UNIVERSITY OF MACEDONIA

SCHOOL OF BUSINESS ADMINISTRATION

DEPARTMENT OF BUSINESS ADMINISTRATION

MASTER IN PUBLIC MANAGEMENT, MPM

DIGITAL TRANSFORMATION IN PUBLIC HEALTH.

THE CONCEPT OF CO CREATION PROCESS AT THE IMPLEMENTATION OF LARGE-SCALE HEALTH PROJECTS

by

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Thessaloniki, 2022

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A thesis submitted in partial fulfillment of the

requirements for the degree of

MASTER IN PUBLIC MANAGEMENT, MPM

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“The author affirms that the content of this work is a result of personal work and that appropriate references have been made to the work of third parties, where such a thing was necessary, according to the rules of academic ethics”

ABSTRACT

The topic of digital transformation in the healthcare industry is complex. With evolving roles and duties for all the stakeholders, health systems have become into complex entities. As we entering the patient era, will be required organizational and behavioral changes for healthcare providers to adopt digital technology that enable them to interact and communicate with other clinicians and the health system as a whole. Participatory approaches enable a collective definition and elaboration of requirements and solutions as well as a form of reciprocal learning: technology developers gain knowledge of users' thought processes, working methods, and daily routines. They also permit a variety of voices, concerns, positions, and usage contexts. Co-creation should encourage the development and implementation of agile and use case–focused innovations by incorporating varied sets of experiences and knowledge from potential users into the development and implementation process. The successful and long-term implementation of health projects require following a strategy. It is not so much an issue of "whether" as "how" should be implemented. This thesis discusses the concept of co-creation of a health program via the presentation of the implementation of ICU4COVID project and it turns out that understanding cultural differences is essential for speeding up the installation of systems. We cannot refer to the sustainability of a project ignoring the social factor. Moreover, we must refer as "socio-technical implementation" of a project in order to be viable.

Keywords Digital transformation, ecosystem, artificial Intelligence, telemedicine, ICU, co-creation, implementation, ICU4covid, stakeholders, socio-technical implementation

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ABBREVIATIONS

AHRQ	- Agency for Healthcare Research and Quality
AI	- Artificial Intelligence
CPS4TIC	- Cyber-Physical System for Telemedicine and Intensive Care
DT	- Digital Technologies
EMR	- Electronic medical record
EU	- European Union
ICCC	- Intellispace Consultive Critical Care
ICT	- Information and Communication Technologies
ICU	– Intensive Care Unit
IT	- Information Technology
IoT	- Internet of Things
IoMT	- Internet of Medical Things
IFR	- International Federation of Robots
PPP	- Public Private Partnership
WHO	- World Health Organization

INTRODUCTION

The current situation, which involves a global pandemic caused by a new virus, has raised public, political, and governance awareness of the importance of digital transformation in the field of health. The critical care and treatment situation that is required when working with patients who are infected by COVID-19, necessitates changes in all stakeholders' daily activities. Medical professionals, patients, and their relatives are included. Furthermore, the pandemic highlighted the uneven distribution of Intensive Care specialists among hospital networks' centers and periphery. System developers and providers, in collaboration with clinical and life scientists, have succeeded in swiftly designing and customizing a cyber-physical system to handle the issues posed by COVID-19 in Intensive Care.

For a long time, there has been a concern that if a health information system is not integrated and accepted by health care professionals (users), then it will not be able to perform at its maximum. In fact, it will not be able to serve the purpose for which it was created. The problem gets bigger when it comes to the development of large-scale projects with full participation of end-users, hospitals, and health-care organizations authorities in different regions or countries. This means that, in addition to developing a technological solution, it will be critical to consider how it will be implemented not only in a variety of socio-cultural contexts, but also with the unique characteristics of local institutional contexts and healthcare systems. The implementation of the presented project, ICU4COVID, goes through the process led by the concept of "co-creation" and incorporates findings from implementation research. Unlike traditional co-creation, which involves partners who are already working on technology solutions, the project strives to personalize and adapt the implementation process to local needs. As a result, the implementation process will not only focus on the technical components of improvement, but will also take into account the social and societal features of such a transformative process. This strategy ensures that execution is done in a collaborative way involving many specialists and stakeholders. Users' way of thinking, work practices, and everyday life in the ICU are learned by technology developers, who allow for variety in users' voices, concerns, positions, and settings of use. Users, on the other hand, participate in learning throughout the implementation process, connecting their own experiences and forms of knowledge with the new technology possibilities.

The aim of this thesis is to outline that deploying new technologies in health field does more than simply adding technical equipment or just implementing a new program, even though we refer to a well-structured quality program. By combining various sets of experiences and expertise from potential users into the development and implementation process, co-creation promote the development and execution of agile and use case-focused innovations, because projects' technologies are more than just technical devices. Although, we are in the era of the fourth industrial revolution, where artificial intelligence (AI), robotics, blockchain and other medical 4.0. applications promise to meet human needs in less time, the human factor will always be important for the sustainability of a program. Understanding cultural differences is essential for speeding up the installation of systems. Via the process of co-creation of the implementation of ICU4COVID project, we see that we must refer as a "socio-technical implementation" of a project in order to become sustainable, empowering, caring, and adaptive to new challenges.

1. TECHNOLOGY IN THE FIELD OF HEALTH

The application of information, tools, and skills to solve issues is known as technology, and it is closely related to practice. This word is used in the realm of health to solve a wide range of issues. Digital health technologies, while pre-existing during the COVID-19 pandemic, rose to prominence as the virus's prevention became increasingly important, and the necessity to give efficient remote help contributed to the usage of new technologies. New needs emerged as a result of the pandemic, both on the part of clients of health services and on the part of providers, who were challenged to address them using new technology means. Both societies and economies are fast altering as a result of digital technologies.

1.1. DIGITAL TRANSFORMATION - A COMPLEX AND MULTIFACETED ISSUE

Public Health is defined as "the art and science of preventing disease, prolonging life and promoting health through the organized efforts of society" (Acheson, 1988; WHO). Digital health – a broad umbrella term encompassing e-health, as well as developing areas such as the use of advanced computer sciences (for example, in the fields of "big data", genomics and artificial intelligence) – has a significant impact in strengthening health systems and public health, increasing equity in access to health services, and in working towards universal health coverage. (https://www.euro.who.int/en/health-topics/Health-systems/digital-health). E-Health is a recent healthcare practice supported by the use of information and communication technologies in the healthcare space. It is a broad term that covers a lot of territory, which is why no single terminology has been accepted as a universal standard for the representation of eHealth. It is a means to provide high-quality care for an increasingly number of people and to do so cost effectively and efficiently. Thus, integrated Information Technology (IT) solutions for optimizing clinical and administrative workflow are the keys to success. Both the terms "Digital Health" and "e-Health" are often used interchangeably but the interpretations regarding the same vary widely. "E-Health" is a healthcare practice supported by the use of information and communication technologies in the healthcare space. "E-Health" encompasses much of medical informatics but prioritizes on promoting the use of information communications technology (ICT) in health development and to do so cost effectively and efficiently (https://www.who.int/westernpacific/activities/using-e-health-and-information-technology-to-improve-health).

"Digital Health" represents an evolutionary adaptation of the art and science of medicine to pervasive information and communication technologies. It is an umbrella term for a wide range of technologies that could meet the healthcare challenges. (http://www.differencebetween.net/technology/difference-between-ehealth-and-digital-health/). "Digital transformation" is a term used often in healthcare, though its meaning differs from organization to organization. Here, five (5) executives from health systems across the USA define what the term means to them.

> ***Karen Murphy, PhD, RN. Chief innovation officer at Geisinger (Danville, Pa.):*** *At Geisinger, digital transformation leverages technology to fundamentally improve patient experience and care delivery. Technology is an enabler, not the strategy. We design the transformation initiative prior to selecting the technology solution. This approach ensures that we are not "digitalizing" our current state. Instead, we are striving to make health and healthcare easier, better and more efficient. (https://www.beckershospitalreview.com/digital-transformation/10-hospital-execs-define-digital-transformation.html)*

> ***Gail Keyser, BSN, RN. Co-interim CIO at Hackensack Meridian Health (Edison, N.J.):*** *Digital transformation within the healthcare industry has enabled our patients, caregivers and community members to change the interactions within healthcare. Transitioning from in-person encounters, digital technologies enable healthcare providers to provide personalized services, access to research, connect supportive community services and enable access to your local care provider from anywhere in the world. Digital technologies have evolved to allow our providers to remotely monitor and manage patients' healthcare needs in a way that fits seamlessly into their lifestyles, keeping the patient and their personalized care needs in focus. (ibid)*

> ***Tom Barnett. Chief information and digital officer of Baptist Memorial Health Care (Memphis, Tenn.):*** *With respect to healthcare, I see digital transformation as a formula: simplified*

patient journey + streamlined employee workflow = a memorable experience. The ability to distill the patient touch points down to only what is necessary, make the behind-the-scenes workflow less cumbersome (reducing silos and friction points) and accelerate the entire throughput with carefully selected and complementary technology is the essence of digital transformation. Process is always upstream from technology, and any digital effort should take that into consideration. (ibid)

Mark Kandrysawtz. Chief innovation officer at WellSpan Health (York, Pa.): *Digital transformation is the ongoing effort to reinvent ourselves for the digital economy. We're focused on business and clinical transformation — both to rise to meet changing consumer expectations and to gain efficiency, reliability and scale. At WellSpan, we think about digital transformation as a continuum that moves us from digitization to automation and beyond. (ibid)*

Kathy Azeez-Narain. Chief digital officer at Hoag Hospital (Newport Beach, Calif.): *I believe digital transformation occurs when technology, humans, data, user experience and solving a key problem through digital products meet. Not only do they meet, but they integrate into your organization in a way that changes how it functions. You see operations, culture, processes, patient feedback and experience change. You also see a talent shift since the majority of that transformation is not even about the technology but also about new skill sets that are brought into the company. Many believe that by buying the software or integrating systems we are moving into the digital age, but for transformation to take place, it goes beyond that. You need to see the new processes, tools, systems and people that are being used to drive new experiences and solve problems that exist in the organization through digital experiences. These experiences become a core part of the business versus just a project. There are four* *areas I would look to when trying to bring digital transformation to life. The first: What is the business strategy? It can't be "we need this tool" but has to focus on the strategic evolution of the organization, such as "how do we bring digital access to care to life that is as strong as the physical locations we have?" The second is that consultants are great, but to really drive the change needed, you have to have internal stakeholders that understand how the business currently functions and what changes will need to be made to be part of the story. The third is including customers in your definition of what digital transformation will look like for your organization and making those outcomes part of what defines success. It cannot only be based on what internal stakeholders think. Lastly, focus on change management and process changes that includes both helping employees get on board with the changes that are coming and operating with the processes that digital will require, such as agile decision-making, product thinking and user experience. While there is no easy path to driving digital transformation, being realistic about what that journey requires and will take is really important for organizations to succeed at it. (ibid)*

We can say that "the digital transformation of health services" is a complicated subject. The tree illustrated in Figure 1, depicts the scope of the influence, the areas affected, and the intricacy of the relationships between digital and health service delivery. This topic tree was created by grouping topics from internet texts that included the terms "digital transformation" and "health services." Health technologies, in the broadest sense of the term, have evolved continuously. The content of health-care systems has changed as knowledge and diagnostic, preventative, therapeutic, and rehabilitative options have grown. As a result, health systems have become complicated entities with shifting roles and responsibilities for patients, health care providers, payers, and other stakeholders. The "digital transformation of health services" is considered as an important and influential process that has already had a significant impact on present health care and health systems, and is likely to have an even greater impact on health care and health care delivery in the future. Throughout history, the "power" of humankind has changed only four times, from manpower to horsepower, steam power, and then electric power. To increase services and productivity, every new power required changes to tools, processes, and people's behavior. The power has not changed (it is still electricity); the only thing that has changed (and led to the transition from an industrial to an information society about 1990) is our ability to more efficiently manipulate "things" that we were able to convert into a digital format. As a result, in some cases, we are able to create "artefacts" not directly with our hands in the location where we are, but rather digitally and at a distance. This can be used (or exploited) in any setting where content and context can be digitized without loss. The possibility for context loss and subsequent loss of meaning is particularly critical in the provision of health care. (European Commission, 2019)

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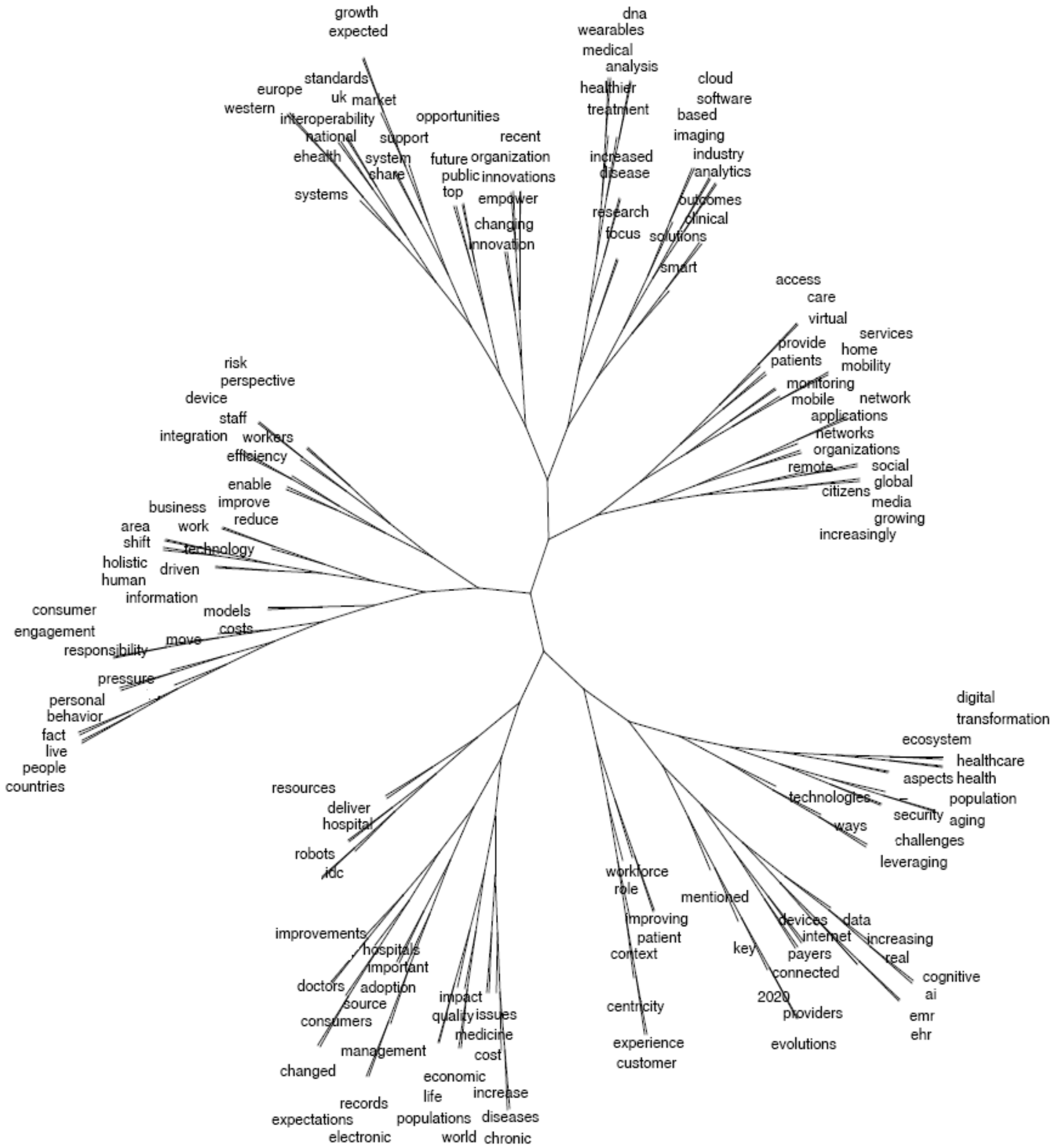


(Figure 1: Illustrating the complexity of the digital transformation of health services. Source: EXPH, 2019)

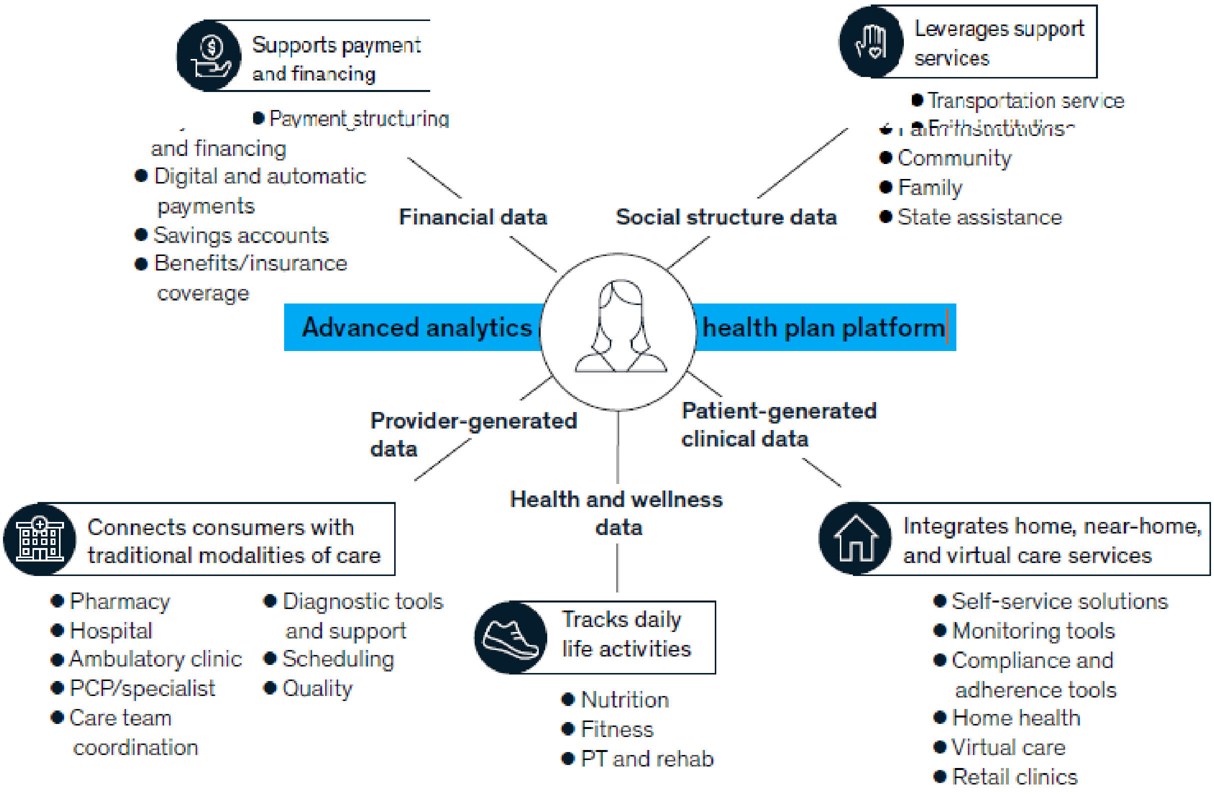
According to WHO (2018) and based on the primary user, the digital health interventions are divided into the following umbrella groups:

- **Interventions for clients:** Members of the public, who are potential or existing users of health services, including health promotion initiatives. This group also includes caregivers of clients receiving health services.
- **Interventions for healthcare providers:** Members of the health workforce who perform health services
- **Interventions for health system or resource managers:** The management and oversight of public health systems are handled by health system and resource managers. This area includes managerial functions such as supply chain management, health financing, and human resource management.
- **Interventions for data services:** This includes crosscutting capabilities to support a wide range of data gathering, administration, use, and exchange activities.

1.2. THE HEALTHCARE ECOSYSTEM

Ecosystems have the potential to transform and disrupt industries. (McKinsey & Co. report, 2019). According to Singhal et al., (2020) they have the potential to provide customers with a tailored and integrated experience, improve provider productivity, engage formal and informal caregivers, and improve results and affordability in healthcare. We define an ecosystem as a set of capabilities and services that connect value chain participants (customers, suppliers, platform and service providers) via a common commercial model and virtual data backbone (enabled by seamless data capture, management, and exchange) to improve and streamline consumer and stakeholder experiences, as well as to address significant pain points or inefficiencies. (ibid). The primary goal today is to prevent and successfully manage chronic diseases. New technologies promise local or at-home care, as well as continuous self - and autonomous care and lower friction costs among supporting parties. The patient will be at the center of healthcare ecosystems. These ecosystems' consumer-oriented character, will also expand the number of healthcare touchpoints, with the goal of changing patient behavior and improving results.

Healthcare ecosystems of the future will be centered on the patient.



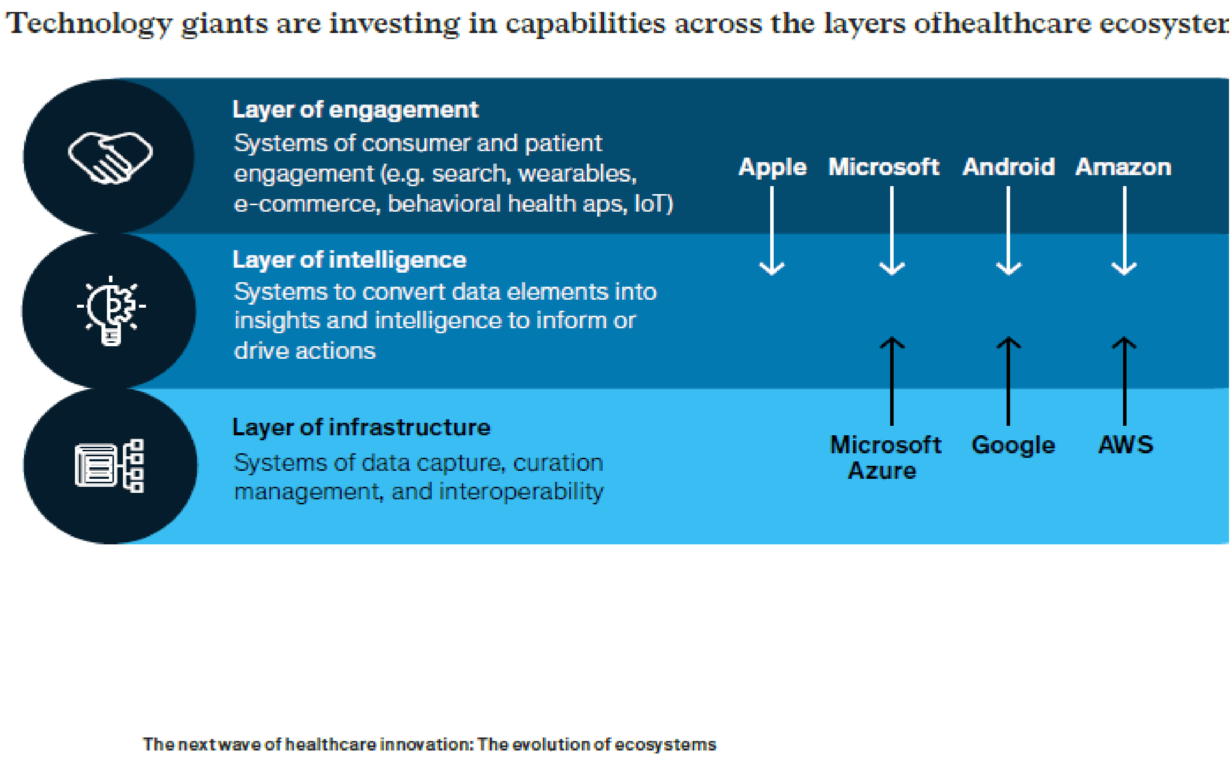
(Figure 2: Adapted from Singhal et al., 2020)

Infrastructure, intelligence, and engagement are the three layers that make up an ecosystem. The infrastructure layer is the backbone of the ecosystem, consisting of efficient data gathering, curation, management, storage, and interoperability to produce a shared data set on which the ecosystem can run. The intelligence layer sits on top of the infrastructure layer, converting data elements into consumable and actionable insights. Finally, to effectively design an end-to-end experience for suppliers who deliver services and offerings to patients, bringing an ecosystem to life necessitates a powerful engagement layer, which is supported by the infrastructure and intelligence layers. Ecosystem curators and players can build, buy, partner, or sell components of these tiers. (ibid)

Data liquidity is required at the infrastructure layer. For the infrastructure layer to serve as the foundation for all insights and decisions made in the ecosystem, data liquidity—the capacity to access, ingest, and change standardized data sets—is essential. This data liquidity allows the ecosystem to produce value and breaks down silos by allowing stakeholders to work together on the same data sets. (ibid)

Advanced analytics are required for the intelligence layer. Advanced analytics are required to successfully translate data from the infrastructure layer to insights in the intelligence layer. Advanced analytics, such as machine learning, natural language processing, artificial intelligence, and big data analytics, are essential for gaining actionable insights that can help stakeholders across ecosystems. Advanced analytics at the intelligence layer will be enabled by data liquidity, resulting in more accurate patient risk assessment, clinical pathway development, and personalized and precision medicine. (ibid)

Shared digital platforms, attractive customer experiences, and new payment structures are all required for the engagement layer. End users interact with services at the engagement layer of the ecosystem, which are backed by underlying data sets from the infrastructure layer and insights from the intelligence layer. The engagement layer necessitates a shared digital platform via which end users can access a curated collection of services and offerings via a single primary channel. Amazon is an example of a non-healthcare ecosystem that allows customers to use a single digital platform to meet a wide range of needs. Appointment scheduling, transportation aid, daily health monitoring, and financial assistance are examples of engagement options in healthcare. Advanced digital medicines and coordinated care will be supported in this layer by data liquidity and infrastructure across traditional and novel care models that rely on up-to-date and comprehensive patient information. (ibid)



(Figure 3: Adapted from Singhal et al., 2020)

1.3. THE SIGNIFICANCE OF INTEROPERABILITY AT THE HEALTHCARE SYSTEM

According to Heart et al., (2017) data analytics has been shown to provide novel insights that can have a substantial impact on the future evolution of healthcare ecosystems, especially when it comes to large-scale collective data (big data). In nowadays, it is suggested that if data or information can flow across healthcare institution boundaries, complete healthcare systems can have significantly more effect and value. (Gottschalk, 2009). In particular, interoperability, as Bhartiya et al., (2016) mentioned, will aid data mobilization across organizational boundaries. The goal of interoperability is to allow data and information to flow freely across diverse parties. Collaboration and synergy across public, business, and civil society partners can be facilitated through collaborative network. In the context of European public administrations, interoperability has been defined as “the ability of organisations to interact towards mutually beneficial goals, involving the sharing of information and knowledge between these organizations, through the business processes they support, by means of the exchange of data between their ICT systems”(European

Commission, 2017). The goal of increasing interoperability is "the development of a European public services ecosystem in which owners and designers of systems and public services become aware of interoperability requirements, public administrations are ready to collaborate with each other and with businesses and citizens, and information flows seamlessly across borders to support a digital single market in Europ*e*" (EXPH, 2019).

As the world population ages, chronic illness becomes more common, necessitating a restructuring of healthcare systems based on information exchange to meet citizen needs and facilitate digital transformation. The concept of healthcare providers adopting digital technologies that allow them to interoperate and collaborate with other clinicians and the health system as a whole is a massive task that will necessitate behavioral and organizational changes. Interoperability promotes continuity of care by allowing information to be shared among various actors working toward a common goal of providing healthcare and well-being. Moreover, interoperability allows for the capture, sharing, and comprehension of data, which leads to better medical care and patient outcomes, while also allowing for knowledge discovery and research in the direction of evidence-based medicine. An interoperability framework is required to create the circumstances for the adoption and use of digital tools in a secure way. Setting clear interoperability policies, guidelines, and governance at the legal, organizational, semantic, and technical levels fosters an interoperable culture among all players in the eHealth and healthcare ecosystems. (Kouroubali et al., 2019)

1.4. THE HEALTHCARE SECTOR'S TECHNOLOGIES

Because the healthcare industry is directly connected with people's social welfare and lives, it is a critical concern for both developing and developed countries. The appearance of corona virus disease enhanced the requirement of new technological advancements, to address a variety of issues related to the viral pandemic. Industry 4.0, often known as the fourth industrial revolution, is a collection of advanced production and information technologies designed to meet the tailored human needs in less time (Javaid et al., 2020). Industry 4.0 is a smart system that uses artificial intelligence (AI), the Internet of Things (IoT), and other digital technologies to offer real-time information for nearly all manufacturing operations. Any medical part can be designed and developed quickly using advanced design tools and digital production technologies (ibid). These powerful computer technologies can help doctors and medical practitioners diagnose ailments earlier. Medical 4.0 technologies can provide staff with real-time data, allowing them to make data-driven decisions. As a result, they are always connected to the patients and kept up to date. People who are empowered have access to all of the resources and information they need to do their best work. Furthermore, there are technologies that contribute to more effective research & development, to more efficient operation health providers while others contribute to more effective patient care. The following are some of the most important Medical 4.0 applications:

1.4.1. INTERNET OF MEDICAL THINGS

The Internet of Medical Things (IoMT) is a subsection of the Internet of Things dedicated to healthcare. This vast network will be home to billions of low-bit-rate and low-energy connected health monitoring devices, remote sensors, and clinical wearables, with 5G serving as the IoT backbone infrastructure. Doctors currently use these devices to collect and transmit data about their patients. The data is received in real time, allowing healthcare providers to analyze it quickly, draw conclusions, and administer or alter therapies. On the diagnostics and prevention front, this information will enable doctors to improve the accuracy of their diagnoses and, as a result, the efficacy of their treatments. (https://blogs.3ds.com/northamerica/what-it-means-to-be-a-patient-in-the-new-era-part-2/). Healthcare 4.0 is one of the fastest industries to adopt IoMT technologies, with the goal of providing individualized services, lowering operating costs, and improving patient care and quality of life (http://www.vph-institute.org/news/healthcare-4-0-a-new-way-of-life.html.)
Nonetheless, the promises of the IoMT have not yet resulted in significant changes in

how most patients and healthcare practitioners experience healthcare (Mavrogiorgou et al., 2019)

1.4.2. CONNECTED HEALTH

In this technological age, healthcare is rife with acronyms and jargon. Health Information Technology, Electronic Medical Record (EMR), digital health, video-enabled telehealth and telemedicine, mobile health, remote patient monitoring, IoT, AI, exponential medicine, e-Patient, hearables, wearables, patient experience and many others. The field of connected health is a mix of technology, sensors, devices, intelligent communications, and data exchange aimed at providing actionable insights to enhance patient outcomes. More integrated care, better-informed health and wellness decision-making, and enhanced access to quality healthcare are all made possible by technology. Telemedicine and Telehealth are the foundations of Connected Health. It is now an umbrella term that encompasses both the technologies described above as well as the processes and workflows that connect them and make the entire system work. It consists of two major components: self-care and remote care, which can be combined in a variety of ways to achieve specific goals for a given patient population, disease area, or care setting (https://blogs.3ds.com/northamerica/connected-health-care-and-the-internet-of-medical-things-iomt/). Telemedicine offers a new way to deliver treatment over long distance. Patients in hard-to-reach locations who can be treated via video connection find telehealth particularly appealing, while telemedicine allows doctors to consult with specialists remotely. (Long et al., 2018). Baratloo et al. (2018) present a review of twenty-six (26) research that assess the program Telestroke, arguing that telemedicine can improve stroke care in rural locations with minimal thrombolysis experience. Telestroke program connects specialists to physicians at a stroke patient's bedside while transmitting critical clinical signs in real time, allowing distant specialists to offer therapeutic guidance (ibid).

1.4.3. SYNTHETIC BIOLOGY

The definition of synthetic biology remains ambiguous because its full potential is unknown, and researchers are experimenting with a variety of problem-solving approaches. However, the discipline is generally regarded as involving the application of engineering principles to “design and construct…new biological parts, devices and systems” and re-design “existing natural biological systems for useful purposes.” (Douglas and Savulescu, 2020). The underlying objective of making biology easy to engineer drives a lot of work. Individuals skilled in a number of areas, including biology, engineering, chemistry, genetics, and computational sciences, perform and enable synthetic biology research. Synthetic biology also encompasses efforts to create biological elements (such as chemicals, genetic sequences, systems, and small organisms) that are not found in nature in order to achieve predictable and dependable execution of certain activities (ibid).

1.4.4. ROBOTICS

The use of robots and automation in healthcare and related fields is growing day by day. The International Federation of Robots (IFR) anticipates that demand for medical robots will continue to rise in the future years (Iqbal, 2017). Robots not only assist physicians and medical staff in performing complex and precise jobs, but they also reduce their workload, enhancing the overall efficiency of healthcare institutions (Taylo, 2016). In light of the current pandemic, robots are well adapted to caring for COVID-19 patients, potentially replacing or at least sharing the effort of medical staff in overburdened hospitals. In today's hospitals, a variety of robotic technologies is employed for medical support (Vanni, 2017). Robots have been given a variety of responsibilities to help prevent the spread of COVID-19, including cleaning and food preparation in contaminated locations that are dangerous to people (Khan et al., 2020). The European Commission formed the Public Private Partnership in Robotics (PPP) inside the Horizon 2020 framework, a body made up of representatives of the "European robotics industry, research, and academia." (https://ec.europa.eu/digital-single-market/en/roboticspublic-private-partnership-horizon-2020). The PPP's purpose is to create a shared roadmap for robotics development in the EU and to explore the criteria that must be met to achieve it. The European Commission's purpose in this group is to create a platform and to utilise the PPP's results in their own funding and legislation strategies. In order to develop a 'common ground,' the PPP is currently focused more on the interrelationship between the issues robotics, AI, and data (euRobotics,2020).

1.4.5. BLOCKCHAIN

Due to the rise of cryptocurrency such as Bitcoin and Ethereum, blockchain and smart ledger research has grown in interest in recent years (Tanwar et al., 2019). Blockchain stores and shares data in a decentralised, trusted, and unchangeable manner, eliminating the need for intermediaries and centralized transaction verification (Mistry, 2019). Transparency in blockchain provides a less sophisticated approach for accessing based transactions through networks; it links with various computing nodes in the blockchain network, making it extremely powerful in terms of calculation speed (Vora, 2018). Healthcare practitioners generate massive volumes of data in a variety of formats, including reports, financial papers, laboratory test results, imaging tests such as x-rays and CAD scans, and vital sign measures, among other things (Rifi et al., 2017). The vast database generated in healthcare settings is rapidly expanding, but healthcare data faces a number of issues, including data access and how that data can be accessible outside of the healthcare facility. The blockchain technology has the potential to improve data verification and integrity. It also aids data distribution inside a network or set of facilities. These attributes have an impact on the system's cost, data quality, and value of healthcare delivery. Blockchain healthcare systems do not necessitate multiple levels of authentication and allow everyone who is a part of the blockchain architecture to access data. Users can see and understand the data because it is made visible and transparent. These features can aid in the resolution of the various challenges confronting the healthcare industry today. Blockchain is an open, decentralized system that eliminates the need for a "middleman" (ibid).

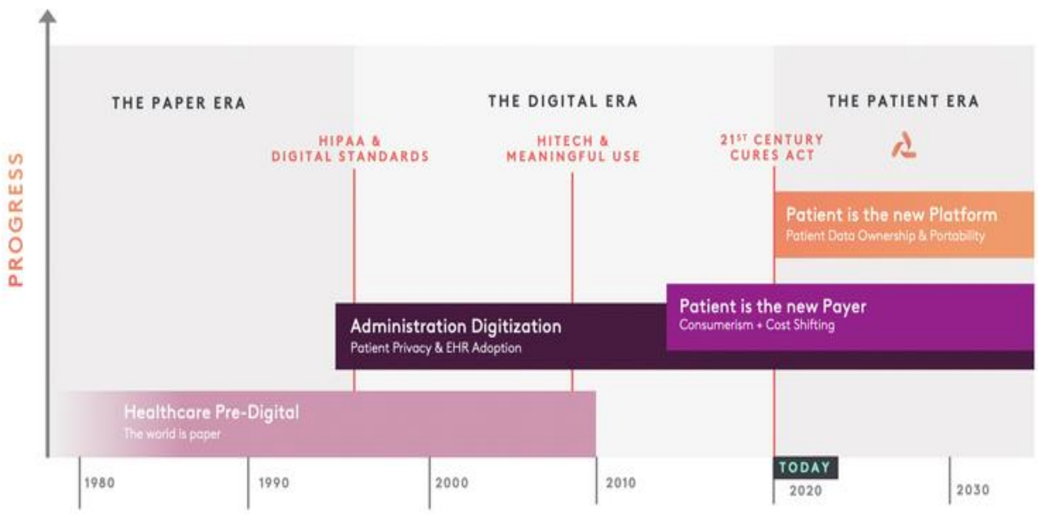
1.4.6. ARTIFICIAL INTELLIGENCE

Artificial Intelligence (AI) is a human intelligence research and prototype in which a wise specialist is a system that understands its circumstances and engages in behaviors that increase its development risk. "Artificial" refers to objects that are created or developed by persons rather than existing naturally, while "intelligence" refers to the ability to define methods to attain goals by associating with a data-rich world. In essence, man-made awareness refers to machine knowledge and the software engineering division that is responsible for generating it. (Raviprolou, 2017).

AI can 'learn' features from a big volume of healthcare data using complex algorithms, and then use the results to aid clinical practice. It could also have learning and self-correcting capabilities to enhance accuracy depending on input. Physicians can benefit from AI systems that provide up-to-date medical information from journals, textbooks, and clinical practices to help them provide effective patient care (Pearson, 2011). Furthermore, an AI system can aid in the reduction of diagnostic and treatment errors that are unavoidable in human clinical practice. In addition, an AI system collects usable data from a huge patient population to aid in real-time conclusions for health risk alert and prediction (Neill, 2013). According to Darcy, (2016), when it comes to devices, there are primarily two types of AI devices. Machine learning (ML) techniques that analyze structured data like as imaging, genomic, fall into the first category. In medical applications, machine-learning algorithms try to cluster patients' features or predict disease outcomes (ibid). Natural language processing (NLP) technologies, which extract information from unstructured data such as clinical notes/medical journals to complement and enrich structured medical data, fall under the second group. NLP processes aim to convert text into machine-readable structured data that may then be analyzed using machine learning techniques. (Murff et al. 2011)

1.5. ENTERING THE PATIENT ERA

Patients are becoming active decision-makers in their medical care process as a result of the rise of digital technologies (DT). Gray et al., (2013) look at the cumulative value of center edge models, such as value chains, value shops, and value networks, to see how DT affects the healthcare provider-patient interaction. Self-service and feedback cycles are the most prominent features of this relationship. Their qualitative empirical findings show that healthcare is a consumer-centric industry that is well-positioned for a fundamental center-edge transition. Mende (2019) argues that healthcare customers are both "co-producers of service" and "partial employees" who must actively participate in their own health management. As we continue to fight the worldwide pandemic (Sars – cov-2), manage the world's largest vaccination distribution, and keep our health systems running, we must focus our attention to the future. While most people will remember 2020 as a year of confusion and pain, there was a hidden signal in the midst of all the chaos: the beginning of the Patient Era, a new era of healthcare that gives promise and hope.



(Figure 4: Adapted from: https://www.lumedic.io/perspectives/introducing-the-patient-era)

The implementation of privacy and data standards, as well as the adoption of Electronic Health Records, heralded the start of the Digital Era. The Patient Era will usher in a new era of digital solutions and ecosystems centered on the individual and consumer, with the patient as the new platform. Patients will have more power over their health information than ever before in this new environment, which will revolutionize how we share information, shop for care, give transparency, and better coordinate the many elements of healthcare. Technology continues to provide new doors to work smarter, faster, at less cost, because of innovation. A new pattern emerges today that allows us to reimagine the processes and systems that constituted the previous era of healthcare, from AI to blockchain to cloud computing and smartphones. The necessary tools exist now, leveraging technologies like verifiable credentials and decentralized identities that will allow health companies to design solutions for patients in ways they haven't been able to unlock until now. (https://www.lumedic.io/perspectives/introducing-the-patient-era).

In 2015, the World Health Organization (WHO) stated that people-centered and integrated health services have been proven to benefit people and health systems in countries of all income levels around the world. People-centered and integrated services, according to the research, are critical components of achieving universal health coverage and can enhance health status. Furthermore, knowledge is a powerful tool. Health and especially the lack thereof, is a highly personal experience. Patients are increasingly empowered to take charge of their own health and wellness, as well as to seek closer relationships with their healthcare professionals to obtain better clinical outcomes, thanks to ever-increasing technological advancements. All of these themes have intensified, from illness prevention to AI for early diagnosis to connected health to digitizing clinical trials. In the fight against COVID-19, even 3D printing has become an important instrument. One thing is certain: the global coronavirus pandemic's setbacks have opened up several chances for the creation of creative technical solutions to the current issue. It also offers the ability to turn the healthcare system's problems into an opportunity for improved patient-centered care (https://www.lumedic.io/perspectives/introducing-the-patient-era).

According to Bakken et al., (2021) patient-centered care is evidence-based, interdisciplinary, and coordinated across the continuum of care among health team members, including the patient and family. Patient-centered care requires information systems that include tools for both healthcare professionals and patients and their families. Although much progress has been made in informatics toward the objective of patient-centered care, such as enhanced interoperability and openness of healthcare systems, several hurdles remain. These include implementing systems into the clinical workflow, increasing the time available for direct patient care, and allowing interdisciplinary teams to coordinate across the continuum of care.

2. ACCESS TO HEALTHCARE

As it mentioned at the previous chapter, because of the widespread both of corona virus disease and the use of information and communication technologies (ICT) in healthcare, the industry has undergone significant digital transformations. Although the patient should be in the center of the healthcare ecosystem, however, too many patients are unable to receive healthcare services due to a lack of awareness of the service's availability, physical or mental incapacity, distance, wars, lockdown, and other factors (Shorbaji, 2021). Electronic health records, artificial intelligence, sensors, wearable devices, the Internet of (medical) things, blockchain, big data, and other applications have all had an impact on access to healthcare services. As many countries had imposed lockdown due to spread of COVID-19, we must admit that at the same time the corona virus disease has established new realities in receiving healthcare services, for example via telehealth and telemedicine services.

2.1. WHAT DOES ACCESS TO HEALTHCARE MEAN?

People, in general, and patients in particular, have been empowered by digital health to access healthcare services at the point of care or remotely. Digital health has been used by healthcare professionals to improve their knowledge, skills, and, more importantly, to enable them to reach out to patients and provide guidance and assistance. Legal, ethical, infrastructural, human and material resources, training, education, attitudinal, cultural, organizational, and behavioral issues can all be encountered while using digital health solutions. Several national, regional, and international organizations have passed resolutions and devised plans to help countries integrate digital health (Shorbaji, 2021).

According to Agency for Healthcare Research and Quality (AHRQ) "The timely utilization of personal health services to obtain the best health results" is what access to healthcare entails and it is made up of four parts:

Coverage: It makes it easier to get into the healthcare system. People who are uninsured are less likely to receive medical care and are more likely to have poor health status.

Services: Adults who have a regular source of care are more likely to receive recommended screening and preventative treatments.

Timeliness: the ability to offer health care when it is needed

Workforce: Providers who are capable, qualified, and culturally competent.

Gulliford, et al., (2001) described health-care access as following "Facilitating access is concerned with helping people to command appropriate healthcare resources in order to preserve or improve their health." They stated that there are at least four aspects:

- A population may 'have access' to healthcare if services are provided in an appropriate amount.
- The amount to which a population “gains access” to healthcare is also influenced by financial, organizational, social, and cultural restrictions. As a result, rather than the adequacy of supply, use is determined by the pricing, physical accessibility, and acceptance of services.
- The services available must be relevant and effective if the population is to “gain access to satisfactory health outcomes”.
- The availability of services, as well as barriers to their use, must be assessed in light of unique views, health requirements, and material and cultural contexts of various groups in society.

According to the Institute of Medicine (IOM), "access to healthcare" means, "having timely use of personal health services to achieve the best possible health outcome." The AHRQ also mentions that “access requires gaining entry into the health-care system, getting access to sites of care where patients can receive needed services, and finding providers who meet the needs of patients and with whom patients can develop a relationship based on mutual communication and trust"(AHRQ, 2009).

Access to healthcare is a human right and a major social responsibility of all nations. There is clear evidence that health is unequally distributed across and within nations, and population health is often used "as a proxy for social wellbeing" (Wickrama & Mulford, 1996). Questions have been raised about how and why subpopulations (in particular gender and socio-economic background) are differently affected, to what degrees their bodies should be understood as group-specific, and how divergent lifestyles matter for health. Data delivers never mere descriptions but also potentially change ways in which we can understand and act on health-related conditions. Therefore, it is essential to integrate diversity perspectives into the construction of the framework of implementing digital solutions, for example into the ICU environment, e.g. being attentive to cultural differences, to different life phases (e.g. age) (ibid).

2.2. UNEQUAL DISTRIBUTION OF ACCESS TO HEALTH-CARE TECHNOLOGIES

According Beckfield et al., (2015) despite popular belief, social gaps in health appear to be expanding in several of the world's most industrialized countries amid a period of fast technological innovation. The connection between technology and health is gaining more attention as the quantification of health in modern society intensifies and novel health technologies form the cornerstone of this change. Technological advancements have led to a growing reliance on technology in society, as well as the collection of advanced data, such as the personal genome, that is then used to influence the decisions and behaviors of not only ordinary citizens, but also health professionals, private businesses, and large institutions (Tuckson et al., 2013). These advancements are typically regarded as positive advances, enhancing disease diagnosis and treatment as well as overall public health, but their socioeconomic ramifications are debatable. As Rogers (2003) mentioned, these technologies appear to have the potential to improve overall public health, but at the expense of rising health inequities. Some studies show that people with a higher socioeconomic status (SES) are the first to adopt and benefit the most from innovative health technologies, resulting in social inequalities in health that were previously very low or nonexistent, or even inverting these inequalities (where improved health outcomes have moved from lower SES groups to higher SES groups) (Chang VW & Lauderdale DS 2009; Korda et. al., 2011)

In accordance with the World Social Report (2020) of the United Nations, rapid, groundbreaking, and often disruptive technology developments are taking place around the world. Advances in biology and genetics, robots and artificial intelligence, 3D printing, and other digital technologies are changing economies and society in unexpected ways. Despite its potential, technological progress tends to produce winners and losers. Moreover, at this rate, new and serious policy issues for traversing uncharted territory are arising. Much depends on how these policies are implemented, particularly on how governments and international organizations deal with distributional impacts and optimize the benefits and opportunities that new technology might provide.

In the sphere of labor, the focus has mostly been on the possible consequences of technological transformation for job loss. However, rather than replacing entire jobs, technology frequently replaces certain responsibilities. The fact that new technologies create new occupations and responsibilities, including those required to use, test, oversee, and sell new products and services, is often overlooked. Digital innovation and artificial intelligence are transforming industries like health care, with far-reaching implications for equality. Health-care delivery and monitoring systems are made available to underprivileged areas and populations using mobile health applications (Ventola, 2014). Improvements in data availability brought about by new technologies can enable individuals and groups voice their thoughts and organize for common causes, enhancing governance and facilitating participation. New technologies' potential to promote sustainable development, on the other hand, can only be achieved if everyone has access to them. In industrialized countries, about 87 percent of the population has access to the Internet, compared to 19 percent in least developed countries (United Nations b, 2021). Furthermore, International Telecommunication Union Statistics estimates that approximately 4.9 billion people – or 63 per cent of the world’s population – are using the Internet in 2021. This represents an increase of 17 per cent since 2019, with 782 million people estimated to have come online during that period. However, this leaves 2.9 billion people still offline (www.itu.int/en/ITU-D/Statistics/Pages/stat/default.aspx). Basic technology like mobile phones have advanced significantly, yet there are still gaps in access to the Internet and computers. New technologies have a lot of potential for youth, but they can also expand the gap between younger and older people.

2.3. INTEGRATION REGARDING ETHICAL ISSUES

As it mentioned before, during the COVID-19 pandemic, digital change has been impressive. In reaction, some organizations have accelerated the deployment of new technologies and digitalization. However, the expanding use of digital technologies in health care and public health presents significant ethical concerns. According to Latulippe (2017), the COVID-19 pandemic brought attention to a vast body of research showing the possible impact of digital technologies in increasing health inequality, as well as concerns like huge technology companies' influence over public health policies. Furthermore, as Lupton (2017) mentioned, the widespread adoption of digital technologies is associated with significant changes in how individuals view and organize their lives, and these changes are intricately tied to health and health-care practices and institutions. New technologies in the health and social care industry raise ethical questions about privacy, security, equity, accessibility, and data protection. Determining what defines ethics and which codes of ethics to adhere to, will be a challenge for anyone involved in the design, development, and deployment of digital health technology and apps.

The most significant topic to consider in the digital health care system, as in all other forms of services, is ethics. When it comes to offering digital health care services, health care providers should be ethical. Patients' rights, responsible behavior of health care providers, governance of health care data, and equity in health care are the four major headings under which ethical problems should be evaluated (Mulvenna et al., 2021). Access to digital health care and interventions that is both reliable and equitable increases the likelihood of healthcare coverage, the spread of health knowledge and literacy, and, perhaps, the efficiency of care. Overall, ethical regulations and rules are required for fair, equitable, and trustworthy digital health, with the goal of empowering service recipients. (Shaw and Donia, 2021)

According to WHO (2021), ethical standards for AI in health and other areas are designed to help developers, consumers, and regulators improve and regulate the design and use of such technology. All other ethical concepts are founded on the core ideas of human dignity and inherent worth. In the context of the development, implementation, and ongoing assessment of AI technologies for health, an ethical principle is a statement of a duty or responsibility. The following ethical standards are based on basic ethical rules that apply to everyone and are deemed noncontroversial:

- Avoid harming others
- Promote the well-being of others when possible
- Ensure that all people are treated fairly, which includes ensuring that no one or group is discriminated against, neglected, manipulated, dominated, or abused
- Deal with people in ways that respect their interests in making decisions about their lives and people, including health-care decisions, based on a thorough grasp of the nature of the choice, its significance, the person's interests, and the likely implications of the alternatives

These ethical principles are designed to give stakeholders with direction on how basic moral principles should influence or constrain their decisions and behaviors in the context of creating, deploying, and evaluating the performance of AI technologies for health. These principles are also intended to highlight difficulties that come from the use of technology that has the potential to affect moral relationships. As a result, ethical considerations are critical for physicians, systems developers, health system administrators, policy-makers in health authorities, and local and national governments seeking advice in the appropriate development, implementation, and evaluation of AI technologies for health. Although ethical principles do not always clearly address limitations in the use of such technologies, governments should prohibit or limit the use of AI and other technologies if they violate or jeopardize human rights, do not conform to other principles or regulations, or are introduced in unprepared or other inappropriate contexts. Many countries, for example, lack data protection legislation or regulatory frameworks to regulate the adoption of AI technologies. On the other hand, in France, the government is expected to provide a broad explanation of how any algorithm it uses works, individualized explanations of algorithm decisions, justification for decisions, and disclosure of the algorithm's source code and additional documentation. (ibid)

In a conference, hosted by the European Parliament, on ‘Robots in Healthcare: a solution or a problem?’ in 2019, Prof. Chatila explained that, despite the many advantages of these applications, they have created new ethical and social risks and tensions in the legal system by highlighting the impacts on privacy, human dignity and autonomy (e.g., isolation), the possibilities of human augmentation, and technical dependencies that can have the opposite effect of fostering learning (e.g., medicine without doctors). Prof. Chatila gave a list of additional ethical problems to address for AI-based systems, noting that in order to attain a degree of "technical dependability," AI and robotized systems that deal with data need be aligned with a specific set of values and principles. Transparency, accountability, explicability, auditability, and traceability, as well as neutrality or fairness, are among these values. He explained that AI-based systems should be transparent and trustworthy by being upfront and open about the decisions that inform their design. Accountability, which he defined in terms of liability and responsibility, entails humans being involved in the chain of command for any output produced by an AI-based system at all times. He emphasized that humans should be ultimately responsible for AI-based judgments. In terms of explicability, auditability, and traceability, producers and developers of these systems should keep track of their decisions and ensure that these decisions are conveyed clearly to users so that users are aware of how decisions that affect them are made. This is especially true for systems that function with a degree of autonomy. Finally, he emphasized the importance of neutrality or fairness in AI-based systems in order to ensure that factors impacting outcomes are not skewed. (European Parliament, 2019, p. 15-18)

2.4. DATA PROTECTION LAWS AND POLICIES

Patients' concerns about their anonymity in digital communication and their privacy being a vital part of trustworthy artificial intelligence were described as a key factor of patient security in digital health care. Patients' safety should be considered by health care workers, and any inadvertent injury should be avoided. Data protection laws are "rights-based methods" to regulating data processing that safeguard individuals' rights while also imposing obligations on data controllers and processors. People increasingly have the right not to be subjected to choices based entirely on automated processes, according to data protection legislation. Over a hundred countries have passed data protection legislation. The General Data Protection Regulation (GDPR) of the European Union (EU) is one well-known set of data protection rules; in the United States, the Health Insurance Portability and Accountability Act, adopted in 1996, pertains to privacy and security of health data. Some rules and standards are especially developed to control the use of personal data for AI. The Ibero-American Data Protection Network, for example, has issued General Recommendations for the Processing of Personal Data in Artificial Intelligence and specific guidelines for compliance with the principles and rights that govern the protection of personal data in AI projects. The network is made up of 22 data protection authorities from Portugal and Spain, Mexico, and other countries in Central and South America and the Caribbean (European Union 2019).

According to Raposo (2016), telemedicine is classified as both a healthcare and an information service under EU regulation. This is significant because it means that when keeping, processing, or transferring data about a patient's health status, regulations governing healthcare practices, as well as data security and privacy regulations, must be followed. Health data is recognized as a unique type of data by the GDPR, which includes a definition for health data for data protection purposes. Though the GDPR's innovative principles (privacy by design or the prohibition of discriminatory profiling) remain relevant and applicable to health data, the GDPR has now addressed specific safeguards for personal health data and a definitive interpretation of the rules that allows for effective and comprehensive protection of such data. Clinical trials and mobile health, for example, require strong data protection safeguards to preserve the trust and confidence of individuals in the rules established to secure their data. (https://edps.europa.eu/data-protection/our-work/subjects/health_en). These measurements necessitate not just new technological requirements, such as secure data storage and transmission, but also new forms of involvement for medical practitioners.

The President of the European Commission, Ursula von der Leyen underlined in a recent talk,

> *"(…) Machine-generated data can be the fuel for Europe's recovery: We are literally sitting on a goldmine. Every day, every European business produces data without even noticing. Research tells us that the potential value of data produced in Europe will soon reach EUR 1.5 trillion a year. Imagine: 1.5 trillion, and we are only using a tiny percentage of this treasure. Data can make our fields more fertile. It can predict a machine's failure and fix it before it even happens. Data can cut Europe's energy consumption massively, with benefits for the planet and for your balance sheets too. For all these reasons and many, many more, data need to be shared and exchanged more widely. And therefore, companies need clear rules on how to access, share and sell available data (…) (https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_21_419)*

With the implementation of the European GDPR regulation, data produced and used in the healthcare field is now better protected. A common set of rules for the storage and processing of health data could be a solution to the problems that European healthcare systems are confronting. If necessary, cross-border collaboration between core and peripheral hospitals, as well as knowledge and expertise sharing, can be accomplished. The construction of a European Data Space, which includes the health sector, is one of the Commission's goals for 2019-2025. A common European

Health Data Space will facilitate the exchange and access to various types of health data (electronic health records, genomics data, data from patient registries, and so on), not only to support healthcare delivery (so-called primary use of data), but also to support health research and policymaking (so-called secondary use of data). As stated in article 20 of the DDPR, the complete data system will be established on transparent foundations that properly secure citizens' data and reinforce the portability of their health data. The European Health Data Space will be built on three (3) main pillars: a) a robust data governance and data sharing rules system b) data quality c) strong infrastructure and interoperability (https://ec.europa.eu/health/ehealth-digital-health-and-care/european-health-data-space_en)

The COVID-19 pandemic has drawn a lot of attention to data sharing, both in terms of public health reporting of disease incidence and contact tracing, and in terms of the necessity for data that can be shared across several countries for joint research. However, the focus on greater data availability and accessibility was already visible in EU policy before to the COVID-19 problem, and it is one of the priority outlined in the Commission's mandate to create a European Health Data Space (EHDS). The EHDS should not be viewed as a large European "data lake," but rather as a system for data exchange and access governed by common rules, procedures, and technical standards to ensure that health data can be accessed within and between Member States while adhering to the GDPR and Member State competences. The goal is to expand the use and re-use of health data for research and innovation in the healthcare sector; to assist healthcare authorities in making evidence-based decisions; to improve the accessibility, effectiveness, and sustainability of healthcare systems; to support regulatory bodies' work in assessing medical products and demonstrating their safety, efficacy, and quality; and to contribute to the EU's industry's competitiveness. Several private companies and research organizations have begun to build technological solutions based on or around healthcare providers' existing data infrastructures. Specific problems must be overcome as a result, particularly when it comes to the storage, processing, and transmission of health data as defined by the European Commission. (DG Health and Food Safety, 2021)

2.5. ARTIFICIAL INTELLIGENCE AND EUROPEAN STRATEGY

The subject of AI has gotten a lot of intention in recent years. This is particularly true in fields where vast volumes of data, recorded "Big Data," are generated and processed. While the first stage of digitization concentrated primarily on the transition from analog to ICT-based information storage and processing systems, the increasing interconnectedness of these data silos has been at the forefront of current efforts. Today, data is about more than just the information that is deliberately collected and kept; it is also about the information that may be derived from such data sets. Apart from its potential, the rising usage of AI raises problems and challenges, particularly in terms of transparency and equality. To solve these critical concerns, new European legislation are therefore required, but also have the potential to benefit AI development and use. The European Commission announced a fresh approach and push in 2018 to encourage the development and usage of AI-enabled systems (European Commission, 2018).

AI and its diverse domains of application - such as healthcare, climate change mitigation, and cybersecurity thread prediction - are positioned as the solution to today's serious concerns that affect the lives of all European residents. According to a recent white paper, the European Commission recognizes that trust is a critical aspect in ensuring that AI advancements are adopted by European society as a whole. All European citizens, as users and consumers of AI systems, should be able to rely on a uniform regulatory framework for AI (European Commission, 2020). According to a study of European Commission about “Ethics Guidelines For Trustworthy AI” (2019), trustworthy AI has three components, which should be met throughout the system's entire life cycle:

- it should be lawful, complying with all applicable laws and regulations
- it should be ethical, ensuring adherence to ethical principles and values and
- it should be robust, both from a technical and social perspective since, even with good intentions, AI systems can cause unintentional harm.

Each component is necessary, but not sufficient, for Trustworthy AI to be achieved. In an ideal world, all three components operate in tandem and overlap. If tensions occur between these components in practice, society should work to align them. Artificial intelligence has the potential to drastically alter society. AI is not a goal in and of itself, but rather a promising means of promoting human happiness, so improving individual and societal well-being and the common good while also delivering progress and innovation. AI systems, in particular, can aid in the achievement of the United Nations' Sustainable Development Goals, such as promoting gender equality and combating climate change, as well as improving our health, mobility, and manufacturing processes, and assisting in the monitoring of progress against sustainability and social cohesion indicators. To achieve this, AI systems must be human-centric, with a commitment to employ them in the service of mankind and the common good, with the objective of increasing human welfare and freedom. While AI systems provide many benefits, they also pose some concerns that must be addressed carefully and proportionately. European citizens want to know that the socio-technical ecosystems in which AI systems are embedded are trustworthy. They also want AI system makers to gain a competitive edge by incorporating Trustworthy AI into their products and services. This comprises attempting to maximize the benefits of AI systems while avoiding or minimizing their risks. (ibid)

2.6. THE TELEMEDICINE CONTEXT

Telemedicine has shown to be a success story in the field of acute care medicine, particularly in the field of intensive care medicine. According to Breslow et al., (2004), the introduction of a remote intensivist program in two US tertiary care hospitals has led to a reduction in mortality (9.4% vs. 12.9%; relative risk, 0.73; 95% CI 0.55–0.95) and has proven to be cost effective. In agreement with WHO (2010), telemedicine is "the delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment, and prevention of disease and injuries”. As reported by Linkous, J.D. (2002), in the framework of telemedicine, the combined use of information and communications technology for the provision of distant health and education services offers significant benefits to health systems and patients. In the framework of telemedicine, the combined use of information and communications technology for the provision of distant health and education services offers significant benefits to health systems and patients, such as a) remote primary care units, which lack such resources, have instant access to rare human and material resources (specialist doctors and pricey biomedical equipment) b) local health-care services are being improved c) medical data evaluation and analysis on a wide scale d) support for health-related briefings (Wootton, 1996 & Wootton, 2001).

The healthcare system, patients, and healthcare professionals can all benefit from telemedicine. This can assist bring treatment to rural areas, make specialty care more accessible, and give patients with remote monitoring and home care. For example, Greece's demographic and geographic dispersion (many islands, isolated highland regions, and imbalanced population distribution) combined with a scarcity of specialized resources (human and material) make the establishment of a telemedicine system a top priority. Furthermore, in this COVID-19 epidemic, telemedicine can help in getting medical appointments faster, monitoring patients at home, preventing contagion, reducing patient movement, and reducing the use of antiseptic materials. Telemedicine activities can be synchronous and run in real-time utilizing video conferencing capabilities, or asynchronous, in which photographs, audio files, or data are delivered to a healthcare expert via ICT for follow-up or opinion seeking. (Vidal-Alaball et al., 2020)

Because telemedicine is a sociotechnical practice rather than a basic technology, the implementation challenges are not restricted to the technology (Papoutsi et al., 2020). We can say that telemedicine is the product of the technology's interaction with the ecosystem that has grown up around this practice. Healthcare experts, patients, technology providers, healthcare organizations, and the National Health System are all part of this health care ecosystem. Users of telemedicine, whether they are health care professionals or patients, may have concerns about changing habits or learning to use the technology (Bokolo, A.J., 2020). Due to increased overwork, patient obligations, or changes in the organization and care process, telemedicine used by healthcare providers is likely to cause dread, stress, and resistance (Mold et al., 2019). Because telemedicine changes the nature of clinical care, new clinical and administrative work methods are required (Wherton et al., 2020). According to Papoutsi et al., (2020), although telemedicine relies on technology, yet it is not the sole factor. As a result, the co-design of technology and care processes is critical to the successful implementation of remote care services.

If telemedicine was the first shift to an enhanced clinical health service at the turn of the century, the quick development of the internet allowed cyber medicine to supply medical services. Desmond Tutu, chairman of Global eHealth Ambassadors Program of the International Society for Telemedicine and eHealth, noted in the World Health Organization's Bulletin that there is a need for “a paradigm shift from information and communications technologies for health to a greater emphasis on information and communications technologies for development”.

Progress in telecare services led to the evolution of Cyber – Physical System (CPS). CPS represent a technological opportunity for new telemedicine applications that ensure better advanced patient care and treatment, since has the potential to drastically alter a variety of medical processes and workflows (Lee E., 2008, 2010). Medical Cyber Physical Systems (MCPSs), a distinct type of CPS, are defined by Lee I. (2010, 2012) as interconnected, intelligent systems of medical devices that support a patient's holistic therapy. The combination of embedded software control of networked medical devices with complicated safety and often life-critical physical processes demonstrated by patients' bodies is an inherent element of MCPS. It includes a network of sensors that collect data that is examined and processed by a control processing unit before issuing commands to control actuators via communication devices.

The literature reveals that the development of such systems and their implementation in critical care health units showed improved outcomes. Tele-ICU programs have been linked to significant reductions in mortality, hospital and health-care expenses. Furthermore, such systems have the benefit of adding artificial intelligence and machine learning, which allows for faster data processing and more effective critical care delivery. Although these benefits are not universal, it is thought that as we gain a better understanding of how to install and operate such systems, the outcomes will become more consistent (Khurrum et al., 2021)

3. WHAT IS AT RISK?

A survey conducted during the pandemic including health care providers (HCPs) working in Intensive Care Units (ICUs) hospitals, in 77 countries, demonstrated that the coronavirus disease 2019 (COVID-19) has severely affected ICUs and critical care health-care providers worldwide (Wahlster et al. 2021). Furthermore, it was reported luck of ICU nurses and intensivists. Intensive care wards in several European Union (EU) countries were overburdened, not only in terms of physical infrastructure like beds and medical equipment (e.g. ventilators), but also in terms of having specialized health workers accessible to keep these beds operational. Many nations reported a lack of intensive care capacity for COVID-19 patients, particularly in the early stages of the pandemic but also in future waves. Furthermore, the pandemic highlighted the uneven distribution of Intensive Care specialists among hospital networks' centers and periphery. (Winkelmann et al., 2022). The significant frequency of provider burnout, as well as its link to insufficient resources and poor supervisor communication, suggests that tailored interventions to assist HCPs on the front lines are needed (Wahlster et al., 2021).

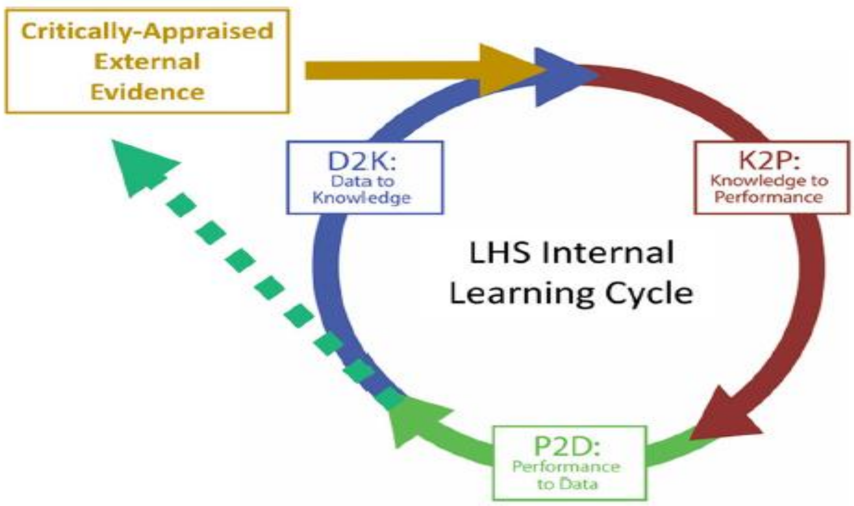
Digital health technologies in intensive care medicine have the potential to improve outcomes by reducing patient length of stay or preventing complications (Kumar et al., 2013). Continuous remote monitoring enables for early detection of deterioration in ICU patients and, as a result, prompt therapeutic action (Khanna et al., 2019). The huge volumes of data generated by ICU monitoring devices can be analyzed by algorithms employed in clinical decision support systems and early warning scores to reduce ICU mortality and the likelihood of complications such as prescription mistakes (Escobar et al., 2020; Prgomet et al., 2017). As an ever-evolving topic, implementation science has resulted in the release of a slew of guidelines and recommendations for the adoption of digital health technologies in health-care settings by a variety of organizations and scholars (European Commission, 2018). Successful and long-term implementation in health care necessitates a holistic approach that incorporates significant strategies at all levels. Increasing the number of intensive care experts available in more remote hospitals is a critical step. Furthermore, telemedical solutions can help ICU work beyond the current crisis by establishing a safer atmosphere for medical workers and patients.

Without a doubt, one of the most difficult challenges in developing the ICU of the future is ensuring that available digital innovations are adopted by all those involved in the ICU, including medical doctors, nursing staff, patients and their families, as well as hospital administrations, and integrated into daily practices at various locations. According to Hull et al., (2019), interventions often fail to be fully "implemented into routine practice and policy" and this goes hand in hand with "an effortful, unpredictable and typically slow process" of integrating innovation into pre-existing structures and practices. There has long been a fear that available digital technologies that could improve treatment or prevention do not successfully integrate into medical professionals' job, do not get understood and adopted by patients/citizens, and hence do not manage to improve patient care (ibid). As a result, if implementation fails, neither patients nor medical professionals, nor the healthcare system as a whole, will profit from the prospective benefits. This helps to explain why, in recent years, we've seen "increased and focused efforts to close the evidence-to-practice gap" (ibid). As a result, increased emphasis is placed on the process of turning evidence into technological advancements, through the concept of co-creation, eg. into everyday practice in the ICU.

3.1. MIND THE GAP: PUTTING EVIDENCE INTO PRACTICE

According to WHO (2005), health research has the potential to improve society by enabling better health. Nevertheless, there has always been a gap between research findings (what is known) and health care practice (what is done), described as the ''evidence-practice'' or ''know-do'' gap. Insights from a research about Putting Evidence into Practice in the Era of Learning Health Systems, (Jeanne-Marie Guise et al., 2016), underlines that closing the evidence-to-practice gap will necessitate the implementation of two critical factors: (1) the integration of locally and rapidly generated evidence—what we are calling “Learning Health System evidence”—with cumulative and comprehensive systematic review evidence from the peer-reviewed literature and (2) making this combined evidence available in standardized computable forms so it can be efficiently and effectively assimilated to inform practice.

As Olsen et al., (2007) argues, the Institute of Medicine first proposed the Learning Health System (LHS) in Crossing the Quality Chasm (2001), and it was re-expressed in 2007, in order to describe the generation of evidence as a by-product of care delivery and the application of that evidence to support continuous improvement, evidence-based care delivery, and population management. Efforts to create evidence must be matched by equally focused efforts to put it to use in improving health. While locally created LHS evidence is essential, it is insufficient. Local results must be combined with the greater body of what is already known about a health concern in order to safely guide practice. An expanded cycle of learning is required, allowing external evidence from trials, studies, and reviews to drive practice inside Learning Health Systems, or any other methods, and data from practice to feed back into the overarching evidence base. LHS’s can and do exist in a variety of shapes and sizes, and at various scales. The importance of accumulating evidence integration has been proven numerous times over several decades (Guise et al., 2018).



(Figure 5: Expanding the cycle of learning through integration of internal and external data and evidence. Adapted from Guise et al., 2018)

Even as they become more agile in n creating and applying locally generated outcomes, organizations that evolve LHS capabilities should be outward facing in putting their data and analytic capabilities to work to contribute to this broader evidence base. Because it does not make use of everything that is known about a health condition, an inward-looking approach in which a single LHS creates and uses its own evidence without blending it with what is already known, would underperform. Furthermore, an inward-looking system will be unable to achieve the greater goal of making data and evidence more shared, cumulative, and easily revisable. Many organizations will need to change their culture to see the potential of shared learning by quickly integrating data from single-system studies, rather than considering data as a carefully held asset. The acknowledgment of the importance of putting knowledge into standardized, computable representations, complementing various representations in text, tables, and figures, is the first step in a process that requires new infrastructure to support the rapid and routine translation of new knowledge to practice (Hongsermeier et al., 2007)

3.2. THE IDEA OF "CO-CREATION"

According to Vargo & Lusch (2004), by definition, co-creation entails the active participation of all stakeholders, including end users, in ongoing collaboration for the continual release of resources, strategic exchange of knowledge and goals, and increased mutual satisfaction. This means that all individuals involved in developing and implementing digital solutions engage with users and stakeholders throughout the development and implementation process, leveraging their expertise, knowledge, especially momentum to address the pandemic problem. As Greenhalgh et al., (2016) mentions, participatory approaches allow for a collective definition and elaboration of needs and solutions, as well as a form of mutual learning: technology developers learn about users' ways of thinking, work practices, and everyday life in the ICU for example, and they allow for a diversity of voices, concerns, positions, and contexts of use. This means that everyone involved in the development and implementation of the digital solutions interacts with users and stakeholders throughout the process putting experience, knowledge, and enthusiasm to work to combat the pandemic issue. Co-creation should encourage the development and implementation of agile and use case–focused innovations by incorporating varied sets of experiences and knowledge from potential users into the development and implementation process. It is hoped that by better integrating new technologies with existing systems and applications, such an integrative strategy will allow for faster innovation and thus higher returns (van Dijk-de Vries et al., 2020).

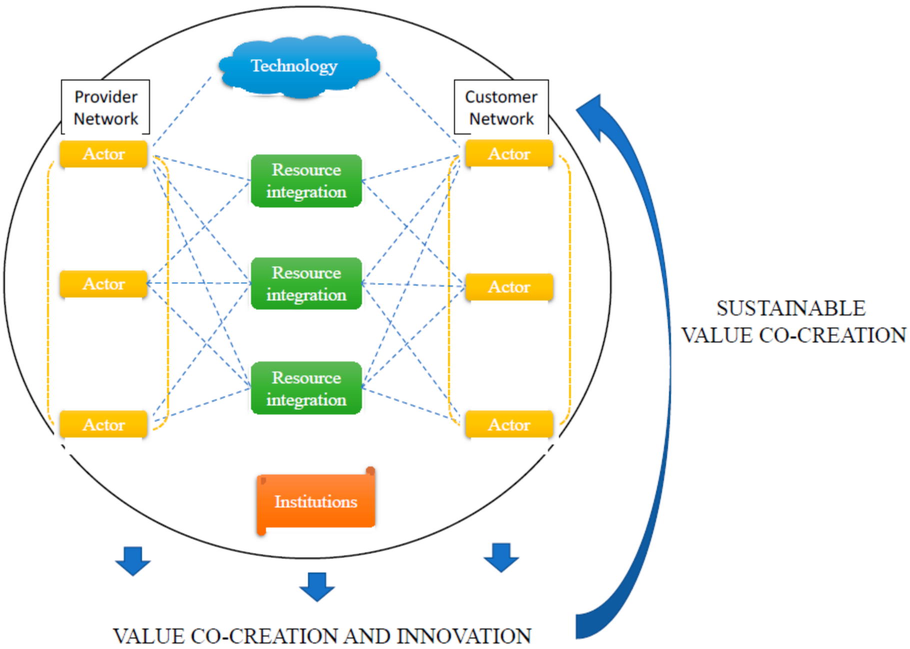
As reported by Payne et al., (2008), value co-creation is a phenomenon in which contemporary management and marketing studies reinterpret the processes of value exchange and diffusion among the actors involved in its creation, focusing on value as a common (sometimes even collective) benefit obtained through intense collaboration between the parties. Porter (2010) defined healthcare value as health outcomes connected to the relative costs and efficiency of patient care. Because there are so many actors in the healthcare ecosystem, value cannot be only linked with patients. As highlighted by Hardyman et al., (2015) patient-centric care, which incorporates patient engagement, participation, and involvement in service delivery activities, has been linked to value in healthcare. Furthermore, using the generic concept of value co-creation as centered on the customer or beneficiary, the customer in this case has been generically defined as the patients, with the production of value for the patients determining the rewards for all system players (ibid). According to Leclercq et al., (2016) investigating what instruments are utilized for individual participation, the motivations and form of engagement among players, as well as the management of the actors, are all-important factors, adjusted with value co-creation. Patients are frequently at the center of healthcare platforms, but ecosystems, on the other hand, have various levels and co-creators.

As stated in Vargo & Lusch (2004), in the previous decade, a new framework, a new scientific culture, and a new way of thinking have arisen in response to recent conceptual shifts found in terms of definition and interpretation on service-related aspects: The Service Dominant (S-D) Logic, which underlines the close connection between the use of technology, the enhancement of the actor and the creation of new value, that leads to the term "service ecosystem" that was coined to describe an organizational structure that encourages a diverse group of players to exchange resources via ICT-mediated interactions based on pre-existing social norms (institutions), finally producing value co-creation. As Vargo et al., (2008) argues, S-D logic contains theoretically: (1) the notions of value, (2) the relationship between customer and provider, (3) the concept of service. S-D logic, in contrast to other theoretical frameworks, asserts that value is no longer solely created by corporations. Each stakeholder, meant as active players, collaborates to co-create value. Customers, in this view, are active players in a co-creation process that comes from the sharing of experience and information amongst stakeholders through reciprocal efforts. According to this concept, the service is envisioned as a process in which two or more entities exchange resources and users use their skills, resulting in mutual advantages for all parties involved (ibid). The central notion of this approach is value co-creation, which refers to the combined generation of value by all service providers (ibid).

Polese et al., (2018), summarized the main elements of service ecosystem as: (1) actors, (2) technology, (3) institutions, (4) resource integration

1) All players involved in the service exchange of services are referred to as actors
2) Technology is one of the most important aspect of service ecosystems since it is responsible for the rapid exchange of information and the creation of new organizations
3) Institutions are social rules, conventions, and shared practices that govern exchanges and serve as intermediaries, a set of requirements for resource integration
4) Resource integration occurs during actor interactions

The four parts of the service ecosystem are (potentially) the drivers of value co-creation. Only by integrating the actors and allowing them to trade resources via technology while adhering to shared standards can the value co-creation process be activated (dynamic level). The value created by the actors' resource exchange (value co-creation), such as customer feedback, generates new aspects (innovation), allowing management to improve the whole service. As Troisi et al., (2018) argue, when the actors' resources are integrated, new resources (new knowledge, new experiences) are created; when technology is strategically used, new ways of interacting are created; when the same objective and rules are shared, new practices and institutions are created (new habits).



(Figure 6: Graphical representation of service ecosystem. Adapted from Botti and Monda, 2020)

As it mentioned before, the collecting and processing of vast amounts of data from health information systems, medical equipment, patients/family members, and external applications is one of the most advantageous features of modern technologies (internet of things, social platforms, telemedicine). According to Santoro et al., (2017), the clinical environment, which is characterized by a complex multi-stakeholder environment with a multi-fragmented decision-making process, with different needs and requirements to be met for different segments and classes of users, is the main impediment to the adoption of these technologies. Users can be:

1) The government and regulatory authorities that approve and consider the usage of certain technologies
2) Healthcare professionals, who must choose and purchase the solution
3) Doctors and other healthcare professionals who assess and select a solution

4) Patients, caregivers, and community organizations who have an influence in whether or not these solutions are successful
5) Providers of technology and medical devices who promote and distribute the solution

As Kristoffer Halvorsrud and co-authors (2019) identified in their systematic review and meta-analysis of the international healthcare literature about the effectiveness in the co-creation process, the co-creation process may improve several health-related outcomes and public health more broadly. The most frequently process elements of effective co-creation projects were "accommodating for co-creation partners' needs and priorities (88.89%), building on their skills (77.78%), adopting an iterative approach of openness and process allowing for continuous amendments (72.22%) and measures of equality, empowerment and power-sharing (50%)".

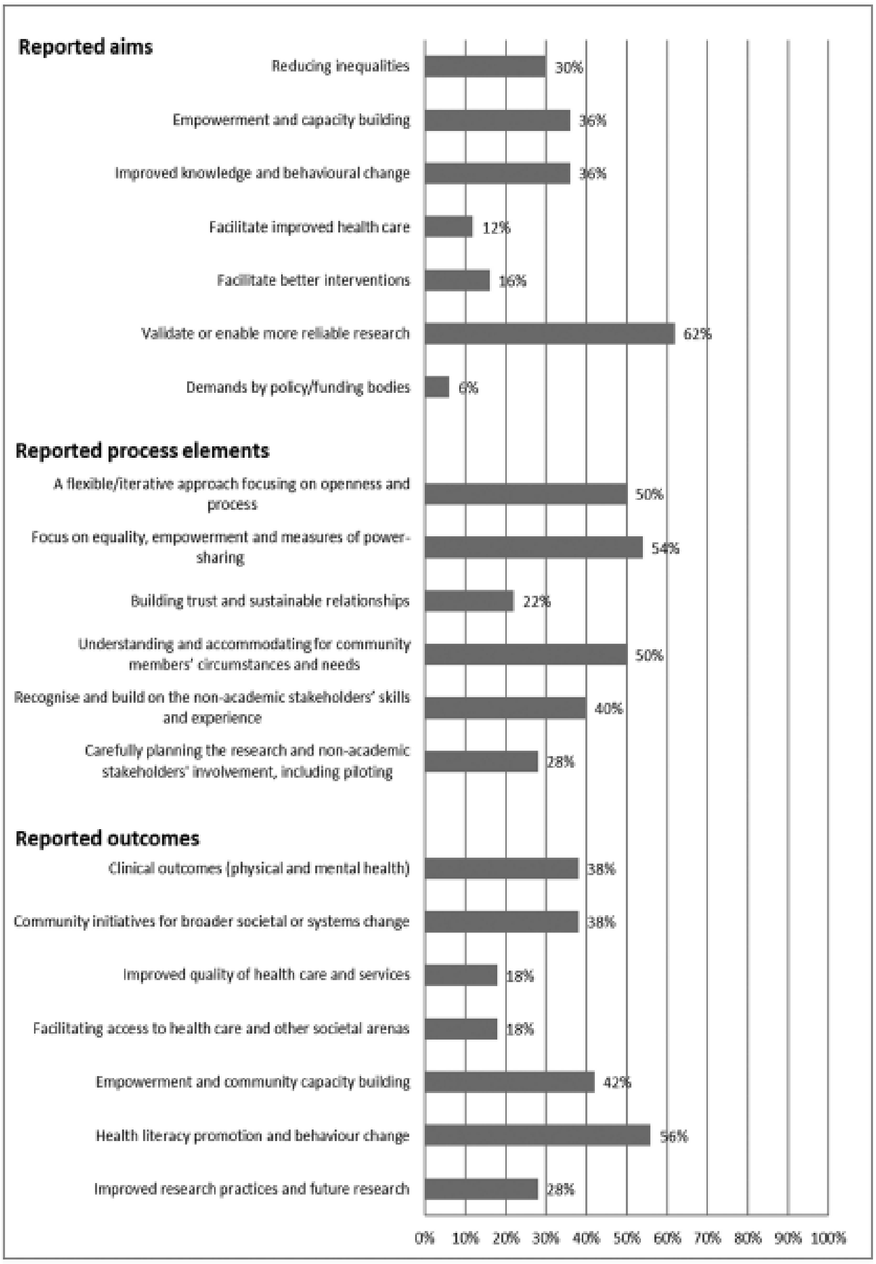


Fig. 2 Reported aims, process elements and outcomes of co-creation (from reviews).

(Figure 7: Adapted from Kristoffer Halvorsrud and co-authors (2019))

Funding and regulating authorities are increasingly advocating including end-users and stakeholders in the co-creation of public health interventions and health promotion campaigns as a more efficient way to achieve positive societal change. Traditionally, top-down approaches have been used to establish public health solutions. These have a wide evidence base and are frequently based on behavior change ideas that are assumed universal. Traditional public health initiatives do not include end-users in their creation. Using end-users in the co-creation of public health interventions, on the other hand, is expected to improve adherence and effectiveness by empowering end-users to generate outcomes that are suited to their needs (Durand M-A et al., 2014)

3.3. Implementing new technological/digital solutions in health care sector

Andersen (2019), speaking more broadly about digital health trends, drew our attention to an intriguing dilemma. While there are strong expectations that digital health would improve our healthcare systems, and the first promising prototypes connecting patients and healthcare professionals are available, the reality is that they will not achieve their full potential. Anderson mentions "Too little time and effort is spent on configuring the systems and adapting the clinical practices and the day-to-day activities" (ibid) of those using the systems. Insights from implementation research, shows that inability to introduce new technological/digital solutions for a health-care concern is primarily due to a lack of well-crafted implementation strategies, and much less due to a lack of quality of the innovation itself. Even if implementation was successful in one setting, the translation into another setting would require i)detailed analysis of the specificities of the new context of implementation, ii) fine-grained documentation of experiences and lessons learnt, iii) a clear description of the conceptual frame underpinning research on previous implementation, and iv) a careful reporting of the overall implementation plan (ibid).

As highlighted by Ross (2018), digital health interventions are "one example of complex interventions that have proved difficult to implement due to factors such as interoperability, cost, fit with existing systems, disruption to interactions between health professionals and patients, and poor implementation planning". According to Ross et al., (2016) for the deployment of digital health in various health care settings, five domains are required: (1) the individual digital health technology (eg. remote patient monitoring systems), (2) the outer setting (eg. external regulations, laws, and patient needs), (3) the inner setting (eg. the direct implementation environment, social factors, networks, and communication), (4) the individual health professionals, and (5) the implementation process. Nevertheless, we have to consider that it is unclear if these five domains can be transferred into ICU given that the ICU environment is unique: several professional groups collaborate; many distinct technologies are already in place, high alarm frequency. In 2022, Mosch et al. conducted a study in the ICU at a large German University hospital, which demonstrated that an unsatisfactory implementation procedure it might be due to a lack of staff participation - engagement. The ICU's strong staff presence and monitoring coverage posed additional implementation challenges. The framework contained techniques to be used before and throughout implementation, such as incorporating all ICU stakeholders in the implementation process, analyzing the intervention's adaptability, supporting the implementation process, and fostering a critical feedback culture. The institutional background of implementation initiatives in the ICU might be improved by establishing a unit responsible for implementation, accepting the advice of an implementation advisor, and expanding on existing institutional capacities.

3.4. Assessment of Technology Maturity

According to Ernst (1997), maturity is the stage where "technology becomes integrated in products or processes and maintains its high competitive impact". The technology life cycle describes how technology progresses from a scientific concept to a fully functioning system. When it comes to acquiring or developing technology, decision-makers must carefully assess how mature it is in their specific environment. For technology maturity assessment, there are now two widely accepted methods, as M. Rodríguez Salvador et al., (2019) mentions, the first is Future-oriented Technology Analysis (FTA), whose maturity evaluation tools—mostly qualitative—are based on Technology Forecasting from the 1950s. The second is the Technology Readiness Level (TRL), a nine-level scale that quantifies "growing levels of technical maturity based on capability demonstrations." (US Government Accountability Office 2016) (ibid). As reported by Mankins (2009), the TRL scale was developed by NASA as a "systematic tool that enables assessments of the maturity of a particular technology and the consistent comparison of maturity between different types of technology”. The following table shows the maturity stages of a project, as it presented at the European Program Horizon 2020, a funding European program for research and innovation.

G. Technology readiness levels (TRL)

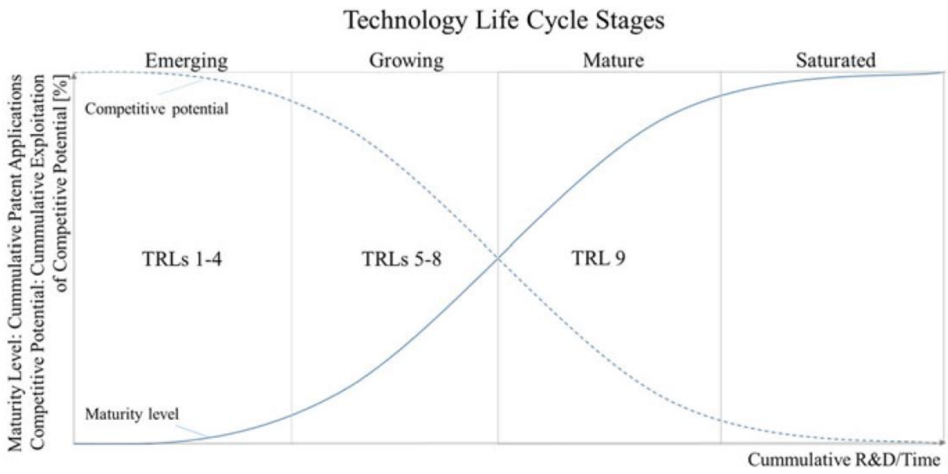
Where a topic description refers to a TRL, the following definitions apply, unless otherwise specified:

- TRL 1 – basic principles observed
- TRL 2 – technology concept formulated
- TRL 3 – experimental proof of concept
- TRL 4 – technology validated in lab
- TRL 5 – technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies)
- TRL 6 – technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies)
- TRL 7 – system prototype demonstration in operational environment
- TRL 8 – system complete and qualified
- TRL 9 – actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space)

(Figure 8: HORIZON 2020 – WORK PROGRAMME - General Annexes)

TRL's failure to anticipate has led to the development of Life Cycle Analysis (LCA). As reported by Ernst (1997), technology can be classified, according to its life cycle stage, as emerging, growing, mature or saturated. The emerging stage is when a technology notion is conceived and validated (TRLs 1–4). It is at the growth stage when it is prototyped and released (TRLs 5–8). Finally, a technology is regarded mature when it flourishes (TRL 9). TRLs are not included in the saturated stage since this stage—where competitive potential is lost—goes beyond TRL's intended assessment (ibid).

According to Reinhart and Schindler (2010), LCA searches for strategies to match technology to different stages of the life cycle. However, it usually tries to do so using qualitative methods. Forecasting advancements was nearly impossible due to the lack of repeatable frameworks, and the boundaries of each stage were not well defined, lowering the assessment's objectivity. The table below depicts the technology life cycle and how TRLs correspond to it.



(Figure 9: LCA by means of maturity level and competitive potential. Adapted from “Lessons Learned in Assessment of Technology Maturity” (https://doi.org/10.1007/978-3-319-96005-0_14))

4. PRESENTATION OF THE PROJECT ICU4COVID

The recent covid pandemic showed that European health systems responded well only in those cases where there was sufficient availability of beds in hospitals and mainly in Intensive Care Units. Also, in those cases where there was cooperation, sharing of knowledge, and were able to prevent the disease from spreading further among the healthcare workforce and patients. However, the pandemic also highlighted the deficiency in number of doctors such as intensivists, pulmonologists, infectious disease specialists, which were very important in the treatment of the virus. In May 2020, the European Commission issued a special request for innovation initiatives that included both maturing innovative solutions and close-to-market assistance solutions, in order to promote and coordinate the development of new technologies that can aid in combating COVID-19 and to establish better and more evenly distributed treatment options across Europe. One of the challenges of this call was that the results should be short due to the spread of the pandemic, otherwise the recipients of health services could not benefit (Proposal 101016000, ICU4Covid, document Ref. Ares(2020)5443341).

System developers and providers, in collaboration with clinical and life scientists, have developed and adapted a cyber-physical system for the express aim of addressing the COVID-19 Intensive Care problem, the ICU4COVID. The developed Cyber-Physical System for Telemedicine and Intensive Care (CPS4TIC) is used in locations where the initial wave of COVID-19 was successfully managed for hundreds of patients and thousands of teleconsultations. The ICU4covid project, aims to develop the existing cyber -physical system to large-scale deployment with full involvement of the end-users, hospitals and health authorities. The fundamental idea behind CPS4TIC is that it enables new or current ICU structures to change into and run as an ICU Hub with a central ICU and connected ICUs in "peripheral" hospitals. With over 15,000 patients each year at large university hospitals and related peripheral hospitals, and a coverage range of over 45 million people, large-scale pilots and implementation will be carried out in real ICU settings in four different countries, Austria, Germany, Greece, and Portugal (Figure 10). This means that in addition to providing just a technological healthcare project, it will be crucial to carefully consider how it will be implemented in a variety of sociocultural contexts as well as how it will fit into the unique characteristics of local institutional contexts and healthcare systems (ibid).

The CPS4TIC consists of a telemedicine cockpit, telemedicine consoles at each peripheral hospital, a connector platform, and smart bedside hubs with robotic arms at both the central and peripheral telemonitoring clinics' bedsides. Telemedicine, continuous real-time telemonitoring, and a bedside smart care environment are all available through the ICU hub. In both central and peripheral hospitals, the bedside smart care environment tends to minimize the risk of infection for the health workforce. Several intensive care units Hubs can form a cluster to provide additional local/regional assistance, share knowledge, such as updated best practices, and intelligence, e.g. COVID-19-induced pathophysiology and mitigating therapeutic methods (ibid).

Expanding the use of this technological infrastructure is intended to help during times of crisis, improve access to healthcare, provide enough space for treating patients regardless of their condition, such as age, improve the standard of care, and lower the risk of infection by utilizing the most recent advancements. In order to succeed this, the project must pay attention to the societal dimension pertinent to ICU4Covid, i.e., the institutional and systemic aspects of the healthcare system and how they are perceived, supported, and shaped by the relevant societal environments. Furthermore, it is important to focus to the social aspects of this technological revolution of the ICU, since it will have a significant impact on medical personnel, patients, and their social environments (ibid).

Novel telemedical approaches have been integrated into patient care routines globally, including in the ambulatory and hospital sectors, to deliver expert care to the patient: Telemedical services are now widely used across the entire healthcare delivery chain, from the home to admission, treatment, and discharge, with new modifications being created to combat COVID-19 outbreaks and other dangers. The COVID-19 crisis has demonstrated that intensive care medicine must be organized digitally and in digital networks in order to attain and apply high performance from all resources in an effort to provide the finest and most timely evidence-based intensive care (ibid).

(Figure 10: 4 ICU HUBS. Adapted from Proposal 101016000, ICU4Covid)

The CPS4TIC solution is at TRL-7 with CE mark close to the market. Because the project consortium of ICU4Covid can build on large expertise in required technology but also will build up on existing project knowledge gains and infrastructure, it will be able to move the overall project from an initial Technology Readiness Level 7 to the Technological Readiness Level 9 with monitoring studies, supporting the post market follow up and adaptation of the certification or re-certification (Medical Device Regulation (EU) 2017/745 class IIa) of a further refined product. Also, ICU4Covid, follow the dimensions of the Consortia for Improving Medicine with Innovation & Technology (CIMIT) Innovation circle as described in the following Figure (ibid).

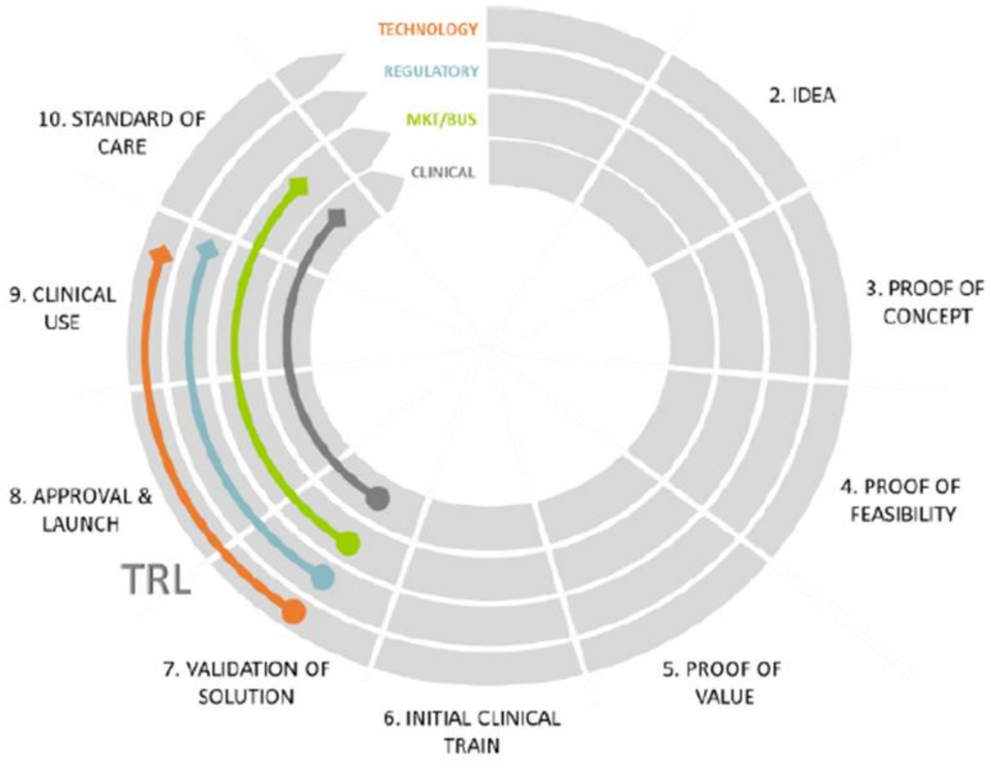


Figure 11: CIMIT circle in ICU4Covid. Adapted from Proposal 101016000, ICU4Covid

4.1. HIGH LEVEL OBJECTIVES OF ICU4COVID

ICU4Covid seeks to deliver the CPS4TIC innovation quickly in order to provide better care for patients and healthcare workers, as well as to limit the outbreak, by lowering infections. It will test the CPS4TIC in large-scale pilots, incorporating recent advances in Tele-Intensive Care Medicine and smart bedside technologies. This enables the rapid and efficient establishment of an ICU collaborative network across Europe, as well as dynamic response and cross-border knowledge exchange by regional experts, and effectively enables high-level exchange of experiences and better patient outcomes. ICU4Covid also creates a seamless connector platform to securely connect ICU Hubs and remote peripheral hospitals for real-time continuous patient monitoring, telemedical consultation based on synoptic data from various sources, and the storage, adaptation, and sharing of prediction models between ICU Hubs. Furthermore, enables improved data and information analytics, resulting in, for example, medical decision support or the development of individualized treatment plans for COVID-19 or comparable infectious illness patients (ibid).

As premier European clinical ICU centers with associated local hospitals that treated critically ill COVID-19 patients in the first strong wave, the University Hospital UKA (UKA) and Medical University of Vienna (MUV) have received practical experience using the CPS4TIC at critical periods and in emergency situations. So, this is an opportunity to share knowledge with other hospital partners and healthcare authorities in Portugal, the Lisbon and Madeira region, Greece, and Austria. The CPS4TIC system and components will be provided by the technical partners, who will also handle operational integration in four member states: Germany and Austria, two member nations that are currently among Europe's leaders in terms of ICU, and Greece and Portugal, two member states with critically insufficient capacity. The inclusion of four more ICU Hubs will allow the CPS4TIC to be deployed to locations that are critically exposed, critically isolated, or where ICU capacity cannot be substantially expanded quickly. It is expected that the CPS4TIC will gain more momentum in terms of integration and co-creation, as well as establish collaboration with more regions and communes, for which the continued roll-out of CPS4TIC is of strategic importance in order to prepare for Covid-19 outbreaks and similar infectious diseases (ibid).

4.2. INTERDISCIPLINARY CONSIDERATION AND STAKEHOLDER KNOWLEDGE

ICU4Covid is an interdisciplinary project that brings together ICT, engineering, life scientists, social scientists, regulatory and legal specialists, and clinical intensive care medical professionals. It makes intensively use of broad and stakeholders' knowledge through its key partners, the project advisory boards, and innovation management, the professional networks of the partners and the direct involvement in knowledge and information initiatives, and cooperation on innovation with the health authorities. Specific and up to date stakeholder knowledge is used from the direct involvement in the national emergency initiatives and task forces in the corona virus crisis, such as for UKA in Germany and Northrhine-Westfalia. It makes stakeholder knowledge available for further use, such as on the robotics elements, the gripper, smart components, and interoperability. Within the project, direct feedback from employees of the clinical partners as well as patients is of utmost importance in order to adapt the development to the stakeholders’ needs and interests. This includes a wide range of stakeholders from across the healthcare value chain, programmers, data scientists, integration experts, and public health officials. Through the implementation of a co-creation environment, the project aims to assure a human-centered innovation, acceptance and functional design, engaging with social and societal dimensions (ibid).

4.3. OVERALL METHODOLOGY

ICU4Covid methodology will be based on agile approach with a strong emphasis on the Digital ICU Hubs, the integration into several clinical structures and workflows and on the conceptual learning to be implemented. In order to secure the rapid and successful implementation, ICU4Covid will perform three twinning cycles for roll-out. The first two cycles are performed by partners of the project: ICU Hubs at Aachen and Vienna are setup followed by Hubs at in Lisbon and Thessaloniki with local connected hospital for each in a concerted approach to gain time and being effective. At least one daily rounding will conduct with each of the partner hospitals within the ICU Hubs. During the rounding, clinical details of each patient on the ward will be discussed in a "doc2doc" communication environment using a customized Tele-ICU cart with experts from the excellence center. Doctors in the central core hospital will be able to see and hear their colleagues and patients in the connected hospital.

The CPS4TIC serves as an interoperable facilitator, with a focus on usability and reliability. As a result, a single ICU Hub, monitors hundreds of ICU beds and provides guidance and advice, which improves the collaborative functioning of the workforce. Technical design, connection with local hospital IT infrastructure, Patient Data Management Systems, and necessary network infrastructure are all included. The initiative includes both partners with established telemedical routines (Germany, and Austria), as well as partners with no or limited telemedical infrastructure (Portugal, Greece). The construction of telemedical networks must be guided by a carefully prepared, tailored implementation and integration plan that takes into account the existing technical infrastructure within the hospitals (ibid).

Country	Hospital	ICU beds	Patient Data Management System
Germany	**University Hospital UKA**	110	Philips ICCA
	Krakenhaus Duren Gem. GmbH (KHDN)	13	none
	Bethlehem Gesundheitszentrum Stolberg Gemeinnutzige GmbH (BETH)	14	ICM Dräger
	Katholische Nord-Kreis Kliniken Linnich unf Julich GmbH (JUL)	10	none
Portugal	**Hospital Santa Maria Lisbon (AIDFM)**	54	ICM Dräger
	SRS Madeira (SRS)	11	ATRIUM (proprietary solution)
Austria	**MUV Vienna**	67	Philips ICCA
	Hospital Hietzing	8	GE
	Hospital Wilheminen	16	GE
Greece	**AHEPA University Hospital, in Thessaloniki (belonging to** 4th Health District of Macedonia and Thrace)	17	proprietary solution
	University Hospital of Alexandroupolis (belonging **to** 4th Health District of Macedonia and Thrace)	16	proprietary solution

(Figure 12: Adapted from Proposal 101016000, ICU4Covid)

The data models from the ICU Hubs will be collected in an Integration Center as part of ICU4Covid, laying the groundwork for more correctly predicting and identifying crucial characteristics. This allows knowledge gains in the form of models, rather than data sharing, to be quickly disseminated to all areas of Europe, for example, a unique illness pattern appearing in one region can be used to treat similar patients across the continent while maintaining absolute privacy. This means that, in the instance of the present COVID-19 epidemic, therapy and diagnostic improvements from high-level centers can be quickly transported to regions with less developed infrastructure (ibid).

According to Carol J., (2019), besides the traditional software integrity and verification strategies, AI methods and tools will require additional cautions and foresight to avoid significant side effects. In this phase, ICU4Covid is only focused on the rapid sharing of models for prediction, diagnosis, and prognostics that are based on evidence and data, as well as expert doctors' decisions. The CPS4TIC allows for the continued enhancement of decision-support models using data-driven AI algorithms, which is considered and planned for within the project to ensure that it is development-ready in the future. To collect data and automate configuration, modifying function modes, and personalizing support, process automation (RPA) techniques in combination with IoT are employed. The models and data gathered will be sent into the connector platform, which will enhance team member cooperation and collaboration while working more efficiently and safely. Smart components such as occupancy detectors, location and tracking sensors, and wearables devices for posture monitoring are used to execute sensing IoT tasks. The information gathered will be utilized to automate robot configuration, adjust robot function modes, and personalize patient and caregiver assistance, including the risk of infection with SARS-CoV-2 or other infectious agents. Caregivers are constantly active in the co-creation process and monitoring of functioning in order to obtain appropriate intuitive control, efficiency, and effectiveness, particularly while dealing with COVID-19 patients at the bedside, enforcing tele-intensive care and mutually supporting system between hospital (ibid).

4.4. USING CO-CREATION TO INTEGRATE THE CPS4TIC

The idea of co-creation will serve as the framework for ICU4Covid's development and implementation process, which will draw knowledge from implementation research. The methodological approach's focus will be setting up, facilitating, and managing the co-creation environment.

The users and the technology suppliers will engage in ongoing reciprocal learning throughout the project in these venues. They will collaboratively categorize and rank the issues and worries that various user groups have, codify them as user needs in terms of desired components and functionalities, and present them in various formats. This will influence the ultimate socio-technical integration of the CPS4TIC through a number of iterations. The implementation viewpoint, in particular the actions, values, and concerns of people who (have to) put it into reality and those who have to accept such innovation as the primary determinant of success or failure, will thus be the emphasis of the co-creation approach. Intense lessons that are applied to practice at the ICU Hubs can be learnt from the experience obtained and the problems that arose during the initial waves of COVID-19 patients. There will be three stages as the project develops.

Phase 1 includes:

- Outlining a process for comprehending how digital technologies are integrated into the intensive care unit environment and highlighting a number of social and societal obstacles to the use of these technology advancements in the ICU
- Building up the co-creation environment in the several locations (Germany, Austria, Portugal, and Greece) that is tailored to the ICU context

Phase 2 will follow and include:

- Intensive field work to follow the integration of the digital in the ICU practices and processes and to accompany the implementation process in the four sites; study how the various actors perceive the change, how the digital technologies affect their work processes and practices, how they value the new digital environment, and many other things

- In co-creation processes, define requirements and performance criteria
- In order to inform the creation of the implementation model, input should be provided and the implementation process should be documented with all options

Then, phase 3 will address:

- Evaluation and validation throughout and following the implementation procedure
- Look into the changes in performers' ICU work methods
- Taking into account diversity and gender issues in these procedures
- Creation of the guide for jointly developing an ICU Hub (ibid).

4.5. IN GENERAL

After briefly sketching the technological innovation at the core of ICU4Covid, it is clear that the project must be sensitive to the societal dimension relevant to ICU4Covid, i.e. the systemic and institutional aspects of the healthcare system and how they are understood, supported, and shaped by the respective societal environments, in order to make the transformation successful. Simultaneously, we must pay attention to the social dimensions, as this technological change of the ICU will have a significant impact on medical professionals' work and care environments, as well as patients' social environments and carers. Without a doubt, one of the most difficult challenges in developing the ICU of the future is ensuring that digital innovations are adopted and integrated into daily practices by all those involved in the ICU, including medical doctors, nursing staff, patients and their families, as well as hospital administrations. As we have already mentioned in chapter 3, there has long been a fear that accessible digital technologies that could improve treatment or prevention are only reluctantly integrated into everyday medical procedures, hence fail to deliver, are not understood and adopted by patients/citizens, and thus fail to improve patient care. The result is patients, medical personnel, and the healthcare system as a whole will not benefit from the potential benefits if implementation fails.

However, we must also keep in mind that, while effective implementation of the offered technology solutions can help to address some of the difficulties at hand, more systematic or structural concerns that differ across locations may still exist.

Many digital health technologies rely heavily on health care providers' adoption and proper application. This could lead to the creation of new health-care professions, as well as the acquisition of new skills and abilities by existing health-care professionals to work with new digital health services. This indicates that proper knowledge and training are required to make this possible. In practice, co-creation in the development of new digital health services can help to boost acceptability and user friendliness. Professionals' experiences with technology are equally important to track and factor into any review. Some systems may take a long time to (learn how to) operate, putting additional stress on already overworked experts (in the short or even longer run). Professionals and patients may find some technologies more or less acceptable (in different ways), which is a clear requirement for successful adoption and regular use. (EXPH, 2019)

In times of crisis, expanding the availability of this technological infrastructure is intended to help improve access to healthcare, provide sufficient capacity for treating patients regardless of age, improve the quality of healthcare, and reduce the risk of infection by utilizing the most recent developments (such as CPS supported decision making).

Increasing the number of intensive care experts available in more remote hospitals is a critical step in this approach. However, these telemedical solutions can help ICU work beyond the current crisis by establishing a safer atmosphere for medical workers and patients.

5. THE RESEARCH

This thesis lays forth the structure that must guide the successful, long-term, and responsible implementation of large-scale healthcare programs like ICU4Covid and beyond. We come to see the ICU as a collection of individuals, machines, and practices that will be forever altered by the introduction of new technological systems. This necessitates the construction of co-creation environments in each of the ICU Hubs, allowing the implementation process to be sensitive to local circumstances and user viewpoints.

5.1. RESEARCH DESIGN AND PROCESS

The research took place over a five-month period, and it was critical to develop and implement a research plan in order to comprehend the next step and how to proceed with the project. A discussion with the Project Manager of the project in Greece and with the coordinator of the project which is the Instituto de Desenvolvimento de Novas Tecnologias (UNINOVA) in Portugal, a multidisciplinary, independent, and non-profit research institute and member of the ICU4Covid consortium, was crucial to grasp their needs and to construct the problem formulation, purpose, and research questions. Following that, the data collection process, which included both primary and secondary sources, began with the goal of identifying current research in the field as well as a research gap. It signifies that new insights and information emerged as a result of studying secondary sources and conducting semi-structured interviews, and the problem formulation took on a new shape. When all of the interviews were completed, the problem definition as well as the research topic were finalized. The research design has been divided into the theoretical framework and research approach through case study exploratory research, which also goes under the definition of a qualitative report. The goal of such a research is to explore the problem and around it and not actually derive a conclusion from it. (https://www.questionpro.com/blog/exploratory-research/).

According to Yin (1989), case study, is an empirical inquiry that investigates a contemporary phenomenon within its real life context using multiple sources of evidence. As Anderson (1993) argues, case study is not intended as a study of the entire organization, but rather is intended to focus on a particular issue, feature or units of analysis. Even though case studies have been criticized by some as lack of scientific rigour and reliability (Johnson, 1994) however, there are some strengths such as the fact that the researcher gains an holistic view of a certain phenomenon (Gummesson, 1991).

The goal of exploratory research is to look into the research questions without coming to any conclusions or specific answers. It's primarily used in study topics that aren't precisely defined, and it's bringing better developed understandings and insights to the field. Furthermore, depending to the substance of the obtained data, the researcher may need to alter his or her approach and method. Semi-structured interviews are the most common and appropriate way for gathering data in exploratory research. The flexibility and adaptability to change are the most significant advantages of exploratory research. Furthermore, they lay the groundwork for future research in the topic. However, because these studies are typically regarded as qualitative, it may be difficult to eliminate biases due to the small number of participants in the data collection procedure. As a result, generalizing the findings of an exploratory study to a larger audience is not suitable (Dudovskiy, 2018).

Unlike quantitative research, which is usually concerned with investigating and describing a phenomenon to a certain level (Hagen, 1992) in terms of numbers, quantities, figures, amounts, and incidences, qualitative research attempts to go beyond descriptions to provide a researcher with an in-depth understanding of a phenomenon. Qualitative data, according to Richards (2005), consists of complex recordings of observations, descriptions, and narratives that are context bound and may be irreducible to numbers. The most used and appropriate method for collecting data in an exploratory research is semi-structured interviews. Interview is a highly used method of collecting data in qualitative social research methods (Holstein & Gubrium, 2004). The goal is to keep interviews informal, so that the interviewees feel free to express themselves and offer their major views and opinions on the issue. The researcher has some conversation topics in mind, but is keeping the interview open-ended in order to obtain a wide range of data (Adams, 2015).

Moreover, the use of theoretical frameworks to guide the development of exploratory research is suggested, as they are based on current knowledge and testing in practice. They are critical in reducing prejudices and avoiding human nature's attachment (i.e., values and beliefs) (Adom et al., 2018).

This thesis used semi-structured interviews as primary sources and theoretical frameworks as secondary sources, in order to assist in the definition of the report's core themes, to assess, implement, and/or synthesize suitable models, and declare any assumptions (ibid). The interviews were conducted via skype, as three of the participants were abroad (Germany, Portugal, and Austria). When it comes to theoretical framework, we'd like to outline how the social and technological aspects of reorganizing the ICU based on the planned CPS4TIC come together. In order to do so, we analyze two concepts, that of Responsible Innovation and that of co-creation via the deliverable of Felt et al., (2021) from a Social Science Perspective.

The sample of the interviewees was nonrandom because the goal was to obtain insights into a phenomenon, as will typically be the case in qualitative research. Then the researcher purposefully selects individuals, groups, and settings that maximize understanding of the phenomenon (Omona, 2013). Critical case sampling was preferred. Here, individuals, are selected that bring to the fore the phenomenon of interest such that the researcher can learn more about the phenomenon than would have been learned without including these critical case (ibid).

5.2. THE INTERVIEWEES (MEMBERS OF THE CONSORTIUM)

5.2.1. UNINOVA INSTITUTO DESENVOLVIMENTO DE TECNOLOGIAS (UNINOVA) (PORTUGAL)

UNINOVA Instituto de Desenvolvimento de Novas Tecnologias is a multidisciplinary, independent, and non-profit research institute employing around 180 persons, located in the metropolitan area of Lisbon. It was formed in 1986 by the Faculty of S&T of the University Nova de Lisboa (FCT-UNL - www.fct.unl.pt), a group of industrial associations, a financial holding, and up to 30 companies. It is an active partner of Madan Parque (www.madanparque.pt), a business facilitator and accelerator, incubating Micro and SME’s through several layers of support to entrepreneurial activity. The main aim of UNINOVA is to pursue excellence in scientific research, technical development, advanced training and education. By working closely with industry and universities, technological innovations are transferred into profitable business concepts and, existing products further developed to match new requirements. Due to its tight connection with the University and Madan Parque, UNINOVA has, since its foundation, hosted and supported the development several PhD thesis, as well as the creation of several successful spin-offs. The institute is strongly committed to UN 2030 Agenda for Sustainable Development as well as to EU Digital Single Market being involved in many activities that support and enable the developments and actions towards the data economy. From the technological point of view, within the Center of Technology and Systems (CTS), UNINOVA provides expertise on strategies for interoperability and information integration using standards, standards’ reuse and harmonization, intelligent mapping, design and development of enablers, integrators, and translators for multi-site applications and web front-ends in integrated manufacturing environments and cloud-based relationships, eHealth and personalised citizen-centred data management, distributed data and process mining, Big Data, machine/deep learning, predictive analytics and visualization, Internet of Things, Cyber-Physical Systems, Embedded Systems, Telerobotics, autonomous robotics, service robotics, etc. UNINOVA is the coordinator of the project and supports the Portuguese ICU Hub. (http://www.uninova.pt/)

5.2.2. UNIVERSITÄTSKLINIKUM AACHEN AÖR (UKA) (GERMANY)

University Hospital Aachen (UKA) is a modern University hospital in Germany located in the „Euregio“ next to Belgium and the Netherlands. It comprises 1.500 beds including more than 200 ICU beds caring for more than 45.000 in-hospital and 250.000 ambulatory patients annually. It offers superior expertise in intensive care, being the national center of excellence. The Department of Intensive Care comprises 103- beds treating more than 5.000 critically ill patients per year. In addition, it has several experimental and clinical research groups within a well-equipped research laboratory. Research expertise includes Telemedicine and Digital Health. Since its foundation, the convergence of medicine and technology is the medical faculty's mission and core area, being part of the RWTH (Rheinisch- Westfälisch Technische Hochschule), which is one of the Universities of Excellence in Germany. Development of innovative, telemedical solutions is part of the mid to long-term strategy of UKA, North Rhine-Westphalia’s and federal authorities. Therefore, UKA founded a center for telemedicine at the UKA in 2012, and in 2018 the Innovation Center Digital Medicine (https://www.ukaachen.de/en/clinics-institutes/innovation-center-digitalmedicine.

html). UKA is responsible for the clinical implementation of the ICU Hubs, CPS4TIC for clinical use, and will be involved in the co-creation process

5.2.3. ASSOCIAÇÃO PARA A INVESTIGAÇÃO E DESENVOLVIMENTO DA FACULDADE DE MEDICINA - AIDFM (AIDFM) (PORTUGAL)

The Associação para a Investigação e Desenvolvimento da Faculdade de Medicina is a non-profit organization that supports medical and translational research at the Faculty of Medicine of Lisbon. It is a comprehensive center uniquely positioned to benefit from the resources of the Lisbon Academic Medical Centre which also includes the Faculty of Medicine of Lisbon, the Centro Hospitalar Universitário Lisboa Norte (Santa Maria and Pulido Valente Hospitals) and the Instituto de Medicina Molecular (IMM) with whom share facilities and specific expertise. AIDFM is devoted to promote research, innovation and excellence in medical and biomedical sciences. Its mission is to contribute to a better understanding of health and disease through interdisciplinary research, to translate this knowledge into clinical practice, to improve patient management and outcomes, care and quality of life, as well as to develop technological innovation, with the goal of playing a leadership in role in training of the next generation of scientists, clinicians and allied health professionals. AIDFM offers a broad portfolio of high-quality services, ensuring compliance with international regulations and contributing to transparency and operational excellence of the research activity. AIDFM is also committed to engage with the public and to be a source of advice for patient’s organizations and policy makers being, also, firmly committed to Europe and to the Lisbon strategy. AIDFM, particularly Hospital de Santa Maria ICU, is the central hospital in the Portuguese ICU Hub

5.2.4. AVAILABLE LEAGUE LDA. (AL) COUNTRY (PORTUGAL)

Available League Lda. (AL) is a consulting company in the European healthcare sector. The company provides a portfolio of services around healthcare properties and institutional funds. The company provided fund concepts and raised capital from institutional investors (pension funds and insurance companies) for a major European company and helped to set up three different funds: one with medical office centers and clinics, one with assisted living facilities and the third one will be launched until May this year investing into nursing homes, assisted living and medical office buildings in Germany. The company also advises Funds which invests into healthcare real estate properties in all European Countries. The company also advised on the asset management, the acquisition and the sale of healthcare properties (European wide). AL has also been involved in the conception and development of nursing homes, medical office buildings and hospitals (e.g. in North of Portugal). AL will support the ICU Hubs in Portugal and Greece.

5.2.5. MEDIZINISCHE UNIVERSITAET WIEN (MUW) (VIENNA)

The Medical University of Vienna (German: Medizinische Universität Wien) is a public university located in the Stadt Wien AKH in Vienna, Austria. It is the direct successor to the faculty of medicine at the University of Vienna, founded in 1365 by Rudolf IV, Duke of Austria. As one of the oldest medical schools in the world, it is the oldest in the German-speaking countries, and was the second medical faculty in the Holy Roman Empire, after the Charles University of Prague. The Medical University of Vienna is the largest medical organization in Austria, as well as one of the top-level research institutions in Europe and provides Europe's largest hospital, the Vienna General Hospital, with all of its medical staff. It consists of 31 university clinics and clinical institutes, and 12 medical-theoretical departments, which perform around 50 000 surgeries each year. The Vienna General Hospital has about 100.000 patients treated as inpatients and 605.000 treated as outpatients each year.

5.2.6. 4TH HEALTH DISTRICT OF MACEDONIA AND THRACE (4RHA) (GREECE)

The 4th Health District of Macedonia and Thrace (YPE) is a government organization supervised by Ministry of Health and is responsible for managing heath policies in the area of central and northern Makedonia and Thrace. Under the responsibility of 4th Health District Directorate there are 16 Hospitals and 47 Health Centers. The main objectives of 4RPA are planning, coordination, supervision and inspection of all Health Service and Social Solidarity operators. Submitting to the Minister of Health and Social Solidarity, suggestions, measures and proposals aimed at more comprehensive and efficient delivery of health and social solidarity services to the population of the Region. Monitoring of the implementation by the Administration of supervised F.P.Y.Y.K.A. 4RHA represents the central and peripheral hospital in the Greek ICU Hub. In this role, 4RHA is involved in CPS4TIC technical establishment in ICU Hubs, CPS4TIC deployment for clinical use, and Co-designing.

5.3. ETHICS

Ethics is defined as a set of moral standards that determines what is right and wrong based on a set of rules or principles (Rogelberg, 2008). Ethical behavior, on the other hand, can serve to protect individuals, communities, and the environment from potential threats, thus increasing goodness in the world (Isreal and Hay, 2006). It is impossible to finish research development without adhering to the required ethical standards of practice (Barriage et al., 2016). According to information scientists, the critical requirement for research and innovation for long-term development necessitates research that adheres to a set of rules or principles (Esteves et al., 2014). Before any research involving (living) humans may begin, the individuals involved, known as participants, must be properly informed and provide their voluntary consent (Gregory, 2003). Analysts note that the contact between the participant and the researcher during data collection can have moral ramifications in a typical qualitative study. As a result, it is necessary to establish clear rules that must be adhered to in order to avoid moral consequences. Confidentiality and informed consent are two difficulties that collectively generate ethical questions in qualitative research. (Corti, Day & Backhouse, 2000; Orb, Eisenhauer & Wynaden, 2001). Anonymity, potential impact, and potential harm to the participant are other factors that are taken into account. (Halai, 2006; Stevens, 2013; Sanjari, Bahramnezhad, Fomani, Shoghi & Cheraghi, 2014).

In our case, all respondents were informed about the research and how it will be conducted by receiving an extended text in their email at the start of the interview. They were also informed about the topics that will be discussed during the interview, as well as their ability to refuse to take part in the investigation. Finally, in order to maintain privacy, anonymity, and safeguard the status of the interviewers, this thesis will include the organization's name of the participants, but not the specific department or branch with which the interview was performed.

5.4. RESEARCH LIMITATIONS

The study's limitations are those features of design or methodology that affected or influenced how the results of the research were interpreted. Study limitations are restrictions on generalizing from the results, describing applications to practice in more detail, or relating to the utility of findings that are a result of the ways in which we initially chose to design the study, the technique used to establish internal and external validity, or the result of unexpected difficulties that arose during the study (Price et al., 2004).

One weakness of this research is the sample size. Perhaps the sample of this thesis is considered small. On the other hand, the aim was to discover the subject's experiences and how they make sense of those experiences, so the research was focused on the experience of the specific participants to draw conclusions through their point of view.

Another weakness of this research is related to the method of conducting the interviews, via skype. Because the research conditions cannot be controlled when the researcher is not present in the area being studied, its reliability is decreased. The level of involvement is higher during in-person interviews, while better body language reading and perception are possible.

6. RESULTS

Speaking with the interviewees, it turns out that the implementation process of the ICU4COVID project, takes place in a collaborative manner, including different users, experts, and stakeholders. In a way, we can support that throughout the entire process, there is a shared sense of responsibility for what is being developed. The "moto" is "together we will make healthier decisions". Additionally, they carry out brainstorming sessions that anyone can participate and add his or her knowledge and experience. There is also an area where the consortium publish surveys and debates, as well as the conclusions that will be reached as a result of the consultation. Following this logic, "involving users and stakeholders in the process of implementing", innovation can be regarded as essential for obtaining appropriate knowledge and experiences about the potential effects of introducing innovations into the ICU, as well as for successfully evaluating both outcomes and solutions in light of the demands of many stakeholders and the moral values at issue.

To improve communication and involvement among the various stakeholders, a range of actions have been implemented: Increasing engagement – the project team conducted ongoing meetings, interviews, and dialogues with hospital medical staff in order to learn more about each hospital's work environments, with a focus on the ICU, infrastructure, health-care arrangements, and resources available to implement the CPS4TIC system. Another facet of public involvement and policy is mutual communication – the ability to communicate and convey the message consistently while yet being able to interact with various target groups. To that purpose, special seminars have been held to ensure that all stakeholders are communicating in a consistent and clear manner. The major purpose is to bring together medical experts and technologists in order to bridge technological knowledge gaps for medical staff on the one hand, and to provide user experience and medical demands to research and development staff on the other. Participants in the session acknowledged a high level of satisfaction. In addition, they created special documents and videos that were published through media channels and the website to promote the project's activities and generate mutual communication in order to reach a wide range of people. Finally, cooperation - another notable good practice of their collaborative effort is the installation teams' collaboration: every two weeks, they hold a joint meeting to share the most recent developments. Furthermore, all parties use a single cloud system to deliver their demands and outputs. As a result, they ensure that as many partners as possible are involved in the implementation processes, and that everyone is working with the most up-to-date and relevant information.

ICU4Covid brings a varied group of healthcare partners together. Each of these hospitals has its own set of characteristics. For example, the healthcare systems in which hospitals are embedded are vastly different, with disparate provisions for how to preserve a patient record and employ telemedicine. Some hospitals use computerized patient data management systems, while others rely on paper records. Telemedicine has been used in several hospitals for quite some time. Others have only lately improvised telemedical alternatives in response to the COVID-19 pandemic's challenges. The ICU4Covid project's technologies must be adaptive to such a wide range of beginning points. When it comes to the design and functionality of the technologies they create, developers always draw on their own experiences, beliefs, and ideas. The MONA, the project's telemedical centerpiece, was designed in response to the situation in the Aachen region. The first implementations in hospitals across Europe has shown that this may not match the circumstances in other places as well. As a result, the project must face the fact that the technologies cannot be implemented as a one-size-fits-all, out-of-the-box solution. To successfully implement MONA and other technologies, future users at various sites, such as doctors and nurses, must be involved as early in the process as feasible - frequently well before the devices arrive in ICUs and can be integrated into daily routines. Only in this way will technologies be able to respond to the specificities, requirements, and wants of the local community.

The projects' technologies are more than just technical devices. These technologies must be adopted and incorporated into clinical practices in order to be implemented successfully and sustainably. They saw how the newly installed technology affected the ICU as a space during their visits to the hospitals. Break rooms have been reconfigured as the telemedical cockpit, and MONA has been added to the existing medical instruments at the bedside. The medical personnel had to design new routines on occasion. Some ICUs that already use MONA for telemedical consultations have created a separate telemedical ward round where patients can discuss with their telemedical counterparts. New techniques of documenting and making decisions are required for telemedical consultations. Users have to develop new abilities, new skills, in order to communicate with a distant consultant, compensating for the reduced sensory experience of the patient in the case of being present at the bedside. These findings demonstrate that deploying new technologies within ICU4Covid does more than simply adding technical equipment to ICUs. It also alters the social dynamics of the ICU, with the goal of forming new networks of support and exchange. As a result, we refer as "socio-technical implementation" of these technologies. A social model of how the technologies will be used in practice must accompany the technological infrastructure. This begins with defining a vision for using telemedicine with prospective users, before the installation. In some cases, medical staff expressed anxiety about not knowing how to incorporate the newly technology into their practices. It continues after the installation with close engagement between producers and users to make telemedicine a routine.

Because ICU4COVID attempts to integrate technological, medical, and social language, they all have a significant impact on one another, and the capacity to skillfully weave them together requires patience, empathy, and a willingness to learn more about what unites them than what divides them. Professionals from various areas interpret terms and ideas in the context of the conversation; they are all familiar with the linguistic shortcuts and specific codes employed in each language. As a result, when persons in the same field communicate in the same language, whether verbally or in writing, the margin of comprehension error is reduced. Discourses that mix multiple fields of practice, on the other hand, can lead to issues of inaccuracy, ambiguity, and confusion, which can be extremely dangerous when trying to save lives. One of the most important lessons that has been learned from this project is how to successfully bridge language gaps - across technology, medical, and social languages. Their differences are not just in their character, but also in how they describe reality.

a) The technological language is intended to aid us in the operation of technological systems. It is a clear and unambiguous language that demands a considerable amount of expertise and is unfamiliar to the majority of people. It has clear and exact lines and connections that even individuals with a basic understanding of technology may find difficult to comprehend.
b) Medical terminology is also quite professional. It provides easy access to complex data and connects a number of critical aspects. Only specialists are fluent in this language, and misunderstandings can cost a lot.
c) The social language is very adaptable; it varies widely from place to location, and it is rich in metaphors and cultural influences. It comprises both physical and non-verbal gestures, as well as verbal gestures. It's more emotive, and it has a lot of political weight in terms of what's acceptable and what's not.

One of the solutions for overcoming language gaps as part of the project was the creation of a collaborative communication plan framework that defined the major project's outputs in terms of technological and clinical dimensions, as well as schedule and budget considerations. It outlines how the total system will function in hospitals and emphasizes its added value to stakeholders (the hospitals). A brief animation film assisted in bridging perceptual barriers. It is used to promote the project at various events. To begin the process of building a shared language, they had to look at the commonalities that tie everything together. The fact that they all rely on traditions, conventions, beliefs, and values to make them who they are is one of the most fascinating things to learn. Operating and progressing securely in a project that connects these three components necessitates significant caution and a focus on explanations and cooperation. They have discovered that "translators," or specialists who are fluent in all three languages, are occasionally required. For example, researchers in the social sciences who are interested in medical technology. Mutual understanding is a very significant factor. They are always thinking of new methods to connect and listen to details that will help them better understand one other.

It also emerges from their experience, that telemedicine takes time. During their visits, they encountered skepticism and worries among staff members regarding the impact of the technologies to which the project must respond. Workflows and routines must be adjusted by medical personnel. It is necessary to create guidelines for performing and recording telemedical consultations. Interlocutors must communicate in a common language. Across the telemedical networks, trust must be established. For almost 10 years, hospitals in the Aachen region have maintained telemedical links across many telemedical initiatives, utilizing various telemedical technologies. Telemedicine has become engrained in their regular practice throughout time. They have noticed that virtual consultations with clinicians at the university hospital in Aachen have become a regular part of the daily routine, with other treatments based on them. The doctors have created an internal classification system for cases that are particularly "difficult," "interesting," or "borderline" that they want to discuss during the telemedicine consultation. On both sides of the screen, the interlocutors have already practiced their lines. This familiarity, however, is only feasible because the social infrastructure for telemedicine has built through several years of (almost) daily telemedicine consultations. Other project hospital partners have little to no expertise with telemedicine. Because ICU4Covid is only a two-year case, it will be difficult to build social infrastructures comparable to those found in and around Aachen in the limited time available.

6.1. RESPONSIBLE INNOVATION IN THE FRAMEWORK OF ICU4COVID PROJECT

According to Felt et al., (2021), in our case, when inventing a medical care system in the ICU, we must focus on the Responsible Innovation (RI) aspect of ICU4Covid, which stands for a group commitment to carefully consider social and ethical concerns. The main goal behind this frame was to support “transparent, interactive processes of innovation” by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process" (von Schomberg, 2011). In the case of ICU4Covid, this would imply carrying out the CPS4TIC implementation process in a way that allows a diverse range of users and stakeholders, such as medical professionals and patients, to speak up. Users and stakeholders must be involved in the implementation of innovation processes, because they can be a significant factor to gather important information and experiences on the potential consequences of introducing innovations into the ICU. As a result, RI can be considered as a reaction to a rising awareness that innovations may have unintended consequences and so fail to deliver on the promises and aspirations expressed at the start of a transformation effort. Simultaneously, we can expect innovations that combine broader sets of values, needs, and expectations by involving a varied collection of users and stakeholders in the processes of integrating CPS4TIC into the ICU. This is extremely significant because the ICU4Covid project, is dealing with a technological advancement that also affects medical treatment and social environments. Consequently, RI can be viewed as an endeavor to ensure that both the process and the results of innovation are acceptable and socially desirable, resulting in more robust and potentially sustainable solutions.

Von Schomberg, (2013), has posed the normative question of "what counts as an improvement" and for whom. According to Felt (2018), mechanisms of interaction and collective assessment - processes that bring together different groups of users and stakeholders – should make it possible to reflect on the value of innovations in a far more inclusive way. Attending to the values associated with innovation also recognizes that different cultural contexts (in our case, different traditions in understanding how to organize healthcare in hospitals) may have different reactions to the technologies that will be implemented in ICU4Covid and may favor certain technical arrangements over others. Stilgoe and co-authors (2013) identified four critical qualities that require special attention and nurturing throughout the innovation process: "anticipation, reflexivity, inclusion and responsiveness".

Anticipation is the process of deliberately considering all of the possible outcomes. In our case, how will the integration of the new project change the work and care environment in the ICU? It also entails accepting our poor forecasting capabilities and being alert to subtle changes. In the ICU4Covid project, we must analyze how and for whom the integration of new technical tools will transform both the work and care environment(s). As Demers-Payette et al., (2016), mentions this will also include user demands, which are sometimes disregarded in favor of a certain technology solution.

Reflexivity encourages us to examine our beliefs, commitments, and assumptions about the relationship between technology breakthroughs and varied users, as well as the influence of telemedical networks. This entails considering whose problems the specific creative solution in the ICU solves, whose work patterns must be adjusted, and what kinds of possibly conflicting interests and obligations users and stakeholders may have.

Inclusion brings up issues of power distribution and who has a voice in the progress of any research and innovation process. In our case this means taking into account the uneven distribution of specific opportunities in the healthcare environment. How adaptable are the established solutions to various sites? It advocates for various forms of user and stakeholder participation in describing problems and recognizing assumptions in problem framing.

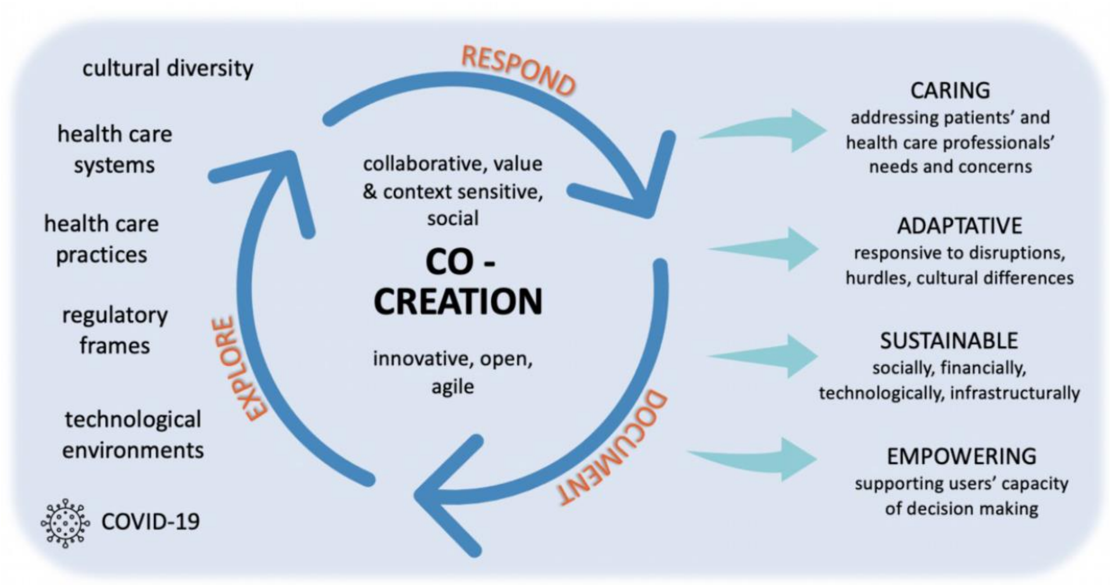
Responsiveness underlines the importance of conducting research and innovation in ways that allow for rethinking. This means that the ICU4Covid project's integration process must be open to learning, progressive adaptation, and modification in response to the specific scenario. This also involves the issue of scalability and how solutions must be modified to accommodate such a process. The implementation phase can then incorporate societal and social requirements and ideals reflected in practice and learned experiences.

6.2. WHY CO-CREATION IS IMPORTANT FOR THE IMPLEMENTATION OF ICU4COVID PROJECT

In May 2020, the European Commission issued a special call for innovation actions for close-to-market support solutions as well as maturing innovative solutions to help support and bundle efforts for developing new technologies that can help deal with and eventually contain COVID-19 and put in place better and more evenly distributed treatment options across Europe. (Call by the European Commission, Topic IDSC1-PHE-CORONAVIRUS-2020 2B:https://ec.europa.eu/info/fundingtenders/opportunities/portal/screen/opportunities/topic-details/sc1-phecoronavirus-2020-2b).

While there is a long history of sponsoring medical improvements, one of the primary problems for this particular appeal is that the results of the funded projects either must be available in a very short period of time, or they will be unable to effectively assist in the current situation. This is related to the issue of transferring developed technologies and the resulting changes in how healthcare is delivered to contexts as diverse as found in the European healthcare landscape. In this environment, methods of co-creation, in addition to supporting technological innovation, are important. It should encourage the development and implementation of agile and use case–focused innovations by incorporating varied sets of experiences and knowledge from potential users into the development and implementation process. As reported by van Dijk-de Vries et al., (2020), it is hoped that by better integrating new technologies with existing systems and applications, such an integrative strategy will allow for faster innovation and thus higher returns. ICU4Covid should engage with the many users throughout the system's implementation, addressing their needs, concerns, and value considerations. Particular attention must be given to regional differences. This will allow key lessons to be learned that are often overlooked, lessons that can only be gained during "use time", that is, when digital technology become an intrinsic part of actual healthcare procedures. The goal is to create a co-creation environment at each ICU Hub that will aid in the deployment of these digital advances. This implies that ICU4Covid intends to ensure that the implementation process is carried out in collaboration with the many users, experts, and stakeholders, engaging with them throughout the process. Bringing individuals who are creating and implementing technical advances together with those who are "living with the consequences" in a co-creation process should result in a shared sense of responsibility for what is being generated throughout the process.

Felt and co -authors (2021), outlying the framework that will be used to guide the successful, long-term, and responsible deployment of CPS4TIC during ICU4Covid and beyond, they see the ICU as a collection of individuals, machines, and practices that will be forever altered by the introduction of new technological systems. This necessitates the construction of co-creation environments in each of the ICU Hubs, allowing the implementation process to be sensitive to local circumstances and user viewpoints. ICU4COVID's understanding of co-creation is an acronym for a collaborative and process-oriented approach to innovation that actively involves experts, stakeholders, and users in general, and is based on the idea that sharing ideas, knowledge, and experiences during the implementation process leads to context-sensitive, long-term solutions that are caring, adaptable, and empowering(ibid). The following is a diagram of the co-creation process used in the context of implementing a CPS4TIC.



(Figure 13: Co – creation process in supporting implementation. Adapted from Felt and co -authors 2021)

The CO-CREATION process lies at the heart of everything. The "CO" stands for collaborative, value-driven, context-sensitive, and socially conscious innovation. CREATION, on the other hand, denotes a process that is evolving innovative and open, indicating the process' inclusiveness and diversity sensitivity. The term "agile" is frequently used here, implying that previous knowledge is applied while continuing to learn from current experience to deliver innovations more smoothly and quickly (ibid). When it comes to context – sensitive, it refers to the fact that when developing, adapting, and implementing a CPS4TIC, it is necessary to consider:

- The variety of well-established health-care systems
- The practices in healthcare that have been in place for a long time
- Different regulatory frameworks (including ethical considerations)
- Several pre-existing technology environments and accompanying processes
- Cultural diversity and the beliefs and practices that go with it

That is why, as Felt et al., (2020) argues, in addition to achieving technological interoperability in the sense of matching data collection and processing methods across sites, "sociocultural interoperability" is equally critical. In our case, the result of this co-creation process is the successful implementation of the project that is Caring, Adaptable, Sustainable, and Empowering.

CARING denotes that the needs and concerns of patients, healthcare professionals, and the general public have been adequately addressed during the implementation process.

ADAPTABLE emphasizes the importance of developing and implementing solutions that can respond to interruptions, roadblocks, and cultural differences in healthcare delivery and consumption.

SUSTAINABLE highlights the notion that a successful implementation must be able to provide sustainability on four separate levels: social, financial, technological, and infrastructure.

EMPOWERING emphasizes that while a technical innovation like this provides decision support, it must also provide enough space for people to develop their ability to make their own decisions and argue for specific choices.

As Felt and co - authors 2021 argued, co-creation is organized as a process and will be structured in three parts – explore, respond, and document – and will be included into the design and implementation of the CPS4TIC.

- Explore means listening to and engaging with various actor groups in the ICU, recognizing needs and concerns through various techniques, and expressing them as "socio-technical user requirements" rather than just technical user requirements.
- Respond means allow for changes and rearrangements to fulfill the demands and concerns; perform it iteratively, which means incorporating feedback much more quickly to gradually arrive at a stable answer.
- And finally, document, which means that contexts and processes, as well as impediments and outcomes from the phases, should be meticulously documented. Explore and Respond to learn from the implementation procedures at many locations.

Given the potential for digital interventions to improve healthcare, it is critical to understand how users — patients (and their relatives), medical physicians, and nursing staff – incorporate these digital advances into the healthcare system. Moreover, it will be critical to consider the social and ethical issues that the introduction of an AI-assisted decision-making system, for example, raises. It will be critical to learn more about how medical professionals trust, rely on, or comply with AI-assisted decision-making circumstances, as well as how they see their role and responsibilities in final decision-making.

Establishing co-creation environment in ICU4COVID project throughout the implementation phase, there will be reciprocal participation and learning. It will take place between people who deploy the technology, medical personnel, patients (and their families), and institutional players in the particular institutions, with social scientists acting as interpreters between these various groups and their perspectives.

6.3. DISCUSSION

Health-care digitization has been discussed for many years. Its purpose is to find a cost-effective solution to improve therapy and patient care. It can be accomplished in a variety of ways. On a worldwide scale, the use of information and communication technologies (ICTs) has moved from specialized contexts like scientific and administrative uses to more general contexts. The global European strategy aims to foster a shared understanding of the importance of digital health solutions among all Member States, as well as a strategy for establishing an interoperable digital health ecosystem, which is defined as a digital interoperable information technology infrastructure primarily used by the health care community across all care settings, in particular by health care providers, health service providers, and patients, as well as by pubic health. Users, health care providers, health system management, and health data services should all be able to exchange health data in a simple and secure manner through an interoperable digital health ecosystem (WHO, 2021). The digitization-driven transition is still occurring, and its consequences are frequently unclear, while affects every area of life. The concept of electronic healthcare, or eHealth, grew increasingly significant as a result of digitalization, but new medical treatment and care methods, such as telemedicine, might also be envisaged and created over time.

President Ursula[1] von der Leyen's current European Commission has set six goals for the period up to 2024. One of these goals is to make Europe "fit for the digital age," which includes promoting digital advances in a variety of fields, including healthcare. The ongoing pandemic crisis has drawn broad attention to the issues facing the healthcare industry, particularly in intensive care units (ICUs). The European Commission has particularly targeted investments in digital technology to boost these areas. Extra funding is targeted to researchers through a special appeal to support close-to-market technological solutions and market innovation of current solutions in response to COVID-19.[2] ICU4covid project is a funded project by European Union, which aims to use telemedicine, artificial intelligence, and robotics to improve the safe monitoring and treatment of patients in intensive care units.

Raposo (2016) argues that telemedicine is classified as both a healthcare and an information service under EU legislation. This is significant because it means that

[1] Keynote speech by President von der Leyen at the 'Masters of Digital 2021' event on February 4, 2021: https://ec.europa.eu/commission/presscorner/detail/en/SPEECH_21_419

[2] Medical technologies, Digital tools and Artificial Intelligence (AI) analytics to improve surveillance and care at high Technology Readiness Levels (TRL) (H2020_SC1-PHE-CORONAVIRUS-2020-2B): https://cordis.europa.eu/programme/id/H2020_SC1-PHE-CORONAVIRUS-2020-2B

when keeping, processing, or transferring data about a patient's health status, regulations governing healthcare practices, as well as data security and privacy regulations, must be followed. Under the General Data Protection Regulations (GDPR), [3]health data, which includes data produced, stored, and transferred via telemedical infrastructures, is given specific protection, necessitating additional safeguards. These measurements necessitate not just new technological requirements, such as secure data storage and transmission, but also new forms of involvement for medical professionals.

According to the European Commission (2018), the transformation of Europe's healthcare system requires financial expenditures to promote the development and implementation of "digitally enabled, person-centered care solutions", entering the patient era. As a result, a digital approach to healthcare is considered as a viable answer to the issues that healthcare systems face, trying to make them more efficient and accessible to all while also giving patients the ability to make their own decisions.

While we agree that technological standards have already been developed, even though they have not yet been implemented everywhere, understanding the socio-cultural ramifications of such a fundamental shift in how healthcare is delivered across different sites is critical too. There has long been a concern that available digital technology that could improve treatment or prevention will not properly integrate into medical professionals' jobs, will not be understood and adopted by patients/citizens, and hence will not improve patient care (Hull et al., 2019). As a result, the European Commission emphasizes the importance of examining the actual needs of medical professionals and patients. Any new technology in the healthcare industry is at risk of failing in practice if these stakeholders are not recognized and incorporated in a co-creation process.

Through this thesis, by examining the implementation of ICU4covid project, we came to some results. We used as secondary source the deliverable of Felt et al., (2021) which outlined the importance of the social science and humanities framework

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[3] Health | European Data Protection Supervisor: https://edps.europa.eu/data-protection/ourwork/subjects/health_en

that will guide the successful, long-term, and responsible implementation of CPS4TIC during ICU4Covid project and beyond. Starting from the assumption that it's not enough to look at telemedicine from a medical, technological, or economic standpoint; otherwise, such research risks not "getting the whole picture"(Halford et al., 2010; Berg, 2001), it is outlined the importance of Responsible Research and Innovation (RRI) which aims to guarantee that research and innovation activities must be conducted in a thoughtful and inclusive manner. "Science with and for society" is how the concept expresses the interaction between science and society. This entails, among other things, the introduction of broader foresight and impact assessment for new technologies, beyond the anticipatory market benefits and risks, as well as a continuous engagement of societal actors throughout the Responsible and Innovation (R&I) process, in order to better align both the process and the outcomes of their research with society's values, needs, and expectations. Furthermore, by recognizing and considering the social and societal aspects of any innovation from the start, taking a Responsible Innovation-informed co-creation approach mitigates potential flaws.

The second assumption of the deliverable of Felt et al., (2021) is that “technologies are never neutral but should be considered as active transformers of health care”(Oudshoorn, 2009; Pols, 2012). This means that relationships between all of the components of an existing assemblage are shifted when a new technical component is added. Establishing the ICU4covid project which means putting data-driven decision support systems in place and introducing robotic arms to ICU bedsides not only adds a (further) technical component to healthcare activities, but it also modifies how they might be conducted in everyday situations.

This thesis goes one step further by outlining the importance of the implementation of co-creation process in every hub of ICU, which takes place in a collaborative manner, including different users, experts, and stakeholders. The active participation of all stakeholders, along with end users, in ongoing collaboration for the continuous release of resources, strategic sharing of knowledge and goals, and greater mutual satisfaction is referred to as co-creation (Vargo & Lusch, 2004). They make certain that as many partners as possible are involved in the implementation process, and that everyone is working with the most up-to-date and relevant data.

Participatory techniques enable a collective definition and elaboration of requirements and solutions, as well as reciprocal learning: Users' ways of thinking and working routines are studied by technology developers (Greenhalgh et al., 2016). Such an integrative strategy is intended to enable speedier innovation and consequently higher returns by better integrating new technologies with existing systems and applications (van Dijk-de Vries et al., 2020). New routines have been designed, and new networks of support and exchange have been formed. We refer as "socio-technical implementation" of a project in order to have sustainability and it is important to start before the implementation.

Furthermore, this thesis underlined that understanding cultural differences is essential for speeding up the installation of systems. Cultural differences are a difficult idea to grasp. It encompasses distinctions in people's views, attitudes, behaviors, and perspectives on the world. In medicine, understanding cultural differences is critical to the effectiveness of adapting new medical technologies in a multicultural and hyper-technological day. Despite the widespread belief that hospitals are "objective" spaces unaffected by "culture," we now recognize that local culture has a significant role in defining the medical environment. The various integration teams made a concerted effort as part of the project preparation to prepare themselves for the significant cultural disparities among the various health centers. They want to understand more about the cultural complexity that exist in the various countries participating in the project, in order to enable the sustainability as effectively as possible. Although the intensive care units in Portugal, Greece, Germany, and Austria, have many similarities, they also have many differences, such as geographic distribution, size, degree of digitization, and experience with telemedicine technologies and connected processes. These differences are a significant factor influencing the system implementation experience within them. These distinctions are represented at the digital administrative level, including geographic distribution, size, degree of digitalization, and expertise with telemedicine technology, among other things. Patient access, therapist-patient relationships, acceptable waiting times, adoption of new technologies, sensitivity to special requirements, and so on are all cultural issues. Already during the design stage, it was evident that these variances would have a substantial impact on the CPS4TIC system's implementation experience in different medical institutions. As a result, they had to be culturally sensitive right from the start. A future that is more efficient, rapid, and connected is certain if modern systems are successfully implemented. A successful process, on the other hand, cannot exist without adhering to local norms and requirements. Last but not least, it takes time to build telemedicine's social infrastructures. It is difficult to build social infrastructures, in a two years period.

6.4. CONCLUSION

We cannot refer to the installation of a project ignoring the social factor. The successful implementation of a program depends not only on its integrity but also on how much we have involved the users and in what way. Moreover, when we refer to users we mean everyone who deal with it. Future users should be involved in its installation from the beginning, from the early stages, before the project comes to the establishment area. The program must meet their needs and at the same time give them space to express themselves. The set up of co-creation environments in each of the ICU Hubs, allowing the implementation process to be sensitive to local circumstances and user viewpoints, empowering a successful and long-term implementation. Digital transformation of medical centers is not a onetime event. Understanding the cultural differences within the medical field, even if we consider that the area of a hospital should remain neutral, is a key for making a project sustainable. Technologies cannot be deployed as a one – size – fits all, out of the box solution. Technical infrastructures need to be accompanied by social models while building social infrastructures takes time in order to assimilate artificial intelligence and telemedicine and become routine.

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8. APPENDIX

Interview's Questions

The successful and long-term implementation of the icu4covid project and beyond requires following a strategy. It is not so much an issue of "whether" as "how" should be implemented. The following questions were asked in order to arrive at certain conclusions:

- What is your role at the project?
- In what ways ICU4COVID project gives voice to a broad range of users
- How such a technology should be implemented in relationship with the different socio environments?
- Can we generalize a technology for all European countries? (What I mean is that it's ok when the implementation concerns different hospitals in various regions of one country, but when it comes to different countries, is the adaptation easy?)
- From your experience, what is a critical factor for the succeed and sustainable implementation of such a project?
- According to your opinion, what structure must guide large-scale healthcare programs like ICU4Covid for a successful, long-term, responsible and sustainable implementation?

- How would a model for co-creation in large-scale implementation health project look like?

- How the introduction of such a project creates changes in the relation between the different stakeholders?

- ICU4Covid is a 2-year project. Is this period enough to be integrated in the daily life of users?

- In which way ICU4COVID will put in place a co-creation environment in each ICU Hub? What will be the specific methods?

- Through what different mechanisms can health care service providers learn from co-creation process?

- Do you have a “lesson” to share with us?