affect their efficiency. Nations are initially clustered based on the twelve competitiveness pillars of the Global Competitiveness Index published by the World Economic Forum (WEF) (Schwab, 2019). Then, a Data Envelopment Analysis (DEA) output-oriented model with assurance region (Zanakis et al., 2007) is run separately for each cluster, taking health-related variables as inputs and COVID-19 response outcomes as outputs. Finally, the relationship between nations' performance in 66 variables published in the Human Development Report of the United Nations (Conceição, 2019) and COVID-19 response efficiency is estimated using Tobit regression (Zeng et al., 2016) to inform policies developed for each nation.

In fact, a country's ability to rapidly detect and isolate infected persons and cure them immediately could end the outbreak. Therefore, the DEA establishes international comparisons on the efficiency of nations to reduce the number of COVID-19 victims and inform nations to prepare for a similar pandemic in the future. For this purpose, the authors collected the data of 107 nations in June and December 2020 and investigated variations among nations in curbing the pandemic through their resources using a novel three-stage methodology. The authors initially clustered nations into highly competitive, competitive, and non-competitive nations to allow each country to be evaluated in a group of comparable countries. The authors found that the USA was the worst performer in the highly competitive nations cluster based on the data until June 2020, whereas the UK was the worst performer based on the data until December 2020. Chile was the worst performer in the competitive nations cluster based on the data until June 2020 while Peru is the worst performer based on the data until December 2020. Brazil was the worst performer in the non-competitive nations cluster based on the data until June 2020 but based on the data until December 2020, Mozambique has the lowest efficiency scores. Air pollution, international inbound tourists, urban population significantly reduce efficiency scores whereas domestic credit and gross national income per capita significantly increase efficiency. On the other hand, the political governance regime of a country does not affect its efficiency.

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The DEA is widely used in the performance analysis of healthcare systems. One of the primary reasons for this is related to its ability to consider multiple inputs and outputs to measure efficiency. The DEA categorises the evaluation criteria as inputs and outputs, where inputs represent the resources used, and outputs represent outcomes of resource transformation. The specification of efficient and inefficient units is based on a simple efficiency frontier analysis, and the model does not require any assumptions about the production function to be used between inputs and outputs. It does not require too much data and can use data with different measurement units simultaneously. Unlike other performance evaluation methods, the DEA does not require any subjective assignment of weights to each performance criterion to calculate an efficiency score. The optimal weights are calculated automatically for all inputs and outputs of each decision-making unit (DMU) by solving a linear programming model. In addition to an efficiency score, the DEA also identifies benchmark DMUs that can serve as a reference for underperforming ones to identify necessary improvements.

The rest of the paper is organised as follows. The second section provides the literature review on pandemic-related studies. The third section presents the proposed methodology. The fourth section presents the cluster analysis results, followed by the efficiency scores from the DEA output-oriented model with assurance region, and Tobit regression analysis results that explain the variation in the efficiency of nations in their struggle against the COVID-19 pandemic. Finally, the fifth section presents the discussion and conclusions.

BACKGROUND

Several researchers analysed the impact of global pandemic on countries' economies as well as the efficiency of national programmes in their fight against this pandemic. The search for efficiency and effectiveness in using resources for prevention, treatment, and care programmes to curb the pandemic has been an essential driver in recently published research. However, only a few studies assess and compare the efficiency of the countries in their ability to use their available resources to combat the pandemic (Santos et al., 2016). Many relevant previous studies focused on the Human Immunodeficiency Virus (HIV) Infection and Acquired Immune Deficiency Syndrome (AIDS) pandemics.

Verikios (2020) uses computable general equilibrium model using quarterly period data in 27 countries and 30 sectors in order to understand the impact of a pandemic and shows that the largest economic impacts are driven by reduced travel and tourism, and lost workdays. The analysis also highlights that travel and tourism reductions are more important in the influenza scenario and that lost workdays are more important in the coronavirus scenario.

To analyse the growth trends in the COVID-19 pandemic and fatalities in West Africa, Bankole et al. (2020) used cross-sectional data on the total reported cases of COVID-19 infection and the number of deaths for Burkina Faso, Ivory Coast, Niger, Ghana, Nigeria, and Senegal at intervals of seven days from 15 March through 19 April 2020. They concluded that the COVID-19 cases were underreported, and the region was not well prepared for the pandemic.

The risk factors associated with deaths from COVID-19 were investigated in four countries: The USA, Italy, Spain, and Germany (de Fátima Cobre et al., 2020). For this purpose, the data from the Institute for Health Metrics and Evaluation with projection information from January to August 2020 were used in a multivariate logistic regression to compare these countries in terms of the number of beds needed for the hospital services, the number of intensive care units (ICU) required, the number of ventilation devices

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needed, and the number of both hospital and ICU admissions due to COVID-19. The low number of both beds in ICU and ventilation devices available per day was associated with an increase of 100-fold in mortality from COVID-19 in all four evaluated countries.

An on-line survey with 4,624 Turkish citizens between 17 March and 1 April 2020 revealed the citizens' most preferable source of information (Geçer et al., 2020). Although the preferences depended on demographic factors such as age, educational attainment, and economic level, Internet journalism and social media were the most preferable sources of information. However, the use of only on-line survey made these results biased due to the fact that only respondents who had access to the Internet were able to respond.

The efficiency of countries in their fights against pandemics has been generally analysed through the DEA method. For example, the efficiency of HIV prevention services across nations was assessed using a DEA model on data from 2008, with five inputs and four outputs to compare the efficiency of 52 low- and middle- income countries in preventing mother-to-child HIV transmission (Santos et al., 2012). Results indicated that to prevent the infection of children, the resources should be used more effectively, and each nation should learn from its peers. A DEA output-oriented model was used to evaluate the efficiency of national HIV/AIDS programmes in transforming funding into services (Zeng et al., 2012). Then a Tobit model was implemented to identify the factors that influenced the efficiency in 68 low- and middle- income countries. A greater participation of civil society in policy making would increase the efficiency of the HIV/AIDS programmes. Similarly, an increase by approximately 40% in the gross national income of the lowest quartile countries would increase the efficiency of AIDS programmes by approximately 45%. A DEA input-oriented model was used to evaluate and compare 45 countries in terms of three types of gaps: performance, resource, and efficiency (Zeng et al., 2016). In line with Zeng et al. (2012), the efficiency of HIV/AIDS programmes should be assessed to reduce the resource needs for HIV/AIDS prevention.

The performance of the health system in 165 countries were evaluated using a refined version of the DEA: the value efficiency analysis (González et al., 2020). For this purpose, healthy life expectancy and disability-adjusted life years were used as health outcomes while health expenditure and education were treated as inputs. The analysis showed that the high-income OECD countries had higher efficiency and lower dispersion of efficiency scores. Additionally, the increase in public share of the health expenditure as well as the weight of health expenditure within the total public budget were found to influence the performance of the healthcare system positively. Also, the healthcare sector efficiency in rural Burkina Faso were analysed using DEA and Tobit to specify the basic reasons for inefficient performance (Marschall & Flessa, 2009). Only quantitative inputs and outputs were used and qualitative variables such as patients' perceptions of the quality of service as well as their satisfaction were not considered.

A DEA model was used to measure healthcare efficiencies of transition economies and then potential policy implications were discussed (Mirmirani et al., 2008), highlighting the importance of making changes in government policies, health education, and public awareness to reduce the absence of sound policies, rising social stress, and an unhealthy lifestyle. Zhao et al. (2020) evaluated the efficiency of Chinese hospitals at the macro and micro levels during 2011–2015 using the DEA. They used the number of hospitals, hospital staff, and hospital beds as input variables whereas the annual number of treatments and discharged patients, bed use, and the average length of hospitalisation as output variables and showed that although the hospital efficiency in China increased during this period there were geographical differences.

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The research on the efficiency of nations in their fight against the COVID-19 is scarce. One of the first papers analysed the most seriously affected countries' performance in terms of their contagion control and treatment of COVID-19 using the DEA (Shirouyehzad et al., 2020). Countries in which at least a month is passed after their first confirmed case of COVID-19 and have had at least 10 confirmed cases as of 25 March 2020 were included in the analysis as the population of the study. In the first stage, a DEA model with two inputs (population density and average of International Health Regulations Core Capacity Scores) and one output (the number of confirmed cases) was built. The solutions to this model were used as the contagion control efficiency for each country. In the second stage, another DEA model was built with one input, which was the number of confirmed cases, and two outputs, which were the number of recovered cases and the number of deaths. However, the analysis was conducted in a limited time period and, hence, the generalization of the results would be inappropriate. Additionally, the selection of the inputs and outputs was not based on scientific analysis. The efficiency of the countries in their fight against COVID-19 was also analysed using the confirmed case fatality rate and the confirmed case recovery rate as the main performance criteria (Jouzdani, 2020). The data were analysed utilising statistical confidence intervals implemented in Python. However, the author did not provide a comparison of the efficiency of the countries using the DEA.

A three-stage methodology based on data envelopment and machine learning algorithms was used to evaluate the performance of 142 countries in the struggle against the COVID-19 outbreak (Aydin & Yurdakul, 2020). Detailed analyses were performed using weighted stochastic data envelopment analysis, decision trees, and random forests. Aydin & Yurdakul (2020) found that 20 out of 142 countries were efficient and parameters such as the stringency index, diabetes prevalence, and the number of hospital beds have a remarkable effect on the fight against the COVID-19 pandemic while GDP, smoking rates, and the rate of diabetes patients did not have a significant impact. However, the authors also underlined that the impact of other factors such as air pollution, air travel, tourism intensity rates should also be analysed in further studies. Table 1 provides a summary of the literature covering the analysed topic, the method used, and the inputs and outputs selected for the DEA analyses if the DEA was used in the study.

As can be seen from the literature, the evaluation of countries in terms of their efficiency in controlling and preventing the pandemics are generally based on HIV/AIDS epidemics, and the DEA is selected for evaluating the efficiency of countries. The DEA is a method of measuring the relative efficiency of a group of DMUs where the relative weights of the variables are unknown. It accommodates multiple inputs and outputs. The DEA utilises the fundamental concept of a production function, and since it uses linear programming as a nonparametric technique, it does not require assumptions about the statistical properties of the variables (Retzlaff-Roberts et al., 2004). On the other hand, except the research conducted by Zanakis et al. (2007), the inputs and the outputs of DEA are generally arbitrarily selected, and there is no built-in test for their appropriateness. However, the selection of inputs and outputs directly influence the expression of DMUs as efficient and inefficient.

To address issues such as the comparability of DMUs, the authors initially performed a cluster analysis to produce meaningful peer sets of nations. Then, to be able to assess the efficiency of nations in their struggle against the COVID-19 pandemic, the authors selected health variables published by the World Bank as the inputs and the COVID-19 response variables as the outputs. The authors used a DEA output-oriented model with assurance region because it prevents extreme weighting divergences in input weights and output weights (Cooper et al., 2007). In line with the literature, the authors then regressed efficiency scores on variables relevant to human development to produce meaningful policies for nations in their struggle against the COVID-19.

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Table 1. The evaluation of nations in fighting against pandemics

Source	Scope	Method(s)	Input Variables	Output Variables	Countries
Zanakis et al. (2007)	Assessing each country's efficiency when fighting against the HIV/AIDS pandemic considering the influence of economic and social factors	Hypothesis Tests + Canonical Correlation + Stepwise Regression Models + DEA output-oriented model with assurance region	• Health system performance index with existing resources • Health private expenditure (% total health expenditure) • Health public expenditure tax-funded (%) • Doctors per capita • Nurses per capita • Adult literacy rate (% of the total adult population) • GNP per capita • Radios per capita	• Percentage of adults living with HIV/AIDS • HIV/AIDS cases per capita • AIDS-related death rate for adults and children	116
Mirmirani et al. (2008)	Newly independent states (former Soviet Union countries) and the Eastern European countries. compared to member countries of the Organisation for Economic Co-operation and Development (OECD)	Output oriented DEA Model (Charnes, Cooper Rhodes model)	• Per capita health care expenditure in U. S. dollars after adjustment for purchasing power parity • Number of inpatient hospital beds per thousand population • Number of physicians per thousand population • Immunizations (Proxy: the percentage of children with measles inoculation)	• The average male life expectancy • The average male female life expectancy • Infant mortality rates	8 countries + OECD average
Marschall & Flessa (2009)	Health care sector efficiency in rural Burkina Faso	DEA and Tobit model	• Personnel Costs • Area • Equipment Depreciation • Vaccine	• Number of General Consultation • Number of deliveries • Number of other care services • Number of vaccinations	1
Santos et al. (2012)	Using 2008 data, aimed to offer an updated overview of the efficiency of recent efforts in fighting against the HIV/AIDS epidemic carried out by Zanakis et al. (2007) who used data from 1998	DEA	• Prevention of mother-to-child HIV transmission domestic spending from public and international financing sources (million US$) • People aged 15 years and older who can, with understanding, both read and write a short simple statement on their everyday life (millions) • People living in urban areas (millions) • Total health expenditure (million US$) • Political stability and absence of violence/terrorism	• Reported number of pregnant women tested for HIV • Number of pregnant women living with HIV who received antiretrovirals for preventing mother-to-child transmission • Reported number of infants born to women living with HIV receiving antiretrovirals for preventing mother-to-child transmission; • Reported number of infants born to women living with HIV receiving co-trimoxazole prophylaxis within 2 months of birth	52
Zeng et al. (2012)	Evaluating the efficiency of HIV/AIDS programmes	DEA and Tobit model	• National HIV/AIDS spending (standardized expenditures into 2007 international dollars after adjusting for purchasing power parity and inflation)	• Volume of voluntary counselling and testing • Prevention of mother to child transmission Antiretroviral treatment	68
Zeng et al. (2016)	Estimated resource needs and decomposed the performance gap into efficiency gap and resource gap of 45 countries	Input oriented DEA Model	• National HIV/AIDS spending (2007 international dollars)	• Volume of voluntary counselling and testing • Prevention of mother to child transmission • Antiretroviral treatment	45
Aydin & Yurdakul (2020)	Assessing countries' performances against COVID-19	DEA Machine Learning Algorithms	• Total deaths • Stringency Index • Extreme Poverty • Covid-19 death rate • Diabetes prevalence • Female smokers • Male smokers	• Population • GDP • Hospital Beds • Total Recovered • Total test	142
Gonzalez et al. (2020)	The performance of the health system by using value-efficiency analysis	DEA	• Health expenditure • Education	• Healthy life expectancy • Disability-adjusted life years	165
Jouzdani (2020)	Evaluated the performance of countries' responses to the COVID-19	Confidence Interval	• Confirmed cases • Recovered cases • Deaths	• Confirmed Case Fatality Rate • Confirmed Case Recovery Rate	90
Shirouyehzad et al. (2020)	The efficiency of countries affected by COVID-19 was evaluated using their health system infrastructures and population density	First Step DEA Second Step DEA	• Population density • Average of 13 International Health Regulations Core Capacity Scores • Confirmed cases	• Confirmed cases • Deaths • Recovered cases	29
Zhao et al. (2020)	The efficiency of Chinese hospitals at the macro and micro levels during 2011–2015	DEA	• Number of Hospitals • Number of Hospital Staff • Number of Hospital Beds	• Annual Number of Treatments • Discharged Patients • Number of beds used • Average length of Hospitalization	1
This paper	COVID-19 Pandemic of 2020.	Cluster Analysis ↓ DEA ↓ Tobit Regression	12 pillars of the WEF Global Competitiveness Index for cluster analysis DEA Inputs: WEF data: Government Health Expenditure Percent, Private Health USD Base, Domestic Private Health Expenditure, Current Health Expenditure, hospital beds per 1K population for DEA DEA Outputs: OWID data: total cases, new cases, total deaths, new deaths, total cases per million, new cases per million, total deaths per million, new deaths per million Efficiency scores from DEA (dependent variables); Human Development Variables (66 variables from Human Development Report of the United Nations Development Programme), country cluster, and political regime tested as independent variables	Three clusters for nations COVID-19 Efficiencies Policies for nations in each cluster	107

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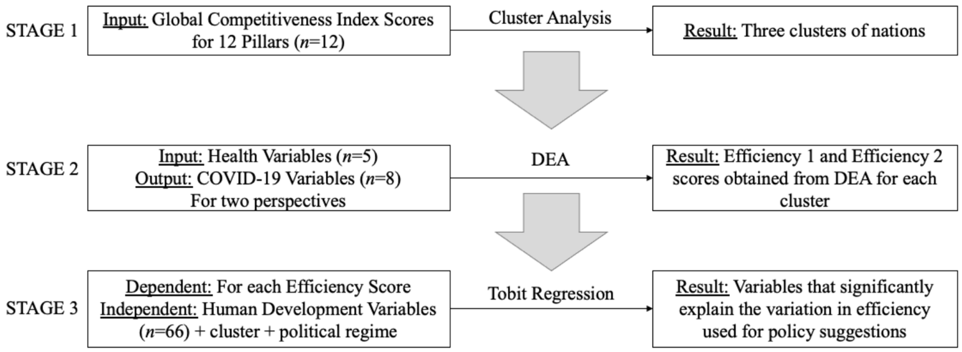
Figure 1. Proposed methodology repeated for June and December datasets



PROPOSED METHODOLOGY AND DATA

In this research, the authors used a three-step integrated methodology to analyse and compare the countries with respect to their efficiency in the struggle against the COVID-19 pandemic. To be able to work with a comparable set of nations to assess their efficiency in curbing the COVID-19 pandemic, the authors performed a cluster analysis in the first stage. Cluster analysis ensures that the set of nations within the cluster have comparable competitiveness performance. The authors then used the DEA output-oriented model with assurance region to avoid near-zero weights for some input variables which hinder the discriminatory power of the classical DEA output-oriented model. In selecting inputs for the nations, the authors considered two perspectives: the maximum number of new cases and the maximum number of new deaths while the authors extracted data for each country to consider variations in the spread of the disease. Finally, the authors applied Tobit regression to explain the variability in efficiency scores with independent variables that reflect a nation's position in achieving human development. The authors also considered the cluster effects and the long-debated concept of political governance regime. The authors used Tobit regression since the efficiency scores are bounded at 1. The proposed methodology for assessing the efficiency of nations in their struggle against the COVID-19 pandemic is presented in Figure 1.

For cluster analysis data in the first stage, the authors used the 12 pillars of the WEF's Global Competitiveness Index. The 12 pillars capture the attributes and qualities of an economy that allow effective use of factors of production (Schwab, 2019). These pillars are

1. Institutions,
2. Infrastructure,
3. Information and Communication Technology (ICT) adoption,
4. Macroeconomic stability,
5. Health,
6. Skills,
7. Product market,
8. Labour market,
9. Financial system,
10. Market size,
11. Business dynamism, and

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12. Innovation capability.

These 12 pillars are all rated on a 0-100 scale. For further explanation of the derivation of these scores, the authors refer the reader to the WEF Global Competitiveness Report (Schwab, 2019). The authors used a model-based approach to perform the cluster analysis, where each component of a finite mixture density is associated with a cluster and executed the analysis using the mclust package in R software (Scrucca et al., 2016). This package allows the modelling of data as a Gaussian finite mixture with different covariance structures and different numbers of mixture components, which captures the compactness, orientation, and shape of the clusters.

In the second stage, for health-related variables, the authors used the latest available WEF health data and selected variables to maximise the number of nations included in the analysis. For COVID-19 variables, the authors used the daily updated data from the Our World in Data (Ritchie et al., 2020), which collates data from reputable sources such as the European Centre for Disease Prevention and Control, World Health Organization, Johns Hopkins University, and national government reports.

As countries and territories around the world reported their first cases of COVID-19 on different days of 2020 varying from January to May and the global number of confirmed cases and deaths are still increasing as of December 2020, it would not be meaningful to compare nations' efficiencies based on the total number of cases on the same day for all nations. It would not be appropriate to take daily new cases on any given day, too. For example, China hit a milestone with no new local infections on 19 March 2020 while the coronavirus cases in the USA passed 10,000 on the same day.

On the other hand, the maximum numbers of cases are critical for hospitalisation due to the capacities of doctors, nurses, beds, and ICUs. For instance, Liu et al. (2020) estimated the maximum values of cases of COVID-19 around the world. Juranek & Zoutman (2020) analysed the effectiveness of social distancing measures on the spread of COVID-19 in Scandinavian countries, and they focused on the maximum number of hospitalisations and ICU patients. Zhan et al. (2020) estimated the maximum cases of the global pandemic for South Korea, Italy, and Iran. Casares and Khan (2020) built a model that analysed the effect of isolation measure on the delay of the peak day of COVID-19. Therefore, in this study, to be able to derive meaningful comparisons of nations, the authors used eight COVID-19 variables in two perspectives:

1. values on the day the nation observed the maximum number of new cases (Perspective 1) and
2. values on the day the nation observed the maximum number of new deaths (Perspective 2).

Hence, the authors ran the DEA output-oriented model with assurance region six times, once for each cluster based on Perspective 1 and then Perspective 2. The authors referred to the efficiencies calculated from each perspective as Efficiency 1 and Efficiency 2, respectively. The DEA output-oriented model finds the optimal output and input weights for each nation to maximise the nation's weighted output while using no more than the number of inputs observed for all nations. The DEA output-oriented model with assurance region imposes lower (L) and upper (U) bounds on the ratios of two input weights to avoid questionable results with a single input or few inputs with positive weights in a nation's optimal solution. The lower and the upper bounds are also imposed on the ratios of two output weights.

The mathematical model of the DEA output-oriented model with assurance region (Cooper et al., 2007) is as follows. In a problem with n DMUs, m inputs, and s outputs, x_{in} denotes the value of the

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i^{th} input for the n^{th} DMU ($i = 1,\ldots,M, n = 1,\ldots,N$). Similarly, y_{kn} denotes the k^{th} output of the n^{th} DMU ($k = 1,\ldots,S, n = 1,\ldots,N$). Finally, μ_s denotes the weight of the output s and ν_m denotes the weight of the input m. The following DEA output-oriented model with assurance region is solved for each DMU o to find its efficiency.

$$\max_{\mu,\nu} \theta = \mu_1 y_{1o} + \ldots + \mu_s y_{so} \tag{1}$$

subject to

$$\nu_1 x_{1o} + \ldots + \nu_m x_{mo} = 1 \tag{2}$$

$$\mu_1 y_{1n} + \ldots + \mu_s y_{sn} \leq \nu_1 x_{1n} + \ldots + \nu_m x_{mn} \left(n = 1,\ldots,N\right) \tag{3}$$

$$L \times \nu_i \leq \nu_j \forall i, j \in M, i < j \tag{4}$$

$$\nu_j \leq U \times \nu_i \forall i, j \in M, i < j \tag{5}$$

$$L \times \mu_i \leq \mu_j \forall i, j \in S, i < j \tag{6}$$

$$\mu_j \leq U \times \mu_i \forall i, j \in S, i < j \tag{7}$$

$$\nu_1, \nu_2, \ldots, \nu_m \geq 0 \tag{8}$$

$$\mu_1, \mu_2, \ldots, \mu_s \geq 0 \tag{9}$$

Eq. 1 is the objective function to maximise the efficiency of DMU o. Eq. 2 ensures the weighted sum of inputs is equal to 1 (input unity) for the DMU in question (DMU o). Eq. 3 is the ratio between the inputs and the outputs for each DMU. Eq. 4 is the lower bound of the ratios of input weights and Eq. 5 is the upper bound of the ratios of input weights. In a similar vein, Eq. 6 and Eq. 7 are the lower and the upper bounds of the ratios of output weights. Finally, Eq. 8 and Eq. 9 are the non-negativity constraints.

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From five input variables (h1-h5) the model has $n \times (n-1) = 5 \times 4 = 20$ constraints to manage the ratios of the weights of two inputs and from eight output variables (c1-c8 for Perspective 1 and d1-d8 for Perspective 2) the model has $8 \times 7 = 56$ constraints to manage the ratios of the weights of two outputs in the assurance region extension of the DEA output-oriented model.

Finally, in the third stage, Tobit regression models were built to explain the variability in Efficiency 1 and Efficiency 2 using 66 variables published in the Human Development Report (Conceição, 2019) as well as the country cluster from Stage 1 and the political governance regime of the country as independent variables. For this purpose, regression models were built from a set of candidate predictor variables by entering and removing predictors based on *p*-values, in a stepwise manner until there is no variable left to enter or remove for Efficiency 1 and Efficiency 2 separately. The full list of these variables is given in Appendix B. For brevity, the authors report in Table 2, only those that were identified as significant to explain the variation in Efficiency 1 and Efficiency 2 scores. The authors report the descriptive statistics of these variables in the Results section.

Table 2. Variables used in the methodology and their definitions and respective stages

Variable	Definition	Stage	Variable	Definition	Stage
p1	Institutions	1	h5	Hospital beds (per 1,000 people)	2
p2	Infrastructure	1	c1, d1	Total number of cases	2
p3	ICT Adoption	1	c2, d2	Number of new cases	2
p4	Macroeconomic stability	1	c3, d3	Total number of deaths	2
p5	Health	1	c4, d4	Number of new deaths	2
p6	Skills	1	c5, d5	Total number of cases per million	2
p7	Product market	1	c6, d6	Number of new cases per million	2
p8	Labour market	1	c7, d7	Total number of deaths per million	2
p9	Financial system	1	c8, d8	Number of new deaths per million	2
p10	Market size	1	cluster	Cluster of the nation from Stage 1	3
p11	Business dynamism	1	regime	Political regime	3
p12	Innovation capability	1	airp	Mortality rate attributed to household and ambient air pollution	3
h1	Domestic general government health expenditure (% of current health expenditure)	2	tourist	International inbound tourists	3
h2	Domestic private health expenditure per capita (current US$)	2	urban	Urban population	3
h3	Domestic private health expenditure (% of current health expenditure)	2	fincredit	Domestic credit provided by the financial sector	3
h4	Current health expenditure per capita (current US$)	2	gni	Gross national income (GNI) per capita	3

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RESULTS

Country Clusters

The cluster descriptive statistics of the WEF pillars is given in Table 3. The first four pillars, namely, Institutions, Infrastructure, ICT Adoption, and Macroeconomic Stability are considered as Enabling Environment (Schwab, 2019).

Table 3. Descriptive statistics of cluster analysis input variables

WEF Pillar	Min	Max	Mean	Standard Deviation
Institutions	25.72	81.22	57.13	11.80
Infrastructure	26.88	95.45	69.64	14.98
ICT Adoption	20.12	92.84	58.83	18.12
Macroeconomic Stability	0.00	100.00	83.00	17.54
Health	33.14	100.00	79.68	15.63
Skills	30.25	86.72	64.55	13.33
Product Market	36.42	81.21	56.51	8.23
Labour Market	41.33	81.23	60.50	8.90
Financial System	38.73	91.27	64.94	13.55
Market Size	32.27	100.00	59.02	15.66
Business Dynamism	14.07	84.21	62.12	10.84
Innovation Capability	18.90	86.83	46.34	17.10

In terms of Institutions pillar, Venezuela is the worst performer and Finland is the best performer. When it comes to Infrastructure pillar, Haiti is at the bottom of the list whereas Singapore is at the top. The picture shifts to Ethiopia and Korea as the worst and the best performers for ICT Adoption pillar. Venezuela is again the worst performer in Macroeconomic Stability pillar whereas 30 countries scored 100 in this pillar.

The next two pillars, Health and Skills are considered as pillars that represent the Human Capital of a nation (Schwab, 2019). In the Health pillar, the worst performer is Mozambique, and the best performers are Spain, Japan, and again Singapore with a full score of 100. Mozambique is again at the bottom in the Skills pillar whereas Switzerland is the highest performer for this pillar.

The next four pillars, namely Product Market, Labour Market, Financial System, and Market Size represent the overarching concept of Markets (Schwab, 2019). In terms of the Product Market pillar, Venezuela is once more at the bottom and Singapore is again at the top. The picture changes a bit for the Labour Market pillar, where the worst performer is Iran this time while the top performer is still Singapore. In terms of the Financial System pillar, the worst and the best performer couple is again Venezuela and Singapore. The bottom and the top performers change for the Market Size pillar, where this time Iceland is at the bottom and China is at the top.

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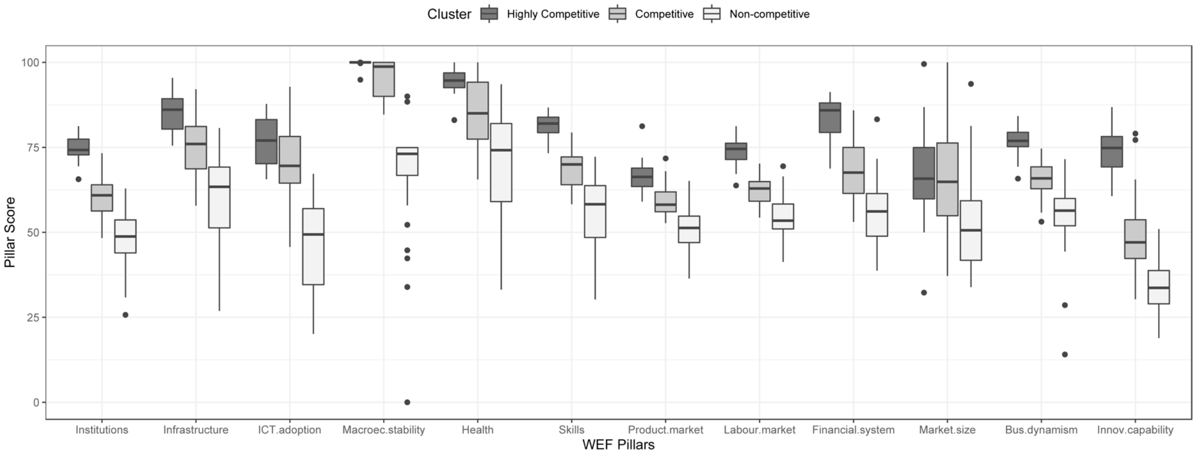
The last four pillars, Business Dynamism and Innovation Capability represent the Innovation Ecosystem of a nation (Schwab, 2019). The worst and best performers for the Business Dynamism pillar are Haiti and the USA, respectively. The picture does not change much for the Innovation Capability pillar, where the worst performer is still Haiti, but the best performer is Germany.

Cluster analysis suggested three clusters. Significant differences exist between clusters across WEF competitiveness pillars (see boxplots of the performance of nations in each pillar in Figure 2). Hence, these three clusters are named as highly competitive, competitive, and non-competitive as was suggested in Onsel et al. (2008).

Figure 2. Performance comparison of nations in each cluster across 12 WEF pillars



In Figure 2, highly competitive nations cluster has 20 countries, competitive nations cluster has 33 countries, and non-competitive nations cluster has 54 countries. The cluster analysis model separates the nations into three meaningful groups where the nations in the non-competitive cluster perform worse than the nations in the competitive and the highly competitive clusters in all of the pillars. Highly competitive nations perform better than competitive nations across all pillars except market size and ICT adoption. Table 4 presents the best and the worst performers of each pillar in each cluster.

Although in Table 4, the authors report the best and the worst performer for each pillar in each cluster, for some pillars, there are multiple best performers. For example, for Macroeconomic Stability, 16 countries score 100 in the highly competitive nations cluster, and three nations (Singapore, the USA, and Ireland) score above 99. The worst performer, Japan, still scores quite high, at 94.89. For highly competitive countries, there is not a difference in performance under the macroeconomic stability pillar. The two highly competitive countries that score 100 in the Health pillar are Japan and Singapore.

Similar to the highly competitive nations cluster; 14 nations (Peru, Chile, Poland, the Czech Republic, Slovenia, the Slovak Republic, Saudi Arabia, Kuwait, Malta, Estonia, Latvia, Lithuania, the United Arab Emirates, Korea) in the competitive nations cluster have Macroeconomic Stability at 100. Two nations share the lowest performance in Product Market: Colombia and the Slovak Republic.

In the non-competitive nations cluster, five nations score the highest in Macroeconomic Stability: India, Morocco, Panama, Croatia, and Hungary. Venezuela is ranked the worst in four pillars, Haiti is

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Table 4. Best and worst performers by cluster

WEF Pillar	Highly Competitive		Competitive		Non-competitive	
	min	max	min	max	min	max
Institutions	64.64 Israel	81.22 Finland	48.29 Mexico	73.26 UAE	25.72 Venezuela	62.90 Bahrain
Infrastructure	75.53 New Zealand	95.45 Singapore	57.83 Philippines	92.09 Korea	26.88 Haiti	80.68 Hungary
ICT Adoption	65.63 Austria	87.78 Sweden	45.7 Peru	92.84 Korea	20.12 Ethiopia	67.19 Bahrain
Macroeconomic Stability	94.89 Japan	100 (16 nations)	84.66 Italy	100 (14 nations)	0.00 Venezuela	90 (5 nations)
Health	83.02 United States	100 (2 nations)	65.58 Philippines	100 Spain	33.14 Mozambique	93.54 Greece
Skills	73.28 Japan	86.72 Switzerland	58.25 Mexico	79.36 Estonia	30.25 Mozambique	72.25 Argentina
Product Market	59.03 Iceland	81.21 Singapore	52.70 (2 nations)	71.74 UAE	36.42 Venezuela	65.11 Bahrain
Labour Market	63.78 Belgium	81.23 Singapore	54.35 Kuwait	70.23 Estonia	41.33 Iran	69.44 Azerbaijan
Financial System	68.77 Ireland	91.27 Singapore	53.07 Kazakhstan	85.87 France	38.73 Venezuela	83.25 S. Africa
Market Size	32.27 Iceland	99.53 United States	37.16 Malta	100 China	33.92 Haiti	93.67 India
Business Dynamism	65.79 Luxembourg	84.21 United States	53.12 Saudi Arabia	74.63 Malaysia	14.07 Haiti	71.52 Azerbaijan
Innovation Capability	60.65 New Zealand	86.83 Germany	30.30 Kuwait	70.47 Korea	18.90 Haiti	50.94 India

ranked the worst in three pillars, and Mozambique is ranked the worst in two pillars. On the other hand, Bahrain is ranked the first in three pillars, Azerbaijan and India each ranked the first in two pillars.

The clustering analysis in this stage produced meaningful clusters to run the DEA in the second stage where nations are compared to their peers in terms of their performance in the 12 pillars of competitiveness. To avoid repetition, the full list of countries in each cluster is presented in the next subsection on Stage 2 results along with their efficiency scores in Tables 13-15 in Appendix A.

Efficiencies of Countries

Descriptive statistics of the data for the DEA output-oriented model with assurance region are given in Table 5. The input data of health variables is downloaded from the WEF, and the output data of the COVID-19 variables is from Our World in Data's GitHub repository (Appel et al., 2022). At the table, the input variables are abbreviated as h1-h5. On the other hand, in Perspective 1, the output variable abbreviations (jc1-jc8) represent the values on the day the nation observed the maximum number of new cases until 15 June 2020, and the abbreviations (dc1-dc8) represent the values on the day the nation observed the maximum number of new cases until 17 December 2020. Finally, in Perspective 2, the output variable abbreviations (jd1-jd8) represent the values on the day the nation observed the maximum

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Table 5. Descriptive statistics of DEA input and output variables

var	Highly Competitive				Competitive				Non-competitive			
	min	Max	mean	sd	min	max	mean	sd	min	max	mean	sd
h1	30	85	72	14	32	87	64	13	12	88	46	19
h2	663	6920	1616	1556	58	1003	398	287	2	601	142	143
h3	14	47	23	9	13	66	35	13	9	85	47	19
h4	2619	10246	5405	1973	115	4380	1240	939	21	1517	347	367
h5	2	13	4	3	1	12	4	3	0	9	2	2
jc1	647	939053	64392	207088	295	221344	41217	59879	212	498440	28655	81245
jc2	95	48529	4106	10674	36	15141	2763	3932	40	33274	1872	5030
jc3	1	53189	4061	11908	0	16448	1471	3073	0	28834	1042	4088
jc4	0	2172	190	504	0	795	109	208	0	956	40	140
jc5	53	4040	1424	1180	24	19181	1760	3657	8	10149	899	1692
jc6	11	374	137	98	4	817	100	154	2	654	67	128
jc7	0	450	78	129	0	174	29	45	0	136	18	29
jc8	0	24	4	6	0	14	2	4	0	5	1	1
jd1	432	639664	57465	142825	124	387623	46620	78811	115	614932	29076	93310
jd2	8	30148	2208	6664	3	8875	1832	2781	2	30916	1416	4516
jd3	2	30985	3590	7933	3	11728	1813	3209	1	34021	1130	4745
jd4	2	4928	406	1098	2	2004	242	480	1	1473	68	213
jd5	74	5224	1676	1353	18	24949	1961	4437	5	10149	772	1574
jd6	2	290	59	66	0	597	73	125	0	628	40	90
jd7	0	298	85	94	0	214	37	53	0	160	19	33
jd8	0	47	11	13	0	34	5	8	0	23	2	4
dc1	797	16964180	1127171	3749241	314	2439163	357422	548394	480	7040608	382114	1182256
dc2	89	247403	21743	54250	41	106091	13813	21208	155	823225	22205	112227
dc3	1	307429	21777	68319	1	81877	10304	18518	16	183735	8045	27725
dc4	0	3656	295	822	0	2789	224	498	0	1132	107	224
dc5	165	51251	17626	14767	9	35364	12489	9497	8	46340	11167	13056
dc6	18	3142	824	910	3	1672	570	488	3	9761	510	1338
dc7	0	976	299	324	0	775	222	234	0	864	186	230
dc8	0	15	5	5	0	22	6	7	0	111	5	15
dd1	1366	16964180	1005975	3769103	143	2574319	364159	558249	414	4657702	252699	685324
dd2	17	247403	16046	54972	15	28206	6477	8686	30	66338	4657	10074
dd3	9	307429	19066	68185	5	81877	11244	19031	14	139808	5992	19782
dd4	2	3656	388	833	2	4143	513	903	3	3351	256	599
dd5	283	63959	15292	19713	28	42299	13882	12830	8	46878	11002	13087
dd6	3	2494	353	592	0	1672	313	358	1	1763	238	336
dd7	2	929	248	279	0	960	284	300	0	971	195	236
dd8	0	45	14	14	0	126	16	24	0	142	12	26

INPUTS h1: Domestic general government health expenditure (% of current health expenditure), h2: Domestic private health expenditure per capita (current US$), h3: Domestic private health expenditure (% of current health expenditure), h4: Current health expenditure per capita (current US$), h5: Hospital beds (per 1,000 people)

OUTPUTS based on max number of new cases jc1, dc1: Total number of cases, jc2, dc2: Number of new cases, jc3, dc3: Total number of deaths, jc4, dc4: Number of new deaths, jc5, dc5: Total number of cases per million, jc6, dc6: Number of new cases per million, jc7, dc7: Total number of deaths per million, jc8, dc8: Number of new deaths per million

OUTPUTS based on max number of new deaths jd1, dd1: Total number of cases, jd2, dd2: Number of new cases, jd3, dd3: Total number of deaths, jd4, dd4: Number of new deaths, jd5, dd5: Total number of cases per million, jd6, dd6: Number of new cases per million, jd7, dd7: Total number of deaths per million, jd8, dd8: Number of new deaths per million

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number of new deaths until 15 June 2020, and the abbreviations (dd1-dd8) represent the values on the day the nation observed the maximum number of new deaths until 17 December 2020.

A few interesting observations can be made for each cluster. In the highly competitive nations cluster (Table 5, left four columns); for h1, domestic general government health expenditure (% of current health expenditure), the highest value (85.47) is observed in Norway and the lowest value (30.49) is observed in Switzerland; for h2, domestic private health expenditure per capita (current US$), the highest value (6920.31) is observed in Switzerland and the lowest is value (663.18) is observed in Japan; for h3, domestic private health expenditure (% of current health expenditure), the highest value (47.13) is observed in Singapore and the lowest value (13.79) is observed in Luxembourg; for h4, current health expenditure per capita (current US$), the highest value (10246.14) is observed in the USA, and the lowest value (2618.71) is observed in Singapore; and for h5, hospital beds (per 1,000 people), the highest value (13.05) is observed in Japan, whereas the lowest value (2.22) is observed in Sweden.

In the competitive nations cluster (Table 5, middle four columns), on the other hand; for h1, the highest value (87.39) is observed in Kuwait, and the lowest value (31.91) is observed in the Philippines; for h2, the highest value (1003.31) is observed in France, and the lowest value (58.41) is observed in Thailand; for h3, the highest value (65.5) is observed in the Philippines, and the lowest value (12.62) is observed in Kuwait; for h4, the highest value (4379.73) is observed in France, and the lowest value (114.97) is observed in Indonesia; and for h5, the highest value (12.27) is observed in Korea whereas the lowest value (1) is observed in the Philippines.

Finally, in the non-competitive nations cluster (Table 5, right four columns); for h1, the highest value (87.87) is observed in Oman, and the lowest value (11.86) is observed in Haiti; for h2, the highest value (601.21) is observed in Greece, and the lowest value (1.89) is observed in Mozambique; for h3, the highest value (85.47) is observed in Armenia, and the lowest value (8.96) is observed in Mozambique; similar to h2, for h4, the highest value (1516.59) is observed in Greece whereas the lowest value (21.07) is observed in Mozambique; and for h5, the highest value (8.80) is observed in Ukraine and the lowest value (0.10) is observed in Mali.

In a similar vein, as can be seen in Table 6, the authors report the highest and the lowest-performing countries in variables jc1-jc8 and dc1-dc8 for Perspective 1 calculations and jd1-jd8 and dd1-dd8 for Perspective 2 calculations. The last row of the table represents the number of different countries (Frequency row) in each column.

In the highly competitive nations cluster, there are five best performers in the COVID-19 output variables (the minimum of the variable) based on the data until June 2020. New Zealand has the lowest records in six outputs (jc1-jc3, jc7, jd2, and jd6) while Singapore in four outputs (jd1, jd3, jd5, and jd7); Australia in three outputs (jc4, jc8, and jd8); Japan in two outputs (jc5 and jc6); and Iceland in one output (jd4) have the lowest records. Based on the data until December 2020, four countries have the lowest records, namely New Zealand in 11 outputs (dc1-dc3, dc5-dc7, dd1-dd3, dd5, and dd7); Singapore in two outputs (dd4 and dd8), Iceland in two outputs (dc4 and dc8), and Australia in one output (dd6).

Regarding to the worst performers of the highly competitive nations cluster in the COVID-19 output variables (the maximum of the variable), based on the data until June 2020, there are seven countries in the list. The USA has the highest records in eight outputs (jc1-jc4 and jd1-jd4). In two outputs each, Luxembourg (jc6 and jd5) and Sweden (jc5 and jc7) have the highest records. The highest records belong to Belgium in jc8, to Iceland in jd6, to the UK in jd7, and to Ireland in jd8. Based on the data until December 2020, the number of countries in the worst performers list drops to five, namely the USA in 10 outputs (dc1-dc5, dd1-dd4, and dd7); Luxembourg in three outputs (dc6, dd5, and dd6); and Belgium,

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Table 6. The best and the worst performers of COVID-19 output variables by cluster

COVID-19	**Highly Competitive**		**Competitive**		**Non-competitive**	
	min	**max**	**min**	**max**	**min**	**max**
jc1	New Zealand	United States	Uruguay	Russia	Jordan	Brazil
jc2	New Zealand	United States	Uruguay	China	Jordan	Brazil
jc3	New Zealand	United States	Latvia	Mexico	Jordan	Brazil
jc4	Australia	United States	Estonia	Italy	Cameroon	Brazil
jc5	Japan	Sweden	Thailand	Qatar	Tanzania	Bahrain
jc6	Japan	Luxembourg	Thailand	Qatar	Mozambique	Ecuador
jc7	New Zealand	Sweden	Latvia	Chile	Jordan	Brazil
jc8	Australia	Belgium	Estonia	Spain	Cameroon	Brazil
jd1	Singapore	United States	Cyprus	Russia	Sri Lanka	Brazil
jd2	New Zealand	United States	Malta	Peru	Costa Rica	Brazil
jd3	Singapore	United States	Cyprus	Mexico	Sri Lanka	Brazil
jd4	Iceland	United States	Malta	France	Sri Lanka	Brazil
jd5	Singapore	Luxembourg	Indonesia	Qatar	Sri Lanka	Bahrain
jd6	New Zealand	Iceland	China	Qatar	Costa Rica	Bahrain
jd7	Singapore	United Kingdom	Thailand	Spain	Mozambique	Brazil
jd8	Australia	Ireland	Thailand	Chile	Mozambique	Ecuador
dc1	New Zealand	United States	Mauritius	Russia	Tanzania	Brazil
dc2	New Zealand	United States	Mauritius	France	Mali	Turkey
dc3	New Zealand	United States	Thailand	Mexico	Tanzania	Brazil
dc4	Iceland	United States	Kazakhstan	Mexico	Ghana	India
dc5	New Zealand	United States	Thailand	Czech Rep.	Tanzania	Panama
dc6	New Zealand	Luxembourg	Thailand	Lithuania	Tanzania	Turkey
dc7	New Zealand	Belgium	Thailand	Spain	Tanzania	Brazil
dc8	Iceland	Sweden	Kazakhstan	Mexico	Ghana	Kyrgyzstan
dd1	New Zealand	United States	Mauritius	Russia	Burkina Faso	Brazil
dd2	New Zealand	United States	Mauritius	Russia	Burkina Faso	Brazil
dd3	New Zealand	United States	Mauritius	Mexico	Guinea	Brazil
dd4	Singapore	United States	Mauritius	Peru	Guinea	Argentina
dd5	New Zealand	Luxembourg	Thailand	Slovenia	Tanzania	Georgia
dd6	Australia	Luxembourg	China	Lithuania	Burkina Faso	Kyrgyzstan
dd7	New Zealand	United States	Thailand	Italy	Tanzania	Macedonia
dd8	Singapore	Ireland	Thailand	Peru	Tanzania	Bolivia
Frequency	5	7	10	12	10	11

OUTPUTS based on max number of new cases jc1, dc1: Total number of cases, jc2, dc2: Number of new cases, jc3, dc3: Total number of deaths, jc4, dc4: Number of new deaths, jc5, dc5: Total number of cases per million, jc6, dc6: Number of new cases per million, jc7, dc7: Total number of deaths per million, jc8, dc8: Number of new deaths per million

OUTPUTS based on max number of new deaths jd1, dd1: Total number of cases, jd2, dd2: Number of new cases, jd3, dd3: Total number of deaths, jd4, dd4: Number of new deaths, jd5, dd5: Total number of cases per million, jd6, dd6: Number of new cases per million, jd7, dd7: Total number of deaths per million, jd8, dd8: Number of new deaths per million

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Sweden, and Ireland in one output each (dc7, dc8, and dd8, respectively). Iceland and the UK are no longer in the worst performers list.

In the competitive nations cluster, there are eight best performers in the COVID-19 output variables based on the data until June 2020: Thailand in four outputs (jc5, jc6, jd7, jd8); Uruguay in two outputs (jc1, jc2); Latvia in two outputs (jc3, jc7); Estonia in two outputs (jc4, jc8); Cyprus in two outputs (jd1, jd3); Malta in two outputs; and Indonesia and China in one output each (jd5 and jd6, respectively). Based on the data until December 2020, the best performers list consists of just four countries. Thailand has the lowest records in seven outputs (dc3, dc5-dc7, dd5, dd7, and dd8). Mauritius enters the best-performing countries list in six outputs (dc1, dc2, and dd1-dd4) and Kazakhstan enters the list in two outputs (dc4 and dc8). China is still the best performer in the 6th output of Perspective 2 (dd6).

There are nine countries in the worst performers of competitive nations cluster, based on the data until June 2020, namely, Qatar in four outputs (jc5, jc6, jd5, jd6); Russia in two outputs (jc1, jd1); Mexico in two outputs (jc3, jd3); Chile in two outputs (jc7, jd8); Spain in two outputs (jc8, jd7); and China, Italy, Peru, and France in one output each (jc2, jc4, jd2, and jd4, respectively). Based on the data until December 2020, the worst performers are still nine countries but instead of Qatar, Chile, and China, there are three new countries in the list, namely the Czech Republic, Lithuania, and Slovenia. Mexico performs worst in four outputs (dc3, dc4, dc8, dd3) while Russia in three outputs (dc1, dd1, and dd2), Peru in two outputs (dd4 and dd8), and Lithuania in two outputs (dc6 and dd6). In the list Italy, Spain, France, the Czech Republic, and Slovenia performs worst in one output (dd7, dc7, dc2, dc5, and dd5, respectively).

Finally, in the non-competitive nations cluster, the best performers of the COVID-19 output variables based on the data until June 2020 are six countries as follows: Jordan in four outputs (jc1-jc3, jc7); Sri Lanka in four outputs (jd1, jd3-jd5); Mozambique in three outputs (jc6, jd7, jd8); Cameroon in two outputs (jc4, jc8); Costa Rica in two outputs (jd2, jd6); and Tanzania in one output (jc5). Based on the data until December 2020, there are five countries in the list. Except Tanzania that has the lowest records in eight outputs (dc1, dc3, dc5-dc7, dd5, dd7, and dd8) at this time, four new countries become best performers: Burkina Faso in three outputs (dd1, dd2, dd6), Ghana in two outputs (dc4, dc8), Guinea in two outputs (dd3, dd4), and Mali in one output (dc2).

Three countries are the worst performers of the non-competitive nations cluster, based on the data until June 2020: Brazil in 11 outputs (jc1-jc4, jc7, jc8, jd1-jd4, and jd7), Bahrain in three outputs (jc5, jd5, and jd6), and Ecuador in two outputs (jc6 and jd8). Based on the data until December 2020, Brazil performs worst in six outputs (dc1, dc3, dc7, dd1-dd3). Besides Brazil, there are eight more countries in the list: Turkey in two outputs (dc2, dc6); Kyrgyzstan in two outputs (dc8, dd6); India, Panama, Argentina, Georgia, Macedonia, and Bolivia in one output each (dc4, dc5, dd4, dd5, dd7, and dd8, respectively).

Totally, the numbers of the highly competitive countries performing best and worst in COVID-19 output variables are five and seven, respectively. For competitive countries, these figures are 10 and 12; for non-competitive ones, 10 and 11. Compared to the highly competitive nations cluster, the worst and the best performers in the competitive nations cluster as well as non-competitive nations cluster are more varied.

The authors converted each input (h1-h5) and output (jc1-jc8 and dc1-dc8 for Perspective 1; and jd1-jd8 and dd1-dd8 for Perspective 2) variable to standardized scores ([value – mean] / standard deviation) to avoid scaling problems in DEA (Zanakis et al., 2007). Thus, large positive standardized numbers imply worse COVID-19 performance. For example, in June 2020, in the highly competitive nations cluster, the UK's total number of cases in Perspective 1 (jc1) is 0.07 standard deviations above the mean whereas

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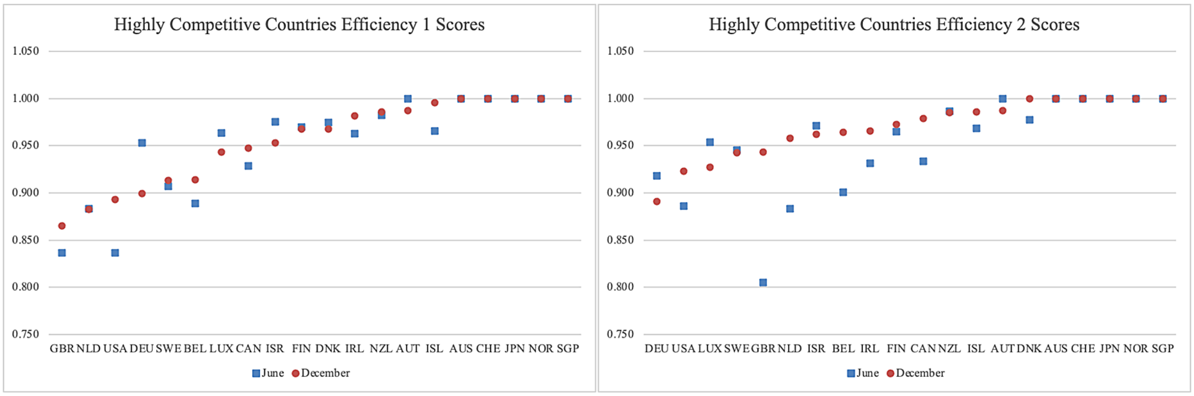
Finland's total number of cases in the same period and perspective (jc1) is 0.50 standard deviations below the mean.

To avoid negative signs in DEA, standard values were subtracted from 5 for highly competitive nations, 6 for competitive nations, and 7 for non-competitive nations clusters in the models built using the data until June 2020. In a similar vein, the standard values were subtracted from 5, 6, and 8 for highly competitive, competitive, and non-competitive nations in the models built using the data until December 2020. These values were chosen so that the maximum value in the standardized dataset for each cluster was slightly less than the selected number. This transformation also changed the directions from the minimum COVID-19 rates with more resources to the maximum outputs with same or less input (shortages), thus complying with the DEA directive. A problem in DEA output-oriented model with assurance region is to determine the values for the lower and the upper bounds on the ratios of two input weights and two output weights (for each combination of two weights). The standardised scores of the inputs and the outputs ranged from -2.87 to 7.14, so the authors selected a k-fold range (Zanakis et al., 2007) where $k = 2.87 + 6.93 = 10.01$ and hence used $L = 0.1$ and $U = 10$.

Table 13 in Appendix A shows Perspective 1 and Perspective 2 efficiency scores of highly competitive countries obtained based on the data until June and December 2020. Tables 14 and 15 in Appendix A show the efficiency scores of competitive and non-competitive countries, respectively.

Figure 3a and Figure 3b show the countries and their efficiency scores in Perspective 1 and Perspective 2 respectively, sorted by the efficiency scores obtained in December 2020 for highly competitive countries. As can be seen in Figure 3a (for detail please see Table 13 in Appendix A), the top performers of the highly competitive nations cluster in both perspectives are Australia, Austria, Switzerland, Japan, Norway, and Singapore based on the data until June 2020. Based on the data until December 2020, among these countries, only Austria loses its top performer status in both perspectives. Denmark also becomes one of the top performers in Perspective 2.

Figure 3. Efficiency comparison of highly competitive countries from June to December



a: Perspective 1 **b: Perspective 2**

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The worst performers of the highly competitive nations cluster in both perspectives are the UK, the Netherlands, and the USA based on the data until June 2020. Based on the data until December 2020, the same countries are the worst performers in Perspective 1 and Germany, the USA, and Luxembourg are the worst performers in Perspective 2.

It can be observed from Figure 3a, among 20 highly competitive countries, efficiency scores of eight of them increase and efficiency scores of five of them decrease in Perspective 1 from June 2020 to December 2020. The biggest improvement is observed in the USA' efficiency, which is improved from 0.837 in June to 0.893 in December. The authors also observe that besides the USA, the efficiencies of the UK, Sweden, Belgium, Canada, Ireland, New Zealand, and Iceland improved. On the other hand, the biggest decline in Efficiency 1 is observed for Germany as from 0.953 to 0.899. Efficiency 1 scores of Luxembourg, Israel, Denmark, and Austria also declined.

In terms of Perspective 2, the authors observe from Figure 3b that efficiency scores of nine countries increased and those of five countries decreased from June to December 2020 in the highly competitive nations cluster. The biggest improvement is observed in the UK's efficiency, which improved from 0.805 in June to 0.943 in December. Many other countries such as the USA, the Netherlands, Belgium, Ireland, Finland, Canada, Iceland, and Denmark improved their efficiency, too. On the other hand, like Efficiency 1 scores, the biggest decline in Efficiency 2 scores belongs to Germany (from 0.918 to 0.891), as well. Efficiency 2 scores of Sweden, Luxembourg, Israel, and Austria also declined from June to December.

The correlation between Efficiency 1 and Efficiency 2 scores was 0.931 and the correlation between the ranks of the countries according to Efficiency 1 and Efficiency 2 was 0.984 in June 2020. In December 2020, the correlation between Efficiency 1 and Efficiency 2 scores was 0.796 and the correlation between the efficiency ranks was 0.901. The reduction in efficiency scores and ranks suggest that the two perspectives, Perspective 1 based on the data available on the day the maximum number of new cases was observed and Perspective 2 based on the data available on the day the maximum number of new deaths was observed, have become more discriminatory to assess the efficiency of countries in their struggle against the COVID-19.

Figure 4a and Figure 4b (for detail see Table 14 in Appendix A) show the countries in the competitive nations cluster with their Efficiency 1 and Efficiency 2 scores, respectively, sorted by the efficiency scores obtained in December 2020. The top performers of the competitive nations cluster in both perspectives are Cyprus, the Czech Republic, France, Korea, Kuwait, Malta, Philippines, the Slovak Republic based on the data until June 2020. Slovenia is a top performer only in Perspective 1 in June. According to the analysis results based on the data until December 2020, the top performers in both perspectives are Cyprus, France, Korea, Kuwait, Malta, Mauritius, and the Philippines. Mauritius also joins the top performer countries in both perspectives in December. Additionally, Estonia becomes one of the top performers in Perspective 2 only. The Slovak Republic and the Czech Republic that are among the top performers in both perspectives in June lose their top performer status in December.

The worst performers of the competitive nations cluster in both perspectives are Chile, Peru, Mexico, and Spain based on the data until June 2020. Based on the data until December 2020, the same countries are the worst performers in Perspective 2. Poland enters the worst performers list instead of Chile in Perspective 1 in December. It can be observed from Figure 4a that among 33 competitive countries, Efficiency 1 scores of eight of them increase and Efficiency 1 scores of 19 of them decrease from June to December 2020. The biggest improvement in Efficiency 1 scores is observed for Chile from 0.715 in June 2020 to 0.883 in December 2020. Similarly, Peru, Saudi Arabia, China, United Arab Emirates,

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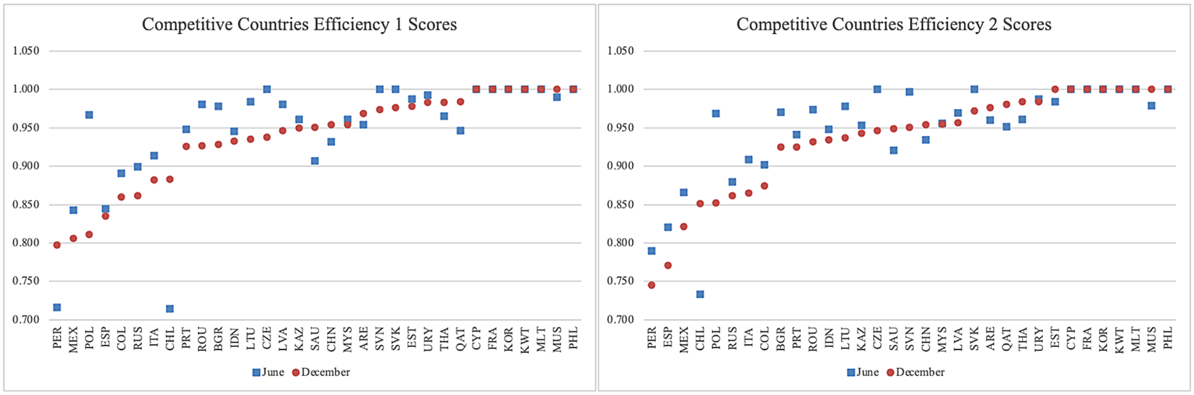
Thailand, Qatar, and Mauritius improved their Efficiency 1 scores. On the other hand, the biggest decline in Efficiency 1 scores is observed for Poland from 0.967 to 0.811.

Figure 4. Efficiency comparison of competitive countries from June to December



a: Perspective 1 **b: Perspective 2**

Figure 4b shows that Efficiency 2 scores of eight countries increased and those of 18 countries decreased from June to December 2020 in the competitive nations cluster. The biggest improvement and the biggest decline in Perspective 2 belong to the same leading countries of Perspective 1: Chile had an increase from 0.733 to 0.852, while Poland had a decrease from 0.969 to 0.852. Besides Chile, many other countries such as Estonia, Saudi Arabia, China, the United Arab Emirates, Thailand, Qatar, and Mauritius improved their Efficiency 2 scores.

The correlation between Efficiency 1 and Efficiency 2 scores of competitive nations is 0.981, and the correlation between the ranks of the countries was 0.989 in June 2020. The correlation between efficiency scores in December is 0.963 and efficiency ranks was 0.973. Although the correlation coefficients reduced from June to December, they have not reduced as much as is observed for the highly competitive nations cluster.

Figure 5a Figure 5b show the countries and their Efficiency 1 and Efficiency 2, respectively, sorted by the efficiency scores obtained in December 2020 for non-competitive countries. As can be seen in Figure 5a and Figure 5b (for detail see Table 15 in Appendix A), the top performers of the non-competitive nations cluster in both perspectives were Armenia, Azerbaijan, Greece, Croatia, Hungary, Ukraine, and Venezuela based on the data until June 2020. Gabon and Lebanon were also top performers in Perspective 1 but not in Perspective 2. Argentina was a top performer only in Perspective 2. On the other hand, based on the data until December 2020, the top performers were Armenia, Azerbaijan, Gabon, Greece, Croatia, Hungary, Sri Lanka, Oman, Tajikistan, Ukraine, and Venezuela in both perspectives. Algeria also entered the top performers list in terms of Perspective 2.

The countries with the lowest efficiency were Brazil, Mozambique, Zambia, and Haiti in both efficiency perspectives based on the data until June 2020. Based on the data until December 2020, the same countries were taking the last places in terms of Perspective 2 and Tanzania entered the worst performers list instead of Brazil in terms of Perspective 1.

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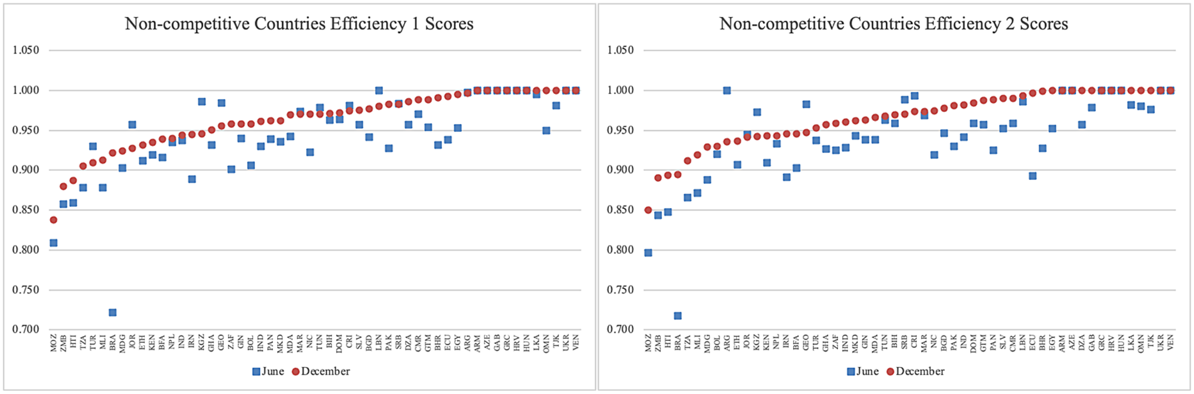
It can be observed from Figure 5a that among 54 non-competitive countries, Efficiency 1 scores of 36 of them increased and Efficiency 1 scores of nine of them decreased from June to December 2020. The biggest improvement in Efficiency 1 scores was observed in Brazil, from 0.722 in June to 0.921 in December. On the other hand, the biggest decline in Efficiency 1 scores was observed for Kyrgyzstan, from 0.986 in June to 0.946 in December. Efficiency 1 scores of Turkey, Jordan, Morocco, Tunisia, Costa Rica, Lebanon, and Serbia also decreased. Figure 5b shows that Efficiency 2 scores of 41 countries increased and those of six countries decreased from June to December 2020 in the non-competitive nations cluster. Again, Brazil showed the greatest improvement from 0.718 in June to 0.894 in December.

On the other hand, the biggest decline in Efficiency 2 was observed for Argentina, one of the top performers in June: Efficiency 2 score of Argentina decreased from 1 in June to 0.935 in December. Efficiency 2 scores of Kyrgyzstan, Jordan, Georgia, Costa Rica, and Serbia also declined.

The correlation between the two efficiency scores of countries in the non-competitive nations cluster was 0.980, and the correlation between the ranks of countries was 0.962 in June 2020. In December 2020 the correlation between efficiency scores was 0.918 and between efficiency ranks was 0.918, reflecting the difference between being able to curb the spread (Efficiency 1) and prevent deaths (Efficiency 2) compared with the scores in June 2020.

Figure 5. Efficiency comparison of non-competitive countries from June to December



a: Perspective 1

b: Perspective 2

In DEA, inefficient countries can learn from efficient countries in their peer set. Table 7 shows peer countries for selected non-efficient countries in each cluster in Perspective 1. The UK and the USA were selected in the highly competitive countries for the varying policies each country followed in the first and the second waves. In the competitive countries cluster, Italy and Spain were among the most discussed countries owing to the rapid spread of the disease. In the non-competitive countries cluster, Turkey and Brazil drew the attention of the media owing to the different policies they had followed.

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Table 7. Peer analysis of selected inefficient countries in Perspective 1

Cluster	Country	June Peers	December Peers
Highly competitive	United Kingdom	Australia, Switzerland, Japan	Australia, Japan
Highly competitive	United States	Switzerland, Norway	Switzerland, Norway
Competitive	Italy	Czech Republic, France, Korea	Korea, Kuwait
Competitive	Spain	Czech Republic, France, Korea	France, Korea, Kuwait
Non-competitive	Turkey	Greece, Croatia	Greece, Oman
Non-competitive	Brazil	Azerbaijan, Greece	Armenia, Greece

Peer Analysis of Highly Competitive Countries

The authors investigate the performance of inefficient countries in relation to the performance of their peer countries. Figure 6 presents the standardized scores of these countries in each input variable. The UK is above-average in h1, and below-average in h2, h3, h4, and h5, showing the lack of investment in healthcare resources compared with its peers. The USA, on the other hand, is above-average in h2 and h4, and below-average in h1, h3, and h5.

INPUTS h1: Domestic general government health expenditure (% of current health expenditure), h2: Domestic private health expenditure per capita (current US$), h3: Domestic private health expenditure (% of current health expenditure), h4: Current health expenditure per capita (current US$), h5: Hospital beds (per 1,000 people),

Figure 6. Comparison of UK and US with their peers in inputs

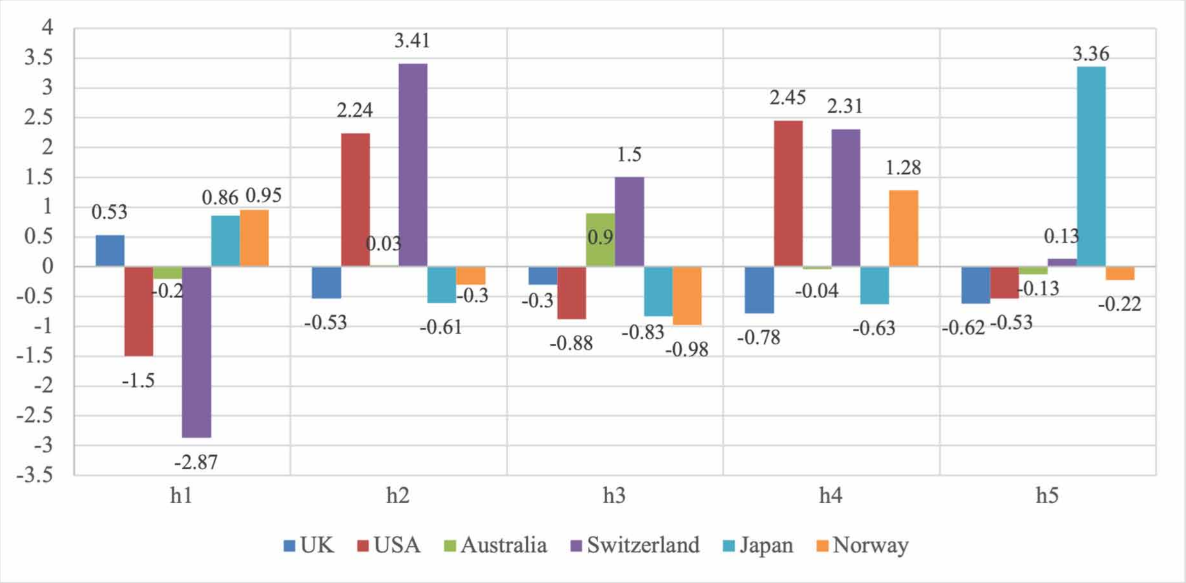

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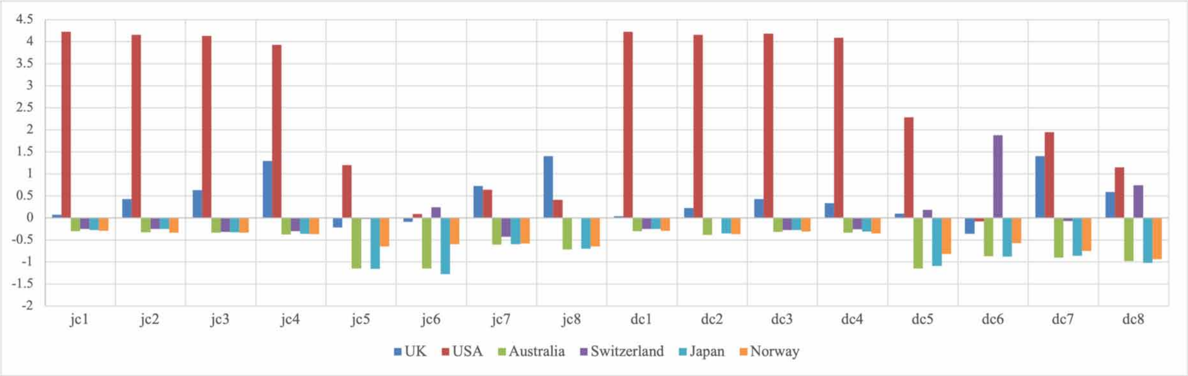
Figure 7 presents the output variables in the two analysis periods for peers with respect to Perspective 1. In June, the UK is above-average in jc1-jc4, jc7-jc8, dc1-dc5, dc7, dc8 and below-average only in jc5-jc6 and dc6. The UK was ranked 19th in June and 20th in Perspective 1 among the 20 countries in the highly competitive nations cluster.

Figure 7. Comparison of the UK and the USA with their peers in standardised outputs in Perspective 1 in June and December 2020



OUTPUTS based on max number of new cases jc1, dc1: total number of cases, jc2, dc2: number of new cases, jc3, dc3: total number of deaths, jc4, dc4: number of new deaths, jc5, dc5: total number of cases / million, jc6, dc6: number of new cases / million, jc7, dc7: total number of deaths / million, jc8, dc8: number of new deaths / million

In Figure 7, the USA is above-average in all COVID-19 variables except dc6. The USA was ranked 20th in June and 18th in December in Perspective 1 within the highly competitive nations cluster. Although one of USA's peers, Switzerland, has above-average performance in four COVID-19 output variables (jc6, dc5, dc6, dc8), the DEA model still identified it as an efficient country and one of the USA's two peers. None of the rest of the peers (Australia, Japan, and Norway) had any COVID-19 variable that was above the average.

Peer Analysis of Competitive Countries

A similar picture can be seen when Italy and Spain within the competitive nations cluster are compared to their peers: the Czech Republic, France, and Korea. The comparison of these countries in input variables is given in Figure 8.

INPUTS h1: Domestic general government health expenditure (% of current health expenditure), h2: Domestic private health expenditure per capita (current US$), h3: Domestic private health expenditure (% of current health expenditure), h4: Current health expenditure per capita (current US$), h5: Hospital beds (per 1,000 people),

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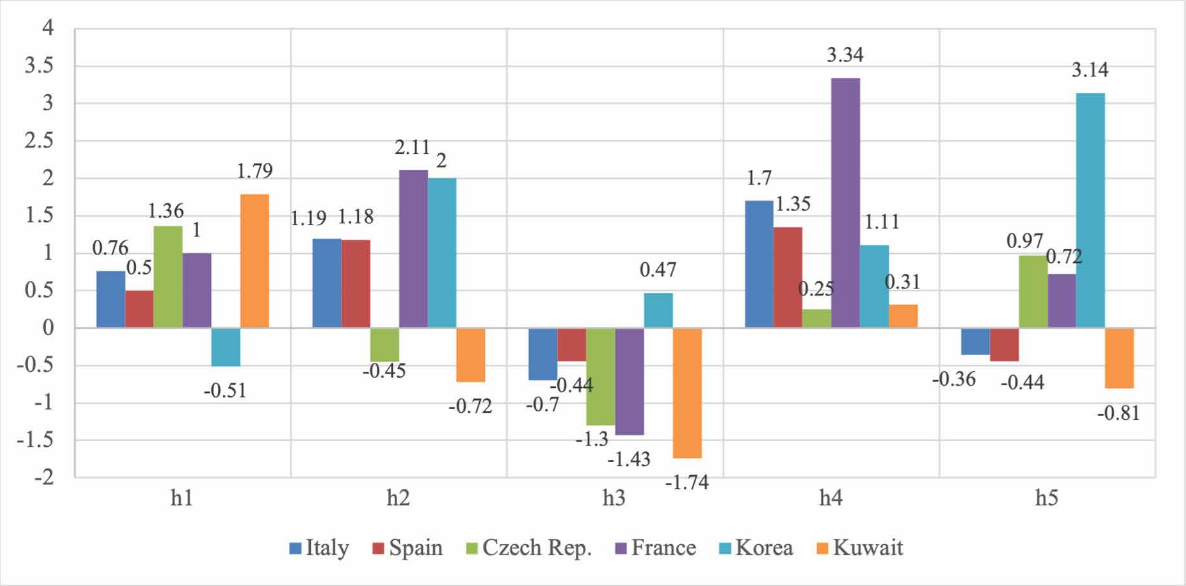
Figure 8. Comparison of Italy and Spain with their peers in inputs



Contrary to the comparison in the highly competitive nations cluster, in the competitive nations, the two inefficient countries selected for comparison, Italy and Spain have above-average performance in h1, h2, and h4; however, they are below-average in h3 and h5. In fact, in h3, not only Italy and Spain but also their peers except Korea also have below zero standardised scores. In Figure 8, the input variable h3 indicates the domestic private health expenditure as a percentage of current health expenditure and only Korea has higher scores in this variable, showing that in these countries, although private health expenditure does exist, it does not have a high proportion within the current health expenditure. France has the highest scores in h2 and h4, and peers tend to score higher than Italy and Spain in h1, h2, and h5. France has the highest current health expenditure per capita, and Korea among the peers has the highest hospital beds per thousand people.

Figure 9 presents the standardised scores of Italy and Spain along with the scores of their peers in June and December for the COVID-19 outputs in Perspective 1. Italy was ranked 26th in June and 27th in December in Perspective 1 among the 33 countries in the competitive nations cluster. Spain, on the other hand, was ranked 30th both in June and December in Perspective 1. It can be observed in Figure 9 that Italy and Spain did not have any COVID-19 outputs below the average except for jc5.

OUTPUTS based on max number of new cases jc1, dc1: total number of cases, jc2, dc2: number of new cases, jc3, dc3: total number of deaths, jc4, dc4: number of new deaths, jc5, dc5: total number of cases / million, jc6, dc6: number of new cases / million, jc7, dc7: total number of deaths / million, jc8, dc8: number of new deaths / million

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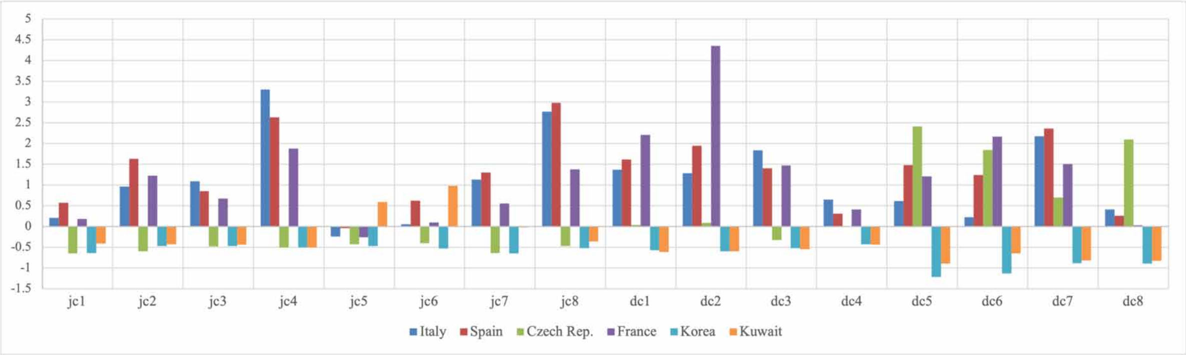
Figure 9. Comparison of Italy and Spain with their peers in outputs in perspective 1 in June and December 2020



In Figure 9, the Czech Republic had all COVID-19 variables below-average in June, but its poor management of the outbreak resulted in all of its output variables except dc3 and dc4 to become above-average in December. In fact, the Czech Republic was among the efficient countries in June but is no longer a peer to any of the inefficient countries in December since itself has become inefficient. Among the efficient peers, France's situation is different from Korea and Kuwait. France had above-average scores in all of the COVID-19 output variables in both periods except for jc5. However, its scores were lower than those of Italy in all of the COVID-19 output variables except jc2, jc6, dc1, dc2, dc5, and dc6. Although the number of new cases for France is the highest in December, its scores in other variables are lower than Italy and Spain. France's investment levels in the health resources variables resulted in it being efficient in both analysis periods. Korea, with no exception, had all of its COVID-19 output variables in both analysis periods below-average while Kuwait also had all of its COVID-19 output variables except jc5 and jc6 below-average.

Peer Analysis of Non-Competitive Countries

In the non-competitive nations cluster, the countries selected for comparison, Turkey and Brazil, are presented along with their peers: Greece, Croatia, Azerbaijan, Armenia, and Oman. Figure 10 shows the comparison of Turkey and Brazil with their peers in terms of health input variables. Turkey has above-average performance in h1, h4, and h5 but below-average in h2 and h3. Specifically, in h3, domestic private health expenditure as a percentage of current health expenditure, Turkey is 1.31 standard deviations below the mean. However, its peers, Greece, Croatia, and Oman are also below-average in h3, -0.38, 1.59, and 1.85 standard deviations below-average, respectively.

INPUTS h1: Domestic general government health expenditure (% of current health expenditure), h2: Domestic private health expenditure per capita (current US$), h3: Domestic private health expenditure (% of current health expenditure), h4: Current health expenditure per capita (current US$), h5: Hospital beds (per 1,000 people),

In Figure 10, Brazil is below-average in h1 and h5 but above-average in h2, h3, and h4. Specifically, in h2, domestic private health expenditure per capita, Brazil is 2.77 standard deviations above the average. In terms of h5, the number of hospital beds per thousand people, Croatia is the highest with 1.57 standard deviations above the average.

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Figure 10. Comparison of Turkey and Brazil with their peers in inputs

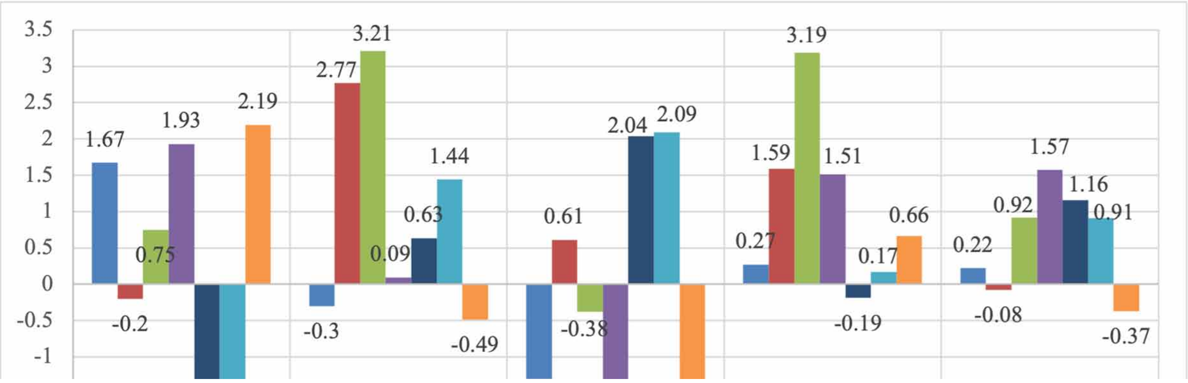
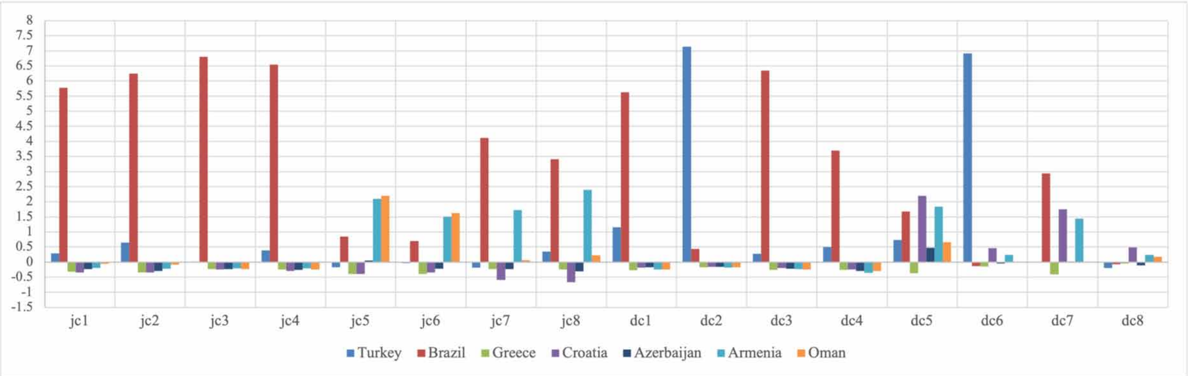


Figure 11 shows Turkey and Brazil, along with their peer countries in terms of the standardised scores in COVID-19 output variables. Turkey was ranked 39th in June and 50th in December in Perspective 1 among the 54 countries in the non-competitive nations cluster while Brazil was ranked 54th in June and 48th in December in Perspective 1. The striking underperformance of Brazil and Turkey are visible. Brazil is above-average in all COVID-19 variables across the two analysis periods, except dc6 and dc8. In June, Brazil scored more than three standard deviations above the mean in jc1-jc4, jc7, and jc8. In December, it was more than three standard deviations in dc1, dc3, dc4 and almost three standard deviations in dc7.

OUTPUTS based on max number of new cases jc1, dc1: total number of cases, jc2, dc2: number of new cases, jc3, dc3: total number of deaths, jc4, dc4: number of new deaths, jc5, dc5: total number of cases / million, jc6, dc6: number of new cases / million, jc7, dc7: total number of deaths / million, jc8, dc8: number of new deaths / million

Figure 11. Comparison of Turkey and Brazil with their peers in outputs in perspective 1 in June and December 2020



In Figure 11, Turkey had the highest extremes in dc2 (7.14 standard deviations above the average) and dc6 (6.91 standard deviations above the average). Among Turkey's COVID-19 variables, only jc5- jc7, dc7, and dc8 were below-average. Greece, which is in the peer set of both Brazil and Turkey,

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had no COVID-19 output variables that were above-average. Croatia had only dc5-dc8 above-average, Azerbaijan only had jc5, dc5, and dc7 above-average. For Armenia and Oman, jc5-jc8 and dc5-dc8 were above-average.

Turkey and Brazil are expected to have lower levels of deaths and cases related to COVID-19 using the same level of health-related expenditures as well as hospital beds. The rapid increase of the confirmed cases in Turkey did not overburden the public healthcare system, and the preliminary case-fatality rate remained lower. This was most probably due to the country's relatively young population and the high number of available ICUs.

Relationship Between Human Development and Efficiency

In the third stage, the authors tested the explanatory power of 66 independent variables published in the Human Development Report (Conceição, 2019) together with cluster and political regime categorical variables on the two efficiency scores using Tobit regression models by entering and removing predictors based on their *p*-values. The variables included in the Tobit regressions are as follows:

- **Mortality rate attributed to household and ambient air pollution (airp):** Age-standardised mortality rate resulting from exposure to ambient (outdoor) air pollution and household (indoor) air pollution from solid fuel use for cooking, expressed per 100,000 people. Ambient air pollution is due to emissions from industrial activity, households, cars and trucks.
- **International inbound tourists (urban):** Arrivals of non-resident visitors (overnight visitors, tourists, same-day visitors and excursionists) at national borders.
- **Urban population (urban):** De facto population living in areas classified as urban according to the criteria used by each country or area.
- **Domestic credit provided by financial sector (fincredit):** Credit to various sectors on a gross basis (except credit to the central government), expressed as a percentage of GDP.
- **Gross national income (GNI) per capita (gni):** Aggregate income of an economy generated by its production and its ownership of factors of production, less the incomes paid for the use of factors of production owned by the rest of the world, converted to international dollars using purchasing power parity rates, divided by midyear population.
- **Country Clusters:** The three country clusters obtained in Stage 1 of the methodology. Cluster 1: highly competitive nations, Cluster 2: competitive nations, Cluster 3: non-competitive nations. Competitive nations cluster is considered as the reference, and the coefficients for highly competitive and non-competitive clusters are reported.
- **Political regime:** Indicates the political regime of a country as published by the Our World in Data (Roser & Herre, 2013). Regime 0: closed autocracy (reference variable), Regime 1: Electoral Autocracy, Regime 2: Electoral Democracy, Regime 3: Liberal Democracy. Table 11 shows the number of nations in each regime under each competitiveness cluster.

All of the variables above except political regime were significant in the Tobit regression. One of the reasons for this could be the relatively few observations in each cluster – regime combination (Table 11). While all countries except Singapore in the highly competitive nations cluster are governed by liberal democracy, only two countries (Costa Rica and Ghana) in the non-competitive nations cluster are gov-

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Table 11. Number of nations in each cluster and each political regime

	Highly Competitive	Competitive	Non-competitive	Total
Closed Autocracy	0	6	4	10
Electoral Autocracy	1	3	24	28
Electoral Democracy	0	13	24	37
Liberal Democracy	19	11	2	32

erned by liberal democracy. The six countries governed by closed autocracy in the competitive nations cluster are the United Arab Emirates, China, Kuwait, Qatar, Saudi Arabia, and Thailand.

The results of the Tobit regression analyses are given in Table 12. The authors report the standardized coefficients of the independent variables, hence the authors could comment on the strength of the explanatory variables. For both efficiency scores, the coefficients are quite similar:

- For one standard unit increase in the mortality rate attributed to household and ambient air pollution (airp), the efficiency score decreases by 0.029 units in both models.
- For one standard unit increase in the international inbound tourists (tourist), the Efficiency 1 score decreases by 0.021 units and the Efficiency 2 score decreases by 0.022 units.
- For one standard unit increase in urban population (urban), there is a 0.019 unit decrease in Efficiency 1 and 0.021 units decrease in Efficiency 2.
- Gross national income per capita (gni) has a greater positive impact than domestic credit provided by the financial sector (fincredit). For one standard unit increase in gross national income per capita, the efficiency score increases by 0.022 units in both perspectives.
- For one standard unit increase in domestic credit provided by the financial sector (fincredit), the Efficiency 1 score increases by 0.016 units and the Efficiency 2 score increases by 0.018 units.

Table 12. Tobit regression results

	Efficiency 1, $R^2 = 0.392$				Efficiency 2, $R^2 = 0.396$			
	Estimate	Std. Err	z Value	Pr(>|z|)	Estimate	Std. Err	z Value	Pr(>|z|)
Intercept1	0.935	0.009	104.743	0.000***	0.934	0.009	99.331	0.000***
Intercept2	-3.109	0.083	-37.317	0.000***	-3.058	0.085	-35.930	0.000***
airp	-0.029	0.007	-4.242	0.000***	-0.029	0.007	-3.951	0.000***
tourist	-0.021	0.006	-3.819	0.000***	-0.022	0.006	-3.626	0.000***
urban	-0.019	0.007	-2.742	0.006**	-0.021	0.007	-2.855	0.004**
fincredit	0.016	0.007	2.267	0.023*	0.018	0.007	2.375	0.018*
gni	0.022	0.009	2.414	0.016*	0.022	0.010	2.274	0.023*
Highly Competitive	-0.016	0.018	-0.899	0.369	0.003	0.019	0.149	0.881
Non-Competitive	0.054	0.013	4.003	0.000***	0.058	0.014	4.075	0.000***

Signif. codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1

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There is no difference between the competitive and highly competitive cluster but being in the non-competitive cluster is significant to explain the variability in efficiency scores in Efficiency 1 and in Efficiency 2. Efficiency 1 score is predicted to be 0.054 unit higher, and Efficiency 2 score is predicted to be 0.058 unit higher when a country is in the non-competitive cluster. This can be explained by the fact that many countries in the non-competitive cluster did increase their efficiency scores and the efficiency scores ranged [0.838, 1] for Efficiency 1 and [0.850, 1] for Efficiency 2 while the same ranges for the competitive countries cluster are [0.798, 1] and [0.745, 1], respectively. Considering the ranges of the efficiency scores, these decreases and increases from each of the independent variables entered into the model are significant. The explanatory power of the Tobit regression models is similar at $R^2 = 0.392$ for Efficiency 1 and $R^2 = 0.396$ for Efficiency 2.

FUTURE RESEARCH DIRECTIONS

In this paper, the authors evaluated the response of countries to the COVID-19 pandemic using data from the first and the second waves. As of submission date of this paper, the pandemic is still evolving, and mass vaccination has started. This methodology can be repeated in the short term once the pandemic is under control to assess how the efficiency of nations has changed over time further with new vaccines and medicines. Such an analysis could provide policy suggestions with long term investment implications in healthcare and mobile applications for contract tracing.

CONCLUSION

This study set out to investigate the COVID-19 response of countries and identify the association between the response performance of a nation and its competitiveness using data from June and December 2020. The authors proposed a novel three-stage approach for assessing the COVID-19 response efficiency of nations. In the first stage, the countries were clustered according to 12 competitiveness pillars, and in the second stage, DEA analyses were conducted separately for each cluster in two perspectives. Finally, in the third stage, Tobit regression models were built to explain the differences in the efficiency scores of nations testing 66 variables from the Human Development Report.

The results show that even the countries being in the same cluster show wide variations in their efficiency of curbing the COVID-19. The governments of all inefficient countries in each cluster could find their peers to take as a role model and can, thus, allocate their resources more efficiently.

Additionally, the regression results show that countries with lower air pollution, lower inbound tourists, lower population density, higher gross national income per capita, and higher credit rate from financial institutions are showing better performance in the fight against the COVID-19. In fact, these findings support the policy suggestions underlined by the special edition of the WEF's Global Competitiveness Report (Schwab and Zahidi, 2020). This special edition encompasses several policy areas to establish synergies across different reform objectives. As such, it provides a road map for the policymakers for the post-covid recovery of the countries. In reality, those policies also highlight the factors which were at the background of the efficiency of the countries during their struggle against COVID-19.

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In parallel to the suggestions of Schwab and Zahidi (2020), our study also finds out that lower population density is important to fight against COVID-19. Increasing population in the developing world and ageing population in the developed world resulted in lower performance of the countries in their struggle against COVID-19. In fact, lower population density permits higher public expenditure on childcare and education as well as on healthcare. It also provides better protection against job loss, disability, old age, and poverty. The coverage rates of child and maternity benefits, support for persons without a job, persons with disabilities, victims of work injuries, and older persons increase with lower population density. This also permits to realise an education with critical and creative thinking ability to the young generation and increase digital skills of the active population.

Additionally, higher credits from financing agents such as central/federal, state/provincial/regional, and local/municipal authorities; extrabudgetary agencies, social security schemes can increase general government expenditure and, this, in turn, enhances the health status of the population and/or the distribution of medical care goods and services among the population.

As is also suggested by Schwab and Zahidi (2020), our research findings underline that the countries should manage climate change, provide more dialogue on travel and migration, and prepare new trade policies for reforming international governance in the long run for better prosperity and efficiency. In fact, net-zero emission importance is also highlighted by D'Aprile et al. (2020). In the post-covid era, companies and consumers should make investments in lower-emitting technologies; the government should provide stimulus programs that accelerate investments in infrastructure, R&D, and supply chain.

The IMF estimates that allocating an additional 1% of GDP to public investment could create approximately 7 million jobs directly, and 20 million jobs indirectly worldwide. Maintaining and, where possible, expanding investments in transport, healthcare, housing, digitalisation, and energy transition would improve competitiveness, create more employment and prepare countries to become more resilient and sustainable (Schwab and Zahidi, 2020). Therefore, as is also highlighted in our research the highly competitive countries that have allocated a significant percentage of their GDP to public investment showed better performance in their struggle against COVID-19 and will also recover faster in the post-covid era.

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Authors Contributions: The second author lead the conceptualisation and design with contribution from all authors. Material preparation and data collection were done by the third author and the fourth author. The first author performed the analysis and wrote the first draft of the manuscript. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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KEY TERMS AND DEFINITIONS

Country Clusters: The three country clusters obtained in Stage 1 of the methodology. Cluster 1: highly competitive nations, Cluster 2: competitive nations, Cluster 3: non-competitive nations. Competitive nations cluster is considered as the reference, and the coefficients for highly competitive and non-competitive clusters are reported.

Domestic Credit Provided by Financial Sector: Credit to various sectors on a gross basis (except credit to the central government), expressed as a percentage of GDP.

Gross National Income (GNI) per Capita: Aggregate income of an economy generated by its production and its ownership of factors of production, less the incomes paid for the use of factors of production owned by the rest of the world, converted to international dollars using purchasing power parity rates, divided by midyear population.

International Inbound Tourists: Arrivals of non-resident visitors (overnight visitors, tourists, same-day visitors and excursionists) at national borders.

Mortality Rate Attributed to Household and Ambient Air Pollution: Age-standardised mortality rate resulting from exposure to ambient (outdoor) air pollution and household (indoor) air pollution from solid fuel use for cooking, expressed per 100,000 people. Ambient air pollution is due to emissions from industrial activity, households, cars and trucks.

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Political Regime: Indicates the political regime of a country as published by the Our World in Data (Roser & Herre, 2013). Regime 0: closed autocracy (reference variable), Regime 1: Electoral Autocracy, Regime 2: Electoral Democracy, Regime 3: Liberal Democracy.

Urban Population: De facto population living in areas classified as urban according to the criteria used by each country or area.

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APPENDIX 1: EFFICIENCY SCORES IN JUNE AND DECEMBER 2020

Table 13 shows the efficiency scores of highly competitive countries in Perspective 1 (Efficiency 1) and Perspective 2 (Efficiency 2) sorted by the December Efficiency 1 scores.

Table 13. Efficiency scores of highly competitive countries in both perspectives

Country	**Efficiency 1 (Rank)**		**Efficiency 2 (Rank)**	
	June	**December**	**June**	**December**
Australia (AUS)	1.000 (1)	1.000 (1)	1.000 (1)	1.000 (1)
Switzerland (CHE)	1.000 (1)	1.000 (1)	1.000 (1)	1.000 (1)
Japan (JPN)	1.000 (1)	1.000 (1)	1.000 (1)	1.000 (1)
Norway (NOR)	1.000 (1)	1.000 (1)	1.000 (1)	1.000 (1)
Singapore (SGP)	1.000 (1)	1.000 (1)	1.000 (1)	1.000 (1)
Iceland (ISL)	0.965 (11)	0.996 (6)	0.968 (10)	0.986 (8)
Austria (AUT)	1.000 (1)	0.987 (7)	1.000 (1)	0.987 (7)
New Zealand (NZL)	0.982 (7)	0.985 (8)	0.986 (7)	0.985 (9)
Ireland (IRL)	0.962 (13)	0.981 (9)	0.931 (15)	0.966 (12)
Denmark (DNK)	0.974 (9)	0.968 (10)	0.977 (8)	1.000 (1)
Finland (FIN)	0.969 (10)	0.968 (11)	0.965 (11)	0.972 (11)
Israel (ISR)	0.976 (8)	0.953 (12)	0.971 (9)	0.962 (14)
Canada (CAN)	0.928 (15)	0.948 (13)	0.933 (14)	0.979 (10)
Luxembourg (LUX)	0.963 (12)	0.944 (14)	0.954 (12)	0.927 (18)
Belgium (BEL)	0.889 (17)	0.914 (15)	0.901 (17)	0.964 (13)
Sweden (SWE)	0.907 (16)	0.913 (16)	0.945 (13)	0.943 (17)
Germany (DEU)	0.953 (14)	0.899 (17)	0.918 (16)	0.891 (20)
United States (USA)	0.837 (20)	0.893 (18)	0.886 (18)	0.923 (19)
Netherlands (NLD)	0.883 (18)	0.883 (19)	0.884 (19)	0.958 (15)
United Kingdom (GBR)	0.837 (19)	0.865 (20)	0.805 (20)	0.943 (16)
Min	**0.837**	**0.865**	**0.805**	**0.891**
Max	**1.000**	**1.000**	**1.000**	**1.000**
Mean	**0.951**	**0.955**	**0.951**	**0.969**
Standard Deviation	**0.054**	**0.045**	**0.052**	**0.031**

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Table 14 presents the efficiency scores of countries in the competitive cluster, sorted by scores in Perspective 1 in December.

Table 14. Efficiency scores of competitive countries in both perspectives

	Efficiency 1 (Rank)		Efficiency 2 (Rank)	
	June	December	June	December
Cyprus (CYP)	1.000 (1)	1.000 (1)	1.000 (1)	1.000 (1)
France (FRA)	1.000 (1)	1.000 (1)	1.000 (1)	1.000 (1)
Korea, Rep. (KOR)	1.000 (1)	1.000 (1)	1.000 (1)	1.000 (1)
Kuwait (KWT)	1.000 (1)	1.000 (1)	1.000 (1)	1.000 (1)
Malta (MLT)	1.000 (1)	1.000 (1)	1.000 (1)	1.000 (1)
Mauritius (MUS)	0.990 (11)	1.000 (1)	0.979 (12)	1.000 (1)
Philippines (PHL)	1.000 (1)	1.000 (1)	1.000 (1)	1.000 (1)
Qatar (QAT)	0.946 (23)	0.984 (8)	0.951 (22)	0.98 (11)
Thailand (THA)	0.965 (18)	0.983 (9)	0.961 (18)	0.984 (10)
Uruguay (URY)	0.993 (10)	0.983 (10)	0.987 (10)	0.984 (9)
Estonia (EST)	0.988 (12)	0.978 (11)	0.984 (11)	1.000 (1)
Slovak Republic (SVK)	1.000 (1)	0.976 (12)	1.000 (1)	0.973 (13)
Slovenia (SVN)	1.000 (1)	0.974 (13)	0.997 (9)	0.951 (17)
United Arab Emirates (ARE)	0.955 (21)	0.969 (14)	0.960 (19)	0.977 (12)
Malaysia (MYS)	0.961 (19)	0.954 (15)	0.956 (20)	0.955 (15)
China (CHN)	0.932 (25)	0.954 (16)	0.934 (25)	0.954 (16)
Saudi Arabia (SAU)	0.907 (27)	0.95 (17)	0.921 (26)	0.949 (18)
Kazakhstan (KAZ)	0.961 (20)	0.949 (18)	0.954 (21)	0.943 (20)
Latvia (LVA)	0.98 (15)	0.947 (19)	0.97 (16)	0.957 (14)
Czech Republic (CZE)	1.000 (1)	0.937 (20)	1.000 (1)	0.947 (19)
Lithuania (LTU)	0.984 (13)	0.935 (21)	0.978 (13)	0.937 (21)
Indonesia (IDN)	0.945 (24)	0.932 (22)	0.948 (23)	0.934 (22)
Bulgaria (BGR)	0.978 (16)	0.928 (23)	0.970 (15)	0.925 (25)
Romania (ROU)	0.980 (14)	0.927 (24)	0.973 (14)	0.932 (23)
Portugal (PRT)	0.948 (22)	0.926 (25)	0.941 (24)	0.925 (24)
Chile (CHL)	0.715 (33)	0.883 (26)	0.733 (33)	0.852 (30)
Italy (ITA)	0.914 (26)	0.882 (27)	0.909 (27)	0.865 (27)
Russian Federation (RUS)	0.899 (28)	0.861 (28)	0.879 (29)	0.861 (28)
Colombia (COL)	0.891 (29)	0.860 (29)	0.902 (28)	0.875 (26)
Spain (ESP)	0.845 (30)	0.835 (30)	0.821 (31)	0.771 (32)
Poland (POL)	0.967 (17)	0.811 (31)	0.969 (17)	0.852 (29)
Mexico (MEX)	0.843 (31)	0.806 (32)	0.866 (30)	0.821 (31)
Peru (PER)	0.716 (32)	0.798 (33)	0.790 (32)	0.745 (33)

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	Efficiency 1 (Rank)		Efficiency 2 (Rank)	
	June	December	June	December
Min	**0.715**	**0.798**	**0.733**	**0.745**
Max	**1.000**	**1.000**	**1.000**	**1.000**
Mean	**0.945**	**0.937**	**0.946**	**0.935**
Standard Deviation	**0.074**	**0.062**	**0.065**	**0.068**

Table 15 presents the efficiency scores of countries in the non-competitive cluster, sorted by December Perspective 1 scores.

Table 15. Efficiency scores of non-competitive countries in both perspectives

Country	Efficiency 1 (Rank)		Efficiency 2 (Rank)	
	June	December	June	December
Armenia (ARM)	1.000 (1)	1.000 (1)	1.000 (1)	1.000 (1)
Azerbaijan (AZE)	1.000 (1)	1.000 (1)	1.000 (1)	1.000 (1)
Gabon (GAB)	1.000 (1)	1.000 (1)	0.979 (15)	1.000 (1)
Greece (GRC)	1.000 (1)	1.000 (1)	1.000 (1)	1.000 (1)
Croatia (HRV)	1.000 (1)	1.000 (1)	1.000 (1)	1.000 (1)
Hungary (HUN)	1.000 (1)	1.000 (1)	1.000 (1)	1.000 (1)
Sri Lanka (LKA)	0.995 (11)	1.000 (1)	0.982 (13)	1.000 (1)
Oman (OMN)	0.950 (27)	1.000 (1)	0.980 (14)	1.000 (1)
Tajikistan (TJK)	0.981 (16)	1.000 (1)	0.976 (16)	1.000 (1)
Ukraine (UKR)	1.000 (1)	1.000 (1)	1.000 (1)	1.000 (1)
Venezuela (VEN)	1.000 (1)	1.000 (1)	1.000 (1)	1.000 (1)
Argentina (ARG)	0.997 (10)	0.996 (12)	1.000 (1)	0.935 (46)
Egypt (EGY)	0.953 (26)	0.995 (13)	0.952 (26)	0.999 (13)
Ecuador (ECU)	0.938 (32)	0.992 (14)	0.893 (46)	0.996 (15)
Bahrain (BHR)	0.931 (37)	0.991 (15)	0.927 (37)	0.999 (14)
Guatemala (GTM)	0.954 (25)	0.989 (16)	0.957 (24)	0.987 (20)
Cameroon (CMR)	0.97 (19)	0.988 (17)	0.959 (20)	0.990 (17)
Algeria (DZA)	0.957 (22)	0.986 (18)	0.957 (23)	1.000 (1)
Serbia (SRB)	0.984 (14)	0.982 (19)	0.988 (10)	0.970 (28)
Pakistan (PAK)	0.927 (40)	0.982 (20)	0.930 (35)	0.981 (23)
Lebanon (LBN)	1.000 (1)	0.980 (21)	0.986 (11)	0.994 (16)
Bangladesh (BGD)	0.942 (29)	0.976 (22)	0.946 (27)	0.977 (24)
El Salvador (SLV)	0.957 (24)	0.975 (23)	0.952 (25)	0.990 (18)
Costa Rica (CRI)	0.981 (15)	0.975 (24)	0.993 (9)	0.973 (27)
Dominican Republic (DOM)	0.963 (20)	0.972 (25)	0.959 (22)	0.984 (21)
Bosnia and Herzegovina (BIH)	0.963 (21)	0.971 (26)	0.959 (21)	0.969 (29)
Tunisia (TUN)	0.978 (17)	0.970 (27)	0.963 (19)	0.967 (30)
Nicaragua (NIC)	0.923 (41)	0.970 (28)	0.919 (42)	0.974 (25)
Morocco (MAR)	0.973 (18)	0.970 (29)	0.969 (18)	0.974 (26)
Moldova (MDA)	0.942 (28)	0.970 (30)	0.938 (31)	0.966 (31)
Macedonia, FYR (MKD)	0.936 (34)	0.962 (31)	0.943 (29)	0.962 (33)
Panama (PAN)	0.939 (31)	0.962 (32)	0.925 (39)	0.988 (19)
Honduras (HND)	0.930 (38)	0.961 (33)	0.928 (36)	0.960 (34)
Bolivia (BOL)	0.906 (45)	0.958 (34)	0.920 (41)	0.930 (47)
Guinea (GIN)	0.940 (30)	0.958 (35)	0.938 (32)	0.963 (32)
South Africa (ZAF)	0.901 (47)	0.958 (36)	0.925 (40)	0.959 (35)
Georgia (GEO)	0.984 (13)	0.955 (37)	0.982 (12)	0.947 (38)
Ghana (GHA)	0.931 (36)	0.950 (38)	0.927 (38)	0.957 (36)
Kyrgyz Republic (KGZ)	0.986 (12)	0.946 (39)	0.973 (17)	0.943 (43)
Iran, Islamic Rep. (IRN)	0.889 (48)	0.945 (40)	0.892 (47)	0.945 (40)
India (IND)	0.937 (33)	0.944 (41)	0.942 (30)	0.981 (22)
Nepal (NPL)	0.935 (35)	0.940 (42)	0.934 (34)	0.943 (41)
Burkina Faso (BFA)	0.916 (43)	0.939 (43)	0.903 (45)	0.946 (39)

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Table 16. Continued

Country	Efficiency 1 (Rank)		Efficiency 2 (Rank)	
	June	December	June	December
Kenya (KEN)	0.919 (42)	0.935 (44)	0.909 (43)	0.943 (42)
Ethiopia (ETH)	0.912 (44)	0.932 (45)	0.907 (44)	0.936 (45)
Jordan (JOR)	0.957 (23)	0.928 (46)	0.945 (28)	0.941 (44)
Madagascar (MDG)	0.902 (46)	0.924 (47)	0.888 (48)	0.929 (48)
Brazil (BRA)	0.722 (54)	0.921 (48)	0.718 (54)	0.894 (51)
Mali (MLI)	0.878 (49)	0.913 (49)	0.872 (49)	0.919 (49)
Turkey (TUR)	0.93 (39)	0.909 (50)	0.937 (33)	0.953 (37)
Tanzania (TZA)	0.878 (50)	0.905 (51)	0.866 (50)	0.912 (50)
Haiti (HTI)	0.859 (51)	0.887 (52)	0.847 (51)	0.894 (52)
Zambia (ZMB)	0.858 (52)	0.880 (53)	0.843 (52)	0.890 (53)
Mozambique (MOZ)	0.809 (53)	0.838 (54)	0.796 (53)	0.850 (54)
Min	**0.722**	**0.838**	**0.718**	**0.850**
Max	**1.000**	**1.000**	**1.000**	**1.000**
Mean	**0.943**	**0.963**	**0.939**	**0.965**
Standard Deviation	**0.053**	**0.036**	**0.055**	**0.035**

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Chapter 18

Technology-Aided Solutions to Promote the Healthcare of Neurodegenerative Diseases:

A Narrative Review

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ABSTRACT

The chapter provides the reader with a narrative overview of technological-aided solutions to help individuals with neurodegenerative diseases. Five categories were identified, namely (1) functional and physical activities, (2) communication skills, (3) positive participation, (4) leisure and recreation, and (5) telerehabilitation. Results were fairly satisfactory although few failures occurred. Findings and implications were critically discussed. Some useful insights for future research and practice were highlighted.

INTRODUCTION

Young and older adults with neurodegenerative diseases (e.g., Alzheimer disease, Parkinson disease, amyotrophic lateral sclerosis and multiple sclerosis) may present relevant problems and pose significant challenges to daily contexts such as families, caregivers, professionals, and medical or rehabilitative centers. Thus, they frequently exhibit communicative, emotional, intellectual, motor, and social disorders while tackling day life requests. Because of their significantly compromised health conditions, individuals with severe disabilities basically experience isolation, passivity, and detachment with negative consequences on their quality of life. That situation may meaningfully hamper their social image, desirability, and status. In

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fact, they constantly rely on caregivers' assistance (Bassi et al., 2020; Gil-Gonzales, Perez-San-Gregorio, Conrad, & Martin-Rodriguez, 2021; Schischlevskij et al., 2021). To favorably overcome this issue, one may rely on assistive technology-based programs (AT). Such approach includes basic supports to help people with relevant disorders within daily settings. AT-based interventions are implemented to fill the existing gap between the individual's capacities and the environmental' s requests. Moreover, AT may build a functional bridge enabling self-determination of persons with different levels of disabilities and decreasing caregivers' burden accordingly (Behera, Condell. Dora, Gibson. And Leavy, 2021; Gongora Alonso et al., 2019). Thus, an active role, constructive engagement, and functional occupation of individuals with neurodegenerative disorders may be enhanced (Leuty, Boger, Young, Hoey, & Mihaillidis, 2013; Savvidis et al., 2018).

Recently, Covid-19 pandemic dramatically exacerbated the precarious conditions of persons with neurodegenerative diseases (NDD) due to quarantine and social distancing preventive measures. Additionally, the unavailability of National Medical Services reduced the opportunity in NDD people to receive adequate medical care. The diffusion of the vaccine partially improved that situation. To overcome this latter issue, one may use telerehabilitation strategies (TR) (Akbas & Mummolo, 2021; Caprì et al., 2021).

For example, Hung and Fong (2019) reviewed the current literature on the application of TR in occupational therapy practice and its clinical outcomes over last decade. Studies retrieved from seven electronic databases were assessed and findings evidenced positive therapeutic effects although data were considered insufficient to demonstrate the validity of TR compared to face – to – face interventions. Caprì et al. (2021) systematically reviewed the literature on the use of TR in individuals with multiple disabilities, and examined the effects of TR on adaptive skills of individuals with severe to profound and multiple delays. Furthermore, the different types of devices and families' satisfaction were assessed. Nevertheless, by including AT, NDD, and TR in Scopus, no records were found.

In light of the above, the first goal of the chapter was to provide the readers with an update and concise narrative overview on the use of AT-based programs and TR to promote cognitive, communicative, and motor functions in persons with NDD. Positive participation and leisure opportunities were additionally examined. The second objective of the chapter was to emphasize advantages and limitations of the adopted technological solutions. Finally, some useful insights for both future research and practice were critically discussed.

BACKGROUND

AT-based strategies may provide persons diagnosed with different neurodegenerative diseases and various levels of disabilities with a valid aid in basic problematic domains. For instance, independent access to positive stimulation, functional activities, physical exercise, reminiscence, communication skills, leisure and recreation, request and choice processes are frequently included (De Pace & Stasolla, 2014; Stasolla, Perilli, & Boccasini, 2016). Furthermore, the area of detachment and passivity encompasses the difficulty of being favorably committed in adaptive behaviors and/or physical activities with beneficial consequences. Functional activities may be considered as crucial for occupational purposes. Communication skills and reminiscence are essential for social interaction and recovery of personal events. Leisure and recreation domains include the inability of manage leisure or recreation opportunities independently. Request and choice processes refer to the awareness and the capacity to select and ask for desired items, and satisfy personal needs (Lancioni & Singh, 2014). AT-based interventions are

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designed to provide devices, instruments, or tools aimed at reducing the distance between the individual's skills and the requested environmental skills to achieve specific objectives. It is critical that an AT-based option is customer tailored and strictly individualized (Lancioni, Sigafoos, O'Reilly, & Singh, 2012).

Beside the aforementioned approach, telerehabilitation (TR) may be considered for assessment and rehabilitative purposes. In fact, TR offers advantages in terms of both synchronous or asynchronous data recording, assessment, and recovery processes. Thus, persons with neurodegenerative diseases may be assessed and recovered for cognitive, communicative, and motor functions through TR strategies (Asano et al., 2021; Kim et al., 2021). Moreover, TR may be viewed as a valid strategy to overcome Covid-19 pandemic negative consequences (Langer et al., 2021).

Although a substantial body of literature exists for both practical and clinical areas of investigation (AT and TR; Belic et al., 2019; Koumakis, Chatzaki, Kazantzaki, Maniadi, & Tsiknakis, 2019; Stamford, Schmidt, & Friedl, 2015), none of the available review papers presents a combination of both domains. Additionally, the published reviews are exclusively focused on a specific disease (e.g., Parkinson or sclerosis) rather than provide the reader with a comprehensive review targeted on different neurodegenerative diseases.

METHOD

A computerized search was performed in Scopus database. Neurodegenerative diseases, Alzheimer disease, Parkinson disease, amyotrophic lateral sclerosis, multiple sclerosis, young and older adults, assessment, rehabilitation, AT, TR, neurological disorders, intellectual disabilities, motor impairments, communication disorders, isolation, passivity, active role, constructive engagement, positive participation, quality of life, pain, reminiscence, functional activities, leisure, occupation, physical exercise, and detachment were merged as keywords. A manual search was added as completion. Including criteria were: (a) empirical studies with an AT-based intervention or a TR-based program, (b) a participant with a neurodegenerative disease with an age of 20 years or older, (c) English language of the paper, and (d) 2011-2021 as time interval publication year. Excluding criteria were: (a) review papers, (b) theoretical papers, (c) book chapters, (d) conference papers, and (e) only children or adolescents as participants (i.e., 19 years old or younger). Five main categories of studies were identified, namely (a) recovering of functional and physical activities, (b) communication abilities, (c) positive participation, (d) leisure and recreation, and (e) telerehabilitation. The following section (i.e., literature overview) includes a concise description of the reviewed studies. Synoptic tables were additionally included to improve the readability and the clarity of the overview. The authors of the studies, the recruited participants, their ages, the setups used, and the outcomes were presented. Irrespective of the number of the studies retained in each section, three contributions were concisely detailed along each category for practical reasons.

LITERATURE OVERVIEW

Functional and Physical Activities

To prevent isolation and passivity, the recovery of daily functional and physical activities may be considered essential. Thus, AT-based programs are commonly focused on reactivate occupational tasks among

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persons with mild to moderate Alzheimer Disease or to promote basic physical exercises of patients with moderate to severe Alzheimer Disease. The completion of daily functional activities may be pursued through a task analysis and either visual or verbal prompts, which may eventually be combined in a unique solution. Otherwise, one can use reminders, step instructions, and praise provision. Backward or Forward chaining may be additionally acknowledged. Different technological devices may be used such as microswitches, laptops, tablets, and/or smart-phones and mobile technologies equipped with an adapted software (Mancioppi, Fiorini, Timpano, Sportiello, & Cavallo, 2019). Physical exercise may be supported by microswitches, contingent positive stimulation, walkers, and both physical and verbal prompts as reminders in case of no responding (Klimova, Valis, & Kuca, 2018; Stasolla, Caffò, et al., 2017). Otherwise, persons with Parkinson disease may be helped along walking process because they may be affected by motor blocks known as freezing of gait (Stamford, Schmidt, & Friedl, 2015). Ten studies were selected along this section with 144 participants included (Imbeault, Langlois, Bocti, Gagnon, & Bier, 2018; Lancioni, Singh, O'Reilly, et al., 2017, 2018, 2019; Lazarou et al., 2019; Oksnebjerg, Woods, & Waldermar, 2019; Rohrbach et al., 2019; Stummer et al., 2015; Wang, Sudhama, Begum, Huq, & Mihailidis, 2017; Zhao et al., 2016; see Table 1).

For instance, Oksnebjerg et al. (2019) evaluated four steps of an interactive user including a rehabilitation program based on cognitive support technology, through an app design process. In the first step, a pilot investigation was carried out to explore beneficial outcomes and challenges of adopting existing off-the-shelf app to support self-management with living with the early stages of dementia. The second step included focus-group interviews conducted in-depth comprehension of the needs and perspectives of potential end-users of the app. The third step consisted of a product benchmarking process, which was useful to further evaluate the design process. The final step considered an iterative co-design process, which encompassed the three previous steps. Twenty-eight participants with dementia who were aged between 53 and 82 years, seventeen family caregivers (i.e., mean age 60 years), and 10 professional caregivers (i.e., mean age 49 years) were enrolled. Results evidenced the effectiveness and the suitability of the app for helping people with dementia in the self-management of everyday life functional activities. Memory support and structure in daily living were recognized as basic needs and the adopted technology was identified as a suitable solution with a tailor-made calendar as key-feature.

Rohrbach et al. (2019) conducted a crossover study with 10 patients who were aged between 51 and 84 years and suffered from mild to moderate Alzheimer Disease using an augmented reality approach including a Microsoft HoloLens to support participants in a tea making task. The participants were tested and post-hoc semi-structured interviews were carried out to assess the usability. The study took place in a qualified medical center for cognitive disorders. Two experimental conditions were implemented, namely (a) natural or control condition and trials (i.e., experimental condition) guided by an augmented reality, which consisted of an application developed within a user centered strategy including four iterative cycles through mutual collaboration between researchers, clinicians, and family members. A step-by-step guidance system for a multi-step activity daily living task (i.e., preparation of a cup of tea) with embedded audio-visual cues was assessed. Results demonstrated that participants failed when they executed the task with or without holographic assistance. No statistical differences emerged in success rates or error frequencies. However, data showed participants' prolonged trial durations when equipped with the augmented reality headset. Moreover, a multiple linear regression revealed an influence of the errors in the control condition and a moderation of the errors in the experimental condition. Participants who presented more severe problems in the natural condition emphasized lower improvements in trials duration once provided with the technology (i.e., augmented reality).

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Table 1. Reviewed studies on physical and functional activities

Studies	Participants	Ages	Technology	Disease	Outcomes
Imbeault et al. (2018)	1	65	Tablet and App	Alzheimer	One positive
Lancioni et al. (2017)	21	72-93	Microswitches	Alzheimer	One negative
Lancioni et al. (2018)	17	70-92	Microswitches	Alzheimer	Two negative
Lancioni et al. (2019)	21	73-96	Smartphone and App	Alzheimer	All positive
Lazarou et al. (2019)	6	69-84	Smart system	Alzheimer	Six positive
Oksnebjerg et al. (2019)	28	53-82	Interactive program	Dementia	All positive
Rohrbach et al. (2019)	10	51-84	Augmented Reality	Alzheimer	Ten positive
Stummer et al. (2015)	18	55-71	Walk-bicycle	Parkinson	Two negative
Wang et al. (2017)	10	59-88	Robot	Alzheimer	Ten positive
Zhao et al. (2016)	12	53-78	Smart-glasses	Parkinson	Twelve positive

Zhao et al. (2016) exposed twelve participants aged between 53 and 78 years and diagnosed with Parkinson disease to a rehabilitative program focused on the improvement of their gait through the use of new mobiles like smart-glasses. The technology was used to deliver external cues that could enhance ambulation process in a natural environment. Specifically, the study analyzed rhythmic visual and auditory cueing in a laboratory with a customer-made application for the Google Glass. Different gait parameters were compared (i.e., walking speed, cadence, stride length, and its variability). Freezing of gait was additionally recorded. Three types of external cues were evaluated, namely (a) metronome, (b) flashing light, and (c) optic flow. A fourth control condition (i.e., no cue) was included. Participants completed several walking tasks with various complexities. Seven inertial sensors attached to the feet, legs, and pelvis monitored and coded motion data for gait analysis. Two professional raters scored gait freezing severity through video-recording. User experience was evaluated with a semi-open interview. During cueing, a more stable gait pattern emerged, specifically on complicated walking courses. Nevertheless, freezing of gait did not decrease. The metronome was more effective compared to the visual cues and more preferred by the participants. The technology was successfully adopted and suitable for fostering gait fluency.

Communication Abilities

Communication skills are considered crucial for social interactions, inclusion, participation and societal affiliation. Additionally, interdependence is embedded based on the principle of give-and-take (Koldrack, Luplow, Kirste, & Teipel, 2013). Being related with other individuals may be viewed as a basic feature of quality of life. Social relations ensure emotional support and positively involve people in daily activities, being constructively engaged (Holthe & Wulff-Jacobsen, 2016). Due to either intellectual dis-

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abilities or extensive motor impairments, young and older adults with neurodegenerative disease may systematically fail to communicate with other people (Kotipalli, Praveen Kumar, Mohan Raju, & Murali Krishna, 2019). AT-based programs and aided-alternative and augmentative communication strategies may be useful to enable people with neurodegenerative disease to profitably cope with their environment (Asghar, Cang, & Yu, 2018; Brownlee & Bruening, 2012; Fried-Oken, Mooney, & Peters, 2015). Thus, computerized systems, tablets, I-PAD, I-POD, Smartphone with adapted software and specific sensors capable of adequately detect even small behavioral response are commonly used (Sigafoos et al., 2019; van der Meer et al., 2017). Ten studies were reviewed with 75 participants involved (Caligari, Godi, Giardini, & Colombo, 2019; Lancioni, Simone, et al., 2015; Lancioni, Singh, O'Reilly, Sigafoos, D'Amico, et al., 2015a, b, 2016, 2017; Lancioni, Singh, O'Reilly, Sigafoos, D'Amico, Sasanelli, et al., 2016; Santos, Licursi, Amaral, Cavalcanti, & Silveira, 2019, see Table 2).

For example, Caligari et al. (2019) designed a new sensor (i.e., the Lever Magnetic-spring Mechanical Switch, LeMMS), ensuring repeated activation and/or releasing cycles requiring a very small action force. Twenty participants, mean aged of 59 years and diagnosed with advanced amyotrophic lateral sclerosis (ALS) were enrolled and exposed to the new technology focused on the enhancement of their communication skills. All the participants regularly used other sensors but they were unable manage the technology due to their clinical conditions, except for the new LeMMS. Observations occurred at the baseline (T0), and after one (T1), six (T2), and twelve months (T3). At baseline, participants were evaluated through standardized clinical scales. The click-Test-30 considered the maximum number of the LeMMS activations along 30 s and thumb/fingers strength evaluation was monitored through the Kendall scale. The QUEST 2.0 Dev questionnaire was administrated at T1. Some use-related information added to the Click-Test-30 were collected at T1, T2, and T3. Results demonstrated that after one training session, all the participants were capable of use the LeMMS with a minimal effort (i.e., minimal residual movement of one finger). The mean score of QUEST 2.0 Dev questionnaire suggested a strong satisfaction with the LeMMS. No significant differences emerged at Click-Test-30 between T0 and T1. However, at T2 and T3 the performance significantly decreased. At T3 half of the participants were able to use their communication device.

Jarosiewicz et al. (2016) exposed a 52-years old man diagnosed with ASL to the use of brain computer interface (BCI) and a kinematic decoder (i.e., a decoder that controlled cursor movements) to demonstrate its calibration using collected data during practical point-and-click control of the BCI. A retrospective inference of the user's intended movement directions was adopted, based on subsequent selections. An extension of such method was investigated to allow the click decoder to also be recalibrated using acquired data during practical BCI use. Neural data patterns were retrospectively labeled as equivalent to click during all time bins in which the click log-likelihood was above the click threshold that was adopted during real-time neural control. The click decoder using standard supervised classifier training method was labeled as "non-click". The participant was enabled to freely type across 11 research sessions spanning 29 days, maintaining high performance neural control over cursor movement and click without needing to interrupt virtual keyboard use for explicit calibration task through a combined real-time bias correction and baseline firing rate tracking. That approach successfully corroborated the clinical validity of intra-cortical BCI for individuals with extensive motor impairments by eliminating the need for calibration task with prescribed targets and click times.

Santos et al. (2019) presented the design process of an AT device for people with Parkinson disease and some tremor in the hands. A user-center design approach was proposed based on the integration of the tools House of Quality (QFD) and TRIZ, seeking for a feasible innovative technical solution focused

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Table 2. Reviewed studies on communication skills

Studies	Participants	Ages	Technology	Disease	Outcomes
Caligari et al. (2019)	20	42-84	Mechanical switch	ASL	Twenty Positive
Jarosiewicz et al. (2016)	1	52	BCI	ASL	One Positive
Lancioni, Simone et al. (2015)	5	54-67	Computer + Microswitch	ASL	Five Positive
Lancioni et al. (2015a)	3	65-85	Computer + Microswitch	Alzheimer	One Negative
Lancioni et al. (2015b)	16	72-93	Computer + Microswitch	Alzheimer	Eight Positive
Lancioni et al. (2016)	8	73-96	Computer + Microswitch	ASL	Four Positive
Lancioni et al. (2017)	4	52-68	Computer + Microswitch	Parkinson	One Negative
Lancioni, Sasanelli et al. (2016)	3	71-80	Computer + Microswitch	ASL	Four Negative
Mc Cane et al. (2015)	14	41-72	BCI	ASL	Fourteen Positive
Santos et al. (2019)	1	60	Design Approach	Parkinson	One Positive

on meeting users' requirements. Additionally, a 3D printing was adopted as a tool to enhance and refine the design, through the manufacture of mock-ups and prototypes used in interaction and testing with users. Four main features were relevantly fostered, namely (a) the communication among members of multidisciplinary team, (b) a clearer identification of the design demands and users' needs, (c) a development time reduction, and (d) creation of feasible and innovative solution. Preliminary test involved a 60-years old man with Parkinson disease, who followed a regular medication treatment and a single-case experimental design was applied to demonstrate the impact on the quality of the feeding task with regard to both performance and satisfaction.

Positive Participation

A further feature that represents a critical basis of constructive engagement, active role, and quality of life is positive participation. Because persons with neurodegenerative diseases commonly experience isolation and passivity, to promote positive participation may be viewed as a primary rehabilitative goal among researchers and clinicians. Thus, AT-based interventions may be helpful to enhance it by fostering social interactions. Accordingly, the technological supports ensure individuals with neurodegenerative disease with the independent access to positive stimulation. That is, participants with neurodegenerative disease will be capable of independently interact with the surrounding environment and positively participate to the daily social life (Klimova, Valis, & Kuca, 2018; Savvidis et al., 2018). Four studies were retained with 34 participants recruited (Lancioni, Bosco, et al., 2015; Lancioni, O'Reilly, Singh, et al., 2013a, b; Lancioni, Singh, O'Reilly, Green, et al., 2013, see Table 3).

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Lancioni, Bosco, et al. (2015) assessed the outcomes of response-related music stimulation versus unrelated-response (i.e., general) music stimulation on positive participation of 11 participants with severe and low-moderate levels Alzheimer disease, who were aged between 71 and 94 years. Positive participation encompassed behavioral signs of singing and/or rhythmic movements and smiles. Both experimental conditions were delivered through a computerized system which provided the participants with preferred music/song and amusing videos. In the experimental condition (i.e., related music stimulation), the participants were requested to activate a pressure circular button to receive brief periods of pleasant events. In the control condition (i.e., general) music stimulation was automatically determined throughout the sessions (i.e., continuously). Six participants evidenced higher intervals of positive participation in the experimental condition, conversely to five participants who emphasized no significant differences between conditions.

Lancioni et al. (2013a) evaluated the impact on positive participation added to social rating of an AT-based program which included six participants diagnosed within the severe range of the Alzheimer disease and who were aged between 76 and 89 years. Two conditions were implemented, namely (a) an active condition, and (b) a passive condition. During the active conditions the participants were equipped with the technology (i.e., computer and microswitch) ensuring them with brief periods of positive stimulation contingent to an active responding (i.e., simple hand response). In the passive condition, the stimulation was automatically provided by the system, irrespective of the participants' responding. The active condition revealed higher levels of intervals with positive participation for five of the six participants. The learning process was consolidated during the post-intervention checks. Social raters favorably endorsed the use of the technology.

Lancioni et al. (2013b) extended the comparison between active (i.e., self-regulated) and passive (i.e., outer-regulated) music stimulation with seven participants who were aged between 75 and 90 years and diagnosed between the severe and low-moderate range of Alzheimer's disease. In the active condition, the participants used a simple hand response and a related pressure microswitch to activate music inputs independently. In the passive condition, music stimulation was delivered through the sessions. Results demonstrated an increased levels of intervals with positive participation during both conditions. The improved performance was higher in the active condition for five of the seven participants. No relevant differences were evidenced for two participants.

Leisure and Recreation

A supplementary feature significantly enhanced by the AT-based programs may be leisure and recreation activities. Thus, individuals with neurodegenerative disease may greatly benefit from technological aids and computerized systems because they may be profitably involved in recreation opportunities, which may be favorably fostered through different technological solutions. Essentially, constructive engagement and positive roles may be improved with beneficial effects on participants' quality of life with a contingent reduction of both caregivers and families' burden (Asghar, Cang, & Yu, 2017). Six studies were reviewed along the section with 102 participants involved (Lancioni, Perilli, et al., 2011; Lancioni, Singh, O'Reilly, 2014; Lim, Wallace, Luszcz, & Reynolds, 2013; Neven et al., 2013; Nijhof, Van Hoof, Van Rijn, & Van Gemert-Pijnen, 2013; Plow & Finlayson, 2013, see Table 4).

For instance, Lancioni et al. (2014) exposed four patients diagnosed with moderate Alzheimer's disease aged between 75 and 89 years to a computerized hierarchical program combined with a microswitch enabling the participants to select desired leisure options. The technology additionally included

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Table 3. Reviewed studies on positive participation

Studies	Participants	Ages	Technology	Disease	Outcomes
Lancioni, Bosco et al. (2015)	11	71-94	Computer + Microswitch	Alzheimer	Five Negative
Lancioni et al. (2013a)	6	76-89	Computer + Microswitch	Alzheimer	One Negative
Lancioni et al. (2013b)	7	75-90	Computer + Microswitch	Alzheimer	Two negative
Lancioni, Singh, et al. (2013)	10	72-92	Computer + Microswitch	Alzheimer	Ten Positive

an amplifier, an interface and adapted software. The participants were requested to choose among four different music styles (i.e., classical, opera, pop male singers, and pop female singers). Each option was automatically scanned and identified with a double (i.e., verbal and visual) cue. Once the participants selected the category, they were asked to choose among the singers of the selected category. Finally, they were asked to select a specific song of the selected singer. Once completed the selection with three different responses useful to minimize unintentional choices, they could listen 2-3 min of the desired song. Results showed that all the participants learned to profitably use the technology for leisure purposes. External raters (i.e., forty-four psychology students) favorably endorsed the use of such technology.

Lim et al. (2013) investigated the usability of tablet computers as part everyday living in people with dementia. Twenty-one participants with an early stage of dementia and career-dyads were recruited for a seven-day in home setting. Sessions were collected to determine whether patients with early stage of dementia were capable of using a tablet-based program independently and reduce caregivers' burden accordingly. Feedbacks were returned through questionnaires from both patients and personnel enrolled. Results evidenced that half of the participants were able to constructively engage with and use the tablet computer independently and demonstrated to be useful to their caregivers. No significant traits were recorded to uniquely identified who were the patients less likely to use the tablet computer. Caregivers' relief was measured by the amount of time participants with dementia spent adopting the device without supervision.

Nijhof et al. (2013) examined the effectiveness and suitability of a technology-supported leisure game for people with dementia in relation to the stimulation of social behavior. Specifically, the additional impact of the technological equipment was assessed in a nursing home and daycare setting compared with a traditional leisure activity. The technology-supported game pursued the stimulation of social behavior and interaction among participants via its design features, which included a TV, radio, telephone, and treasure box. A mixed-method research design was implemented. Ten participants diagnosed with a moderate range of dementia were recruited. Data demonstrated that social behaviors occurred more frequently than non-social behavior during the sessions. Females scored higher than males in social behavior. Caregivers were significantly facilitated and their work was easier with the use of the technology. The activities resulted more person-centered.

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Table 4. Reviewed studies on leisure and recreation.

Studies	Participants	Ages	Technology	Disease	Outcomes
Lancioni, Perilli, et al. (2011)	1	85	Technological equipment	Alzheimer	One Positive
Lancioni et al. (2014)	4	75-89	Computer + Microswitch	Alzheimer	Four Positive
Lim et al. (2013)	21	55-70	Tablet Computer	Dementia	Eleven Negative
Neven et al. (2013)	36	27-63	GPS tracking device	Multiple Sclerosis	Fifteen Negative
Nijhof et al. (2013)	10	61-78	Technological equipment	Dementia	Ten Positive
Plow and Finlayson (2013)	30	52-68	Technological equipment	Multiple Sclerosis	Thirty Positive

Telerehabilitation

TR as part of telemedicine, is currently adopted to remotely supervise and evaluate users in a synchronous or asynchronous way (Brunner, Hemsley, Togher, & Palmer, 2017). During Covid-19 pandemic both strategies may be helpful to promote participants' active role, constructive engagement, and functional occupation, next to assessment and diagnosis objectives. Thus, users' s quality of life (QoL) might be enhanced with families and professionals' burden reduction. Although both approaches were documented in the literature, no records were found on both combined approaches in NDD. Five studies were included in the current section (Albiol-Perez et al., 2017; Bernini et al., 2021; Cikajlo & Potisk, 2019; Mantovani et al., 2020; Matamala-Gomez etal., 2021).

Bernini et al. (2021) conducted a perspective study and proposed a home-care rehabilitation equipment to recovery cognitive functions in young and older patients with neurodegenerative diseases. A usable and safe cognitive rehabilitation tool was assessed. Its use was demonstrated in clinical settings with evidence-based data and several advantages for both patients and professionals. It provided users, families, professionals, and caregivers with a valid instrument to be remotely monitored and supervised.

Cikajlo and Potisk (2019) designed a randomized study with 97 patients diagnosed with Parkinson diseases with only 20 eligible participants randomized in two groups. A first group used a 3D technological system and a second group used a traditional laptop. Both groups participated to a 10-session 3 weeks training with a pick and a place task in the virtual world requiring precise hand movement to manipulate virtual cubes. Results showed a higher performance of participants in the experimental group. The 3D immersive, remotely controlled, technology was helpful to enhance users' motor performance.

Albiol-Perez et al. (2017) exposed 10 participants with Parkinson disease to 15 rehabilitation sessions. A groundbreaking system based on a virtual motor rehabilitation. Two points observations (i.e., baseline and end of the intervention) were recorded. A customizable intervention was performed. A low-cost telerehabilitation system was used. Postural control was examined as an outcome measure. Results demonstrated the effectiveness and the suitability of the technological system to improve motor performance and postural control.

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Table 5. Reviewed studies on TR.

Studies	Participants	Ages	Technology	Disease	Outcomes
Albiol-Perez et al. (2017)	10	not specified	virtual reality	Parkinson	Ten positive
Bernini et al. (2021)	not applicable	not applicable	Intelligent System NDD	not specified	Cognitive Rehabilitation
Cikajlo and Potisk (2019)	20	not specified	virtual reality	Parkinson	Twenty Positive
Mantovani et al. (2020)	not applicable	not applicable	Virtual reality +TR	Neurological diseases	Cognitive Rehabilitation
Matamala-Gomez et al. (2021)	not applicable	not applicable	Flow healthcare	Neurological diseases	Remote Supervision

DISCUSSION

Data of the reviewed studies demonstrated that AT-based interventions were suitable and effective to promote daily life skills of persons with neurodegenerative diseases. Results were largely positive although some failures occurred. The recruited participants were progressively capable of independent responding and enabled with profitably coping with their environment. Their self-determination was fostered and positive participation relevantly improved. Both caregivers and families' burden were significantly reduced. External raters involved in social validation procedures favorably corroborated the clinical validity of the implemented programs. TR and new technologies were helpful to assess and recover individuals with neurodegenerative disease through remote supervision. Healthcare and well-being of the participants involved were enhanced along the rehabilitative interventions. The findings were largely supported by the existing literature (Gongora Alonso et al., 2019; Stasmford, Schmidt, & Friedl, 2015; Stasolla, Boccasini, et al., 2014) and suggested the following considerations.

First, AT-based programs may be considered a great practical and rehabilitative resource helping young and older adults with neurodegenerative diseases to promote daily adaptive skills and enhance self-determination. Thus, patients with neurodegenerative enrolled in the retained studies diseases were capable of achieving both functional and physical activities. The participants' communication skills were relevantly promoted and leisure opportunities were fostered. Accordingly, caregivers and families' burden were meaningfully reduced. The management of daily life was improved (Lancioni et al., 2004; 2007a; Stasolla & De Pace, 2014).

Second, positive participation and functional occupation were supported. Thus, the recruited participants were constructively engaged in the proposed activities and/or tasks with beneficial outcomes on their quality of life. Consequently, isolation, passivity, and detachment were practically prevented. The participants improved their active role and were profitably included in the implemented programs. Their positive mood, whenever recorded, was inceased accordingly. One may reasonably argue that AT-based interventions had a beneficial impact on the participants' wellbeing, pleasure, and fulfillment (Lancioni et al., 2007b; Stasolla, Damiani, et al., 2014).

Third, the participants consolidated the learning process over the time. Thus, the performances were encouraged over the time and across settings along the studies in which both features were recorded. One may argue that the learning process was significantly enhanced and strengthened. Thus, the assiduity

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and regularity of the collected sessions allowed the acquisition of the participants' adaptive behaviors. Moreover, data indicated that their adaptive responding was purposeful (Catania, 2012).

Fourth, external raters included in social validation assessments, either professionals (e.g., caregivers, neurologists, psychologists, and physiotherapists), or families' members (i.e., parents) favorably scored the use of the technology. Traditionally, they evaluated the dimensions of (a) participant's comfort, (b) program's rehabilitative and/or practical impact, (c) participant's independence and/or self-determination, (d) suitability in home and medical centers care settings, and (e) rater's involvement as researcher in that implemented program (Lancioni, O'Reilly, et al., 2006).

Fifth, TR and new technologies seemed to be a valid way for both clinicians and researchers to assess and recover adaptive behaviors and cognitive skills of individuals with neurodegenerative diseases remotely. Researchers could either track behavioral responses or evaluate brain activities through virtual environments. Furthermore, TR included experimental controlled settings and/or ecological contexts. One may argue that differences between younger and older adults emerged with regard to the acquired confidence with the technology itself. That differences might influence their performance (Caffò et al., 2016, 2020).

Sixth, despite the aforementioned positive outcomes some failures occurred. By reading the synoptic tables included along the chapter, one may emphasize that that TR approach seemed to be an encouraging and promising strategy as a future perspective. Data on AT-based interventions were mixed. Although extensively encouraging and promising, the different participants failed, as above reported. Two considerations can be emphasized with this regard. Next to the technological solutions adopted to be further customized, one may argue that the selected behavioral responses required an excessive effort. A further explanation might be that the collected sessions were not systematically conducted over the time to corroborate the learning process (Chalmers, Hurst, Mackay, & Fergus, 2019; Tang, Wang, Ramhumar, & Nair, 2020).

CONCLUSION

The current overview emphasized five categories of studies on the use of AT and TR to support adaptive responding of individuals with NDD. Technological aids enhanced the participants' active role, self-determination, and positive participation. The users were enabled in communication skills, physical activities, leisure, and occupation opportunities. Moreover, they were easily monitored and supervised remotely through TR strategies. During Covid-19 pandemic it was very useful because the pandemic event suddenly interrupted medical assistance and rehabilitation care. With virtual reality setups and telerehabilitation, professionals could easily assess the users' daily performances and provided feedback on learning process. Technological supports were effective and reliable to help persons with neurodegenerative diseases even if physically distanced. Thus, through TR professionals were capable to provide timely feedback on daily use, with beneficial outcomes on both users and families. Their constructive engagement and positive occupation were fostered accordingly. Assessment and rehabilitative objectives were successfully achieved.

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FUTURE RESEARCH

New research within this framework should deal with the following features and topics: (a) extension to a larger sample including further pathologies (e.g., stroke and/or post-coma), (b) design new technological solutions and/or options to adequately satisfy both behavioral minimal responses, and more complex environmental requests (e.g., virtual reality-based setups, mobile or wearable technologies), (c) a systematic inclusion along the conducted studies of maintenance and/or generalization phases, added to social validation procedures, and (d) differentiate between single-subject and between groups experimental designs.

For example, one could rely on robots-assisted programs to enhance positive, physical, and social participation of patients with stroke. Otherwise, a combination of microswitches and VOCA could be implemented in post-coma persons in a minimally conscious state to enable the participant with self-administration of positive stimulation and/or asking for social contact with a caregiver. Finally, systematic comparisons of virtual reality setups, mobile technologies, and wearable technologies could be envisaged (Stasolla, 2021; Stasolla et al., 2021).

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KEY TERMS AND DEFINITION

Assistive Technology: Umbrella term which includes any device, piece, tool, or equipment ensuring individuals with neurodegenerative diseases with self-determination and independence.

Constructive Engagement: Participant' active role and positive occupation to daily activities.

Healthcare: Effort to maintain or restore mental, physical, or emotional well-being, specifically by trained or licensed professionals.

Neurodegenerative Diseases: Neurological disorders caused by progressive loss of structure or function of neurons, which may ultimately involve cell death.

Quality of Life: Complex psychological construct which includes happiness, pleasure, satisfaction, and fulfillment.

Telerehabilitation: Part of telemedicine with professionals who are able to remotely assess, monitor and supervise users in a synchronous or asynchronous way.

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