Master's Thesis
in BIOMEDICAL ENGINEERING

Development and Implementation of a Telemedicine System for Wound Care in Different UE Environments

Rosanna Cavazzana

October 3, 2024

Supervisors: Professor Jacopo Secco,

POLITECNICO DI TORINO
BIOMEDICAL ENGINEERING

Corso Duca degli Abruzzi 24
10129 Politecnico di Torino

Contents

1. Introduction

A skin ulcer is a condition that manifests itself as a chronic wound that has failed to heal completely or recover its anatomical and functional integrity. Such wounds are divided into four classes: arterial ulcers (AU), diabetic foot ulcers (DFU), venous leg ulcers (VLU) and pressure injuries (PI). The condition is mainly found in individuals over 65 years of age and is mainly associated with pre-existing chronic conditions such as diabetes, vascular problems, heart disease and obesity. It affects approximately 1-2% of the world's population while in Europe more than 4 million patients suffer from this condition. Early detection, assessment and treatment of the injury is crucial for healing; indeed, it has been found that after four weeks there is a 30% chance that the wound will never heal, a 50% chance of loss of the affected limb and a 50% chance of mortality in the next five years [1]. Chronic pain, limited mobility and psychological and emotional stress are just some of the obstacles frequently encountered by patients with this skin condition. In addition, the treatment of skin ulcers can be protracted for long periods, taking several months or even years to achieve complete wound healing. In many cases, complications that require urgent surgery occur, leading to prolonged hospitalisation. Until recently, hospitalisation and care in a hospital environment was considered the safest and most effective method of providing wound care and constant monitoring. However, it is increasingly relevant to pay more attention to care-related infections, i.e. acquired infections, which, according to Ministero della Salute in Italy, represent the most frequent and serious complication in the healthcare setting. In fact, a prevalence study, conducted according to the ECDC protocol, found a frequency of patients contracting an infection after hospitalisation of 6.3 per 100 hospitalised patients [2]. One of the main causes of hospital-acquired infections is a weakened immune system or severe concomitant diseases, circumstances commonly found in the elderly population with skin ulcers, who are therefore inherently predisposed to this risk. According to the World Health Organisation's (WHO) first global report, care-related infections lead to longer lengths of stay, long-term disability, increased antimicrobial resistance, an additional economic burden on healthcare systems and significant excess mortality. In Europe, these infections generate 16 million additional hospitalisation days, 37.000 directly attributable deaths and 110.000 deaths for which the infection is a contributory cause, with direct costs estimated at EUR 7 billion per year [2]. This leads to a preference for a Telemedicine approach involving remote monitoring, which is more suitable from the point of view of both economics and patient experience. According to the indications of the WHO [3] there is a need for a reformulation of health care systems aimed at optimising the use of available health professionals, which could be achieved through a collaborative approach to primary care based on teamwork and exploiting the potential offered by recent technological developments. In this context, the implementation of Telemedicine systems is of considerable utility, as they enable the enhancement of patient care through objective assessment and constant and possibly remote monitoring of the evolution of the injury. Such technologies also facilitate communication between healthcare professionals, facilitating the formation of a multidisciplinary and competent team to ensure the highest quality of care.

2. Skin Ulcer

2.1 Skin Ulcer: The pathology

Skin ulcers are skin wounds characterised by delayed or inhibited healing with the occurrence of tissue loss. In 70% of cases, these lesions result from vascular causes, particularly disorders of the venous circulation, mainly affecting the lower limbs as well as the legs and feet [4]. The main causes of the pathology are:

- Wrong lifestyle: poor diet, smoking and sedentary lifestyle
- Concomitant diseases such as diabetic foot, immune and systemic diseases, neuropathies
- Decubitus injuries due to prolonged periods of bed rest
- Trauma
- Burns

Identifying the cause of such skin lesions is crucial in order to pursuing the appropriate and patient-specific treatment. Generally, skin ulcers can be divided into acute or chronic. Acute ulcers may result from traffic accidents, burns or surgery; while chronic ulcers may be related to:

- Diabetic foot, decubitis, skin cancer, autoimmune and systemic diseases
- Vascular system impairment leading to reduced blood supply and consequent oxygen deficiency

Skin ulcers and wounds that do not heal represent a failure to achieve complete reepithelialization in the appropriate temporal sequence of tissue repair. Such wounds are characterized by excessive inflammation, by senescent cell populations with impaired proliferative and secretory capacities and by defective mesenchymal stem cells [5].

2.2 Skin Ulcer: between history and modernity

The category of professionals dealing with skin wounds has operated for many years without official recognition, within hospital departments and general outpatient clinics. Skin ulcers, despite their presence in human history for over two thousand years, are often neglected and considered a secondary pathology in contemporary medicine. It is likely that ulcers emerged when humans adopted an upright posture, exposing their legs to possible venous hypertension. Hippocrates (460-377 B.C.), in his treatise *'De Ulceribus'*, first suggested a connection between the occurrence of ulcers and the presence of varicose veins, proposing a rudimentary compression method with primitive sponges. The first evidence of a structured approach to the treatment of skin ulcers is attributed to Arcagatus, a surgeon of Greek origin practicing in Rome around 219 B.C., known by the title of *'vulnarius'* or *'vulnerarius'*, meaning *'wound healer'*. In the absence of antibiotics and sterilization techniques, infections prevailed in those times and demolitive surgery was necessary. It was in the 16th century that the first treatments for skin ulcers began to appear as results of study and experimentation; but it was not until 1843, with Joseph Lister, that a medical approach as opposed to a surgical one began to be used for the treatment of skin lesions. Skin ulcers represent skin lesions characterized by tissue loss, particularly common among the elderly and those with vascular disease and fragile skin. Chronic venous insufficiency, arterial disorders, bed rest and diabetes are among the most common causes of the onset of the condition. The lower limbs are the site most affected by skin ulcers, as blood circulation is usually most impaired in this body district. Currently, it is appropriate to consider this pathology as a 'social disease', since it is estimated that approximately 4 million people in Europe suffer from it, an incidence related to the aging population, sedentary lifestyles, poor diet, cigarette smoking, and environmental pollution, which promote circulatory disorders, in addition to chronic diseases that limit mobility. It is also important to emphasize that the clinical context in which the injury develops is influenced not only by physical factors, such as underlying pathologies, but also by psychological and social aspects. The complexity of the clinical condition inevitably affects the quality of life of the patient and family members, often generating discomfort in everyday life. Anxiety, depression, sleep disorders and pain are common in such patients, often leading to social isolation and a loss of self-confidence. Therefore, the most appropriate approach to skin ulcers must be multidisciplinary, involving close collaboration between different medical specialists, including dermatologists, infectivologists, vascular and diabetic surgeons, nurses and psychologists, in order to allow an adequate response to clinical and organizational-welfare issues.

2.3 Skin Ulcer: Treatment protocols

Regardless of their origin, skin ulcers, defined as wounds that do not respond to standard therapies in an orderly and timely manner, have a substantial impact causing discomfort in the daily lives of patients and their caregivers and increasing the burden on the healthcare system. This phenomenon has been termed the *'Silent Epidemic'*. Living with a chronic lesion can profoundly affect quality of life, manifesting as pain, distress, social isolation, anxiety, prolonged hospitalization, or, in some cases, mortality. Many of these issues can be prevented through early diagnosis, adequate treatment and monitoring of the condition, which need to be defined through standardized treatment protocols.

Recently, the Italian Association of Skin Ulcers (AIUC) and the Association of Patients Affected by Chronic Skin Lesions (SIMITU) have made a pressing appeal to the Piedmont Region for targeted and timely intervention regarding the important issue of chronic skin lesions. It is estimated that this problem affects between 60.000 and 80.000 people in Piedmont alone, while in Italy as a whole, there are over 500.000 patients receiving treatment for this condition. [6]

There are over 140 different causes that can hinder the healing process, including pressure ulcers, diabetic foot lesions and vascular ulcers. While it represents a widespread problem, Italian investments in dressings are very limited amounting to only 0.83 cents per capita per year.

There is, therefore, an urgent need to develop a Regional Diagnostic and Therapeutic Assistance Protocol (PDTA) dedicated to chronic skin lesions to improve care pathways, patient access and to rationalize expenses. The Piedmont Region has already recognized the importance of vulnological visits; however, patients often lack clarity on where to turn for adequate care. The PDTA would establish a standardized diagnostic and therapeutic pathway reducing wait times for appropriate treatment.

Between October 11th and 14th, 2023, the National Congress of the AIUC was hosted at the Lingotto Congress Centre in Turin [7] . On this occasion, a comparative analysis was conducted regarding the treatment protocols adopted in various Italian regions, through interviews with participants at the fair. In particular, twenty-four experts in the field of vulnology were involved, fourteen of whom were nursing professionals and ten were medical and surgical professionals. The survey revealed a marked lack of a standardized protocol for the management and treatment of skin ulcers, an alarming finding considering that this condition affects 2% of the world's population, with 70% of cases not resolving and 32% requiring amputation. Hence, there is a need to introduce an objective and uniform approach for wound assessment and monitoring of their evolution to prevent worsening of the patient's clinical condition, overcome the lack of

experts in the field of vulnology and improve overall clinical outcomes.
There is also a need for an automatic and objective evaluation of clinical parameters of the lesions, which could significantly shorten the time of a traditional manual measurement, which requires approximately 20 minutes and the use of approximate tools and can sometimes cause discomfort to patients with injured and sensitive skin.
Among nursing professionals, there is also a need for centralized hospital-level clinical data of individual patients to track wound evolution and applied dressings and thus ensure continuous specific patient treatment and improve communication and cooperation among healthcare professionals.
The survey also highlighted a substantial lack of experts in the field at nursing homes, where the type of patient most affected by this condition usually resides, namely patients over 65 affected by debilitating conditions or bedridden for prolonged periods.
During the Congress, the telemedical device *'Wound Viewer'* was presented, a non-invasive medical device designed to acquire and automatically process images of skin lesions within a few minutes using specific sensors and an Artificial Intelligence (AI) algorithm. The introduction of such innovative technology in the field of vulnology has generated great interest among the interviewed experts, particularly appreciating aspects related to:

- Continuous monitoring of wound evolution, even remotely
- Facilitation of communication among clinicians and formation of multidisciplinary teams
- Simplicity in accessing and sharing patient clinical data by specialists and healthcare professionals

Overall, the shared experience between patients and healthcare professionals during the global coronavirus pandemic has made it clear and increasingly urgent to adopt tools that facilitate the use of new remotely accessible healthcare services, including telemedicine services. The analysis conducted during the Congress revealed a growing level of trust and optimism towards such solutions, which allow access to essential remote care and overall improve individual healthcare assistance.

2.4 Imaging and measurement technologies in Wound Care

To measure something, it is crucial to perceive it and, preferably, to see it. Historically, looking beneath the skin has been one of the main obstacles to overcome. In the past, doctors were limited to seeking different symptoms by touching the patient, searching for rashes, lesions and wounds, or even listening to the body by placing their ear directly on the patient's skin. These were the only known and utilized methods until the 13th century, mainly because it was considered dangerous to incise the skin to examine the entire body unless absolutely necessary.

In the 19th century, two significant discoveries gave rise to what is now called *'medical imaging'*. The first was the invention of photography in 1827 by Nicéphore Niépce in collaboration with Louis Jacques Mandé Daguerre. The second was the invention of the X-ray tube by Wilhelm Rontgen. The evolution of these techniques led to the birth of the field of medical imaging.

The term *medical imaging* refers to a set of techniques and processes used to create images of the human body for clinical and medical purposes. This field harnesses a wide range of physical phenomena, such as ionizing and non-ionizing radiation, ultrasound and optical phenomena, along with various types of sources (external, internal with tracers, endogenous internal), imaging acquisition techniques and types of acquired information (morphological or functional).

In the context of evaluating skin lesions, the use of imaging plays a fundamental role, not only in representing the wound itself but also in helping medical and nursing staff to thoroughly understand the evolution of the ulcer's condition.

Wound care specialists require more efficient tools and devices to accurately capture the characteristics of the lesion. These characteristics, often complex and subtle, are not always visible to the naked eye. Digital imaging provides valuable support to the field specialists, adapting to the various clinical parameters that need to be evaluated. However, not all imaging technologies are widely employed in this specific medical domain, due to multiple factors such as the specific etiology of the wound, the availability of necessary equipment and the actual need to distinguish various clinical features. Nevertheless, the diagnostic resources currently used enable doctors and nurses to conduct detailed measurements and analyses, thereby raising the standard of care and consequently improving the effectiveness of the healing process In mathematical, physical and natural sciences measurement involves assigning a range of values to a specific physical or chemical property, referred to as the *'measurand'*, assuming the existence of a measurement system. The term *measurand* does not refer to the object or phenomenon being measured, but rather to a specific quantity that characterizes it. As Lord Kelvin stated in 1883: "When you can measure what you are speaking about and express it in numbers, you know something about it; but when you cannot express it in numbers, your knowledge is of a meagre and unsatisfactory kind".

Due to experimental and theoretical challenges, the concept of measurand cannot be reduced to a single numerical value, even considering infinite measurement precision.

Instead, each measurement is defined as a range of values within which the measurand is presumed to lie. The width of this interval determines the measurement precision: the wider the interval, the lower the precision associated with it. The development of metrology has led to defining the concept of measurand statistically and introduced the idea of measurement uncertainty. The latter can be approximately defined as the extent of the interval of values: the greater this interval, the higher the measurement uncertainty. In the most common case, uncertainty is determined by the statistical distribution of a sample of measurements taken on the measurand, with the interval associated with a numerical value identified as the mean of the measurements. Consequently, in metrology, a measurement is always characterized by three components: numerical value, unit of measure or scale of the property and uncertainty associated with the measurement.

Focusing on wound care, Electronic Digital Imaging (EDI) systems utilize three different wound measurement techniques: analog, digital, and neuromorphic. It is important to note that each method involves one or more types of measurement errors. In scientific studies, the choice of the optimal method depends not only on the absolute magnitude of the error but also on the consequences it may have on the measurement itself. In other words, it is essential for this field specialists to consider whether the measurement error resulting from the method used can significantly influence clinical outcomes.

In wound care, wound measurement remains an area where there is no universally accepted standard model among leading experts of this field. This is because there are many variables to consider when accurately assessing a wound, ranging from its chemical to morphological properties.

Historically, the assessment of skin lesions has always been primarily based on accurately assessing their physical dimensions over time. A famous example is that of King Henry VIII of England (1491-1547), known to have suffered from a skin ulcer on his right leg, resulting from an injury during a hunting expedition. Historical evidence now allows us to assert with certainty that this wound, initially acute and traumatic, never healed due to the Cushing's syndrome afflicting the King. Although treatments at the time mainly included phlebotomy, soothing herbal compresses, and removal of necrotic tissue, it is evident that the most understandable variable for surgeons was the size of the wound. Furthermore, several studies indicate that wound morphology is at least one of the main indicators of an effective healing process.

Wound size measurement remains one of the quickest and simplest ways to understand its clinical status, utilizing imaging modalities. Therefore, in clinical settings, it is crucial to provide wound care specialists with tools that allow them to perform precise, rapid and accurately measured assessments. Optical measurement techniques are the most reliable, portable and integrated methods in routine clinical wound care procedures.

Analog and Digital Measurement Methods.

The distinction between analog and digital measurement methods lies primarily in the responsibility for comparing what is being measured to the reference measurement. In analog measurement, this comparison is made directly by the operator, such as measuring a line with a ruler. In contrast, in digital measurement, a specialized device processes the acquired information and, through specific mathematical rules, returns a numerical value representing the entity being measured. In the last decade, the first EDI devices have been introduced to the market, undergoing testing in standard clinical procedures for wound assessment and monitoring. These devices, while differing in the techniques used, have been designed to perform shape measurements of wounds. Despite their increasing popularity, many specialists continue to use analog measurement methods, even though some exhibit high subjectivity. For example, wound surface measurement has traditionally been performed using rulers and cotton swabs inserted into the wound bed to estimate depth. However, these approaches have several drawbacks, including patient discomfort and the possibility of errors due to the irregular shape of wounds. In contrast, digital measurements, performed via EDIs, utilize CMOS cameras and distance sensors to obtain images of the wound, which are then processed to calculate its surface area. This approach allows for greater precision and non-invasive assessment, enhancing the overall patient experience during wound analysis. However, both methods may present errors due to operator positioning or intrinsic device characteristics.

Neuromorphic Solutions in Wound Care.

In recent years, a new generation of EDIs has proven to be extremely effective in the field of wound care due to their measurement and classification precision. These EDIs, termed neuromorphic, differ from others in their implementation of Artificial Intelligence (AI) algorithms capable of analyzing clinical images and automatically identifying and classifying wounds according to various clinical criteria. Neuromorphic engineering is a field that emerged in the 1970s with the goal of creating systems, both hardware and software, capable of analyzing large amounts of data, drawing inspiration from biological neural architectures. Among the most commonly used AI algorithms are Artificial Neural Networks (ANNs) and their variants, which are computational structures designed to solve specific problems, such as classification or statistical inference, using nodes and connections that simulate biological neurons and synapses.

- Nodes: basic computational structures of the network symbolizing input, transfer and output data. They should function like biological neurons

- Connections: mathematical relationships between two or more nodes simulating biological synapses

ANNs, like biological brains, maintain their basic structure but adapt the weights of connections between neurons in response to input data. This process of adapting connection weights is what distinguishes AI algorithms from traditional computational routines, as ANNs learn through training rather than following a predefined sequence of instructions. During training, input data are presented to the network and the algorithms adjust the network's internal parameters to handle this data based on the specific problem being solved, a process known as Machine Learning (ML). This training process involves extracting the most relevant features from the data, which can vary but are generally those attributes that allow data to be grouped and correlated for classification and analysis purposes.

Neuromorphic EDIs offer several advantages over traditional devices. Firstly, they eliminate measurement errors due to human subjectivity: if trained correctly, they can automatically analyze images and identify desired elements with the highest possible precision. Additionally, these devices can perform additional analyses, such as distinguishing between tissues composing the wound, allowing for more detailed clinical classification according to validated standards. However, like all measurement means, they are still subject to some errors, such as instrumental errors due to measurement components and interface errors due to the quality and quantity of data used for the algorithm training.

An example of a promising neuromorphic EDI is the Wound Viewer, developed by Omnidermal Biomedics. This non-invasive tool, equipped with a high-resolution camera and precise distance sensors, is designed for the assessment of skin wounds, providing accurate and detailed evaluation to support wound care management.

3. Telemedicine

3.1 Definition

The ongoing demographic change and the consequent evolution of society's health needs, characterized by an increasing percentage of elderly individuals and chronic medical conditions, require a structural and organizational redefinition of the health-care service network, with particular attention to strengthening community-level care. Telemedicine is an approach to healthcare service delivery that leverages innovative technologies, particularly Information and Communication Technologies (ICT), to enable the provision of healthcare even when the medical professional and the patient (or two professionals) are not in the same physical location. This method involves the secure transmission of medical data, such as texts, sounds, images or other forms of information necessary for the prevention, diagnosis, treatment and monitoring of patients.
Telemedicine services are comparable to any other diagnostic or therapeutic healthcare provision. However, it should be emphasized that telemedicine does not aim to replace traditional medical consultation based on the direct relationship between doctor and patient but rather to integrate it to potentially enhance the effectiveness, efficiency and appropriateness of care. Additionally, Telemedicine must adhere to all the rights and obligations inherent in any healthcare intervention.
It is important to clarify that ICT technologies for managing healthcare information or sharing data and information do not constitute Telemedicine services in themselves. For example, healthcare information portals, social networks, forums, newsgroups, email or other similar forms of online communication are not included in the Telemedicine definition.
Telemedicine can be realized through the following modalities:

- Secondary prevention: services dedicated to individuals already identified as at risk or suffering from conditions such as diabetes or cardiovascular diseases
- Diagnosis: services aimed at transferring diagnostic information rather than the patient themselves. Although a complete diagnostic process is difficult to perform

exclusively through Telemedicine tools, it can provide support or allow for useful insights into the diagnosis and treatment process. For example, it allows for the receipt of diagnostic test reports conducted by specialists directly at the general practitioner's office, pharmacy or patient's home

- Treatment: these services are aimed at making therapeutic decisions and assessing the prognostic progress of patients with clear diagnoses. For example, they may include tele-dialysis services or the possibility of performing remote surgeries
- Rehabilitation: services delivered at the patient's home or other care facilities, intended for patients prescribed with rehabilitation interventions, such as fragile patients, children, disabled individuals, chronic patients or the elderly
- Monitoring: a service concerning continuous management of vital parameters over time, through data exchange between the patient (at home, in a pharmacy or at dedicated care facilities) and a monitoring station for data interpretation

The introduction of new technologies can promote a restructuring of healthcare, especially by shifting focus from hospital environments to the community through innovative care models centered on citizens and facilitating access to services on a national scale.
The modes of delivery of healthcare and socio-health services supported by Telemedicine are of great importance in this context, ensuring:

- Equality in access to care in remote areas
- Support for the management of chronic diseases
- A channel for access to high specialization
- Better continuity of care through more effective and efficient multidisciplinary collaboration
- Essential assistance for emergency services

Considering this demographic context characterized by a progressive aging population, Telemedicine emerges as a fundamental resource to address the challenges associated with the frailty of health affecting the elderly. This category of individuals not only requires continuous care but also experiences increasing difficulties in accessing traditional healthcare facilities.
The introduction of Telemedicine aims to optimize the activities currently carried out in the healthcare sector, thus improving the performance of the involved facilities and

actively engaging various healthcare professionals, such as physicians, nurses and operators. This approach aims to increase the efficiency and productivity of healthcare workers while providing a superior quality service that contributes to improving patients' quality of life.

Telemedicine encompasses various treatment modalities and exploits a wide range of advanced technological instruments. It enables the transfer of various types of data, including audio, video, images, and text, through various communication technologies such as telephone lines, satellites, wireless, wired and the Internet. Common user interfaces include devices such as desktop and laptop computers, fax machines, landline and cellular phones, video cameras and standalone systems.

The concept of telemedicine emerged in the 1970s, initially mainly referring to teleconsultation services. Over time, its meaning has expanded, indicating the application of ICT to improve the efficiency of healthcare services, especially in contexts where distance between the involved parties, both recipients and providers, is a determining factor.

Through Telemedicine, spatial barriers between the actors involved are overcome, as the fundamental idea is that information moves rather than the patient themselves. Telemedicine systems facilitate both the transmission and secure management of medical, clinical and administrative data and information, in the form of texts, multimedia files such as audio, images, and videos, necessary for the diagnosis, monitoring and prevention of the patient's health status at home.

Due to its transversal nature in the healthcare field, the term Telemedicine does not have a unique definition, but over its evolution, it has taken on various facets.

The WHO characterizes Telemedicine as the provision of healthcare and assistance services when distance is a significant barrier to access to care. The provision of services occurs through the use of computer and communication technologies for the transmission of essential data for diagnosis, monitoring, treatment and prevention.

The European Union (EU), in 1990, established a unique meaning for the term Telemedicine, defining it as follows: "the monitoring, monitoring, and management of patients, as well as their education and that of personnel, through the use of systems that allow timely access to expert advice and patient information, regardless of where the first or second reside."

According to the Ministero della Salute in Italy, given the growing diffusion of healthcare services delivered through Telemedicine in an unorganized manner, it becomes indispensable to develop a shared governance model for these initiatives, placing the specific skills of the healthcare sector at the center. It is essential to harmonize the directions and implementation models of Telemedicine to ensure the interoperability of services and to move from an experimental approach to widespread structured implementation of Telemedicine.

It is crucial to emphasize that Telemedicine does not aim to replace the traditional approach to healthcare services, which are mainly based on a direct relationship between doctor and patient. Rather, it integrates with such services, acting as a support to improve the effectiveness and efficiency of care. Telemedicine requires teamwork between specialist doctors and entails the development of new working methods, no longer based on direct contact with the patient but rather on available information and data.

However, the adoption of this approach raises various issues, including the security and integrity of patient data and the inadequacy of the necessary infrastructure for transferring large quantities of data.

3.2 Services Classification

Figure 3.1 shows Telemedicine services classification and description.

TELEMEDICINE					
Classification		**Field**	**Patients**		**Relationship**
Specialist Telemedicine	Televisit	Healthcare	It can be directed towards acute, chronic or post-acute conditions	Active patient engagement	B2C B2B2C
	Tele-Consultation			Absence of the patient	B2B
	Tele-Healthcare Cooperation			Presence of the patient, in real time	B2B2C
Tele-Health		Healthcare	It is mainly directed towards chronic conditions	Active patient engagement	B2C B2B2C
Tele-Assistence		Social Assistence	It can be aimed at elderly and frail individuals as well as differently abled individuals		

Figure 3.1: Telemedicine services. B2B identifies the relationship between doctors, B2C: identifies the relationship between doctor and patient, B2B2C: identifies the relationship between a doctor and a patient mediated through a healthcare operator

Specialist Telemedicine

Specialist Telemedicine encompasses various modes of delivering medical services remotely within a specific medical discipline, which may involve interaction between the physician and the patient or solely between physicians and other healthcare professionals.

- Televisit: A healthcare act in which the physician interacts remotely with the patient, being able to prescribe medication or treatments based on the diagnosis resulting from the visit. During the Televisit, a healthcare operator near the patient may assist the physician and the connection must allow for real-time or deferred interaction.

- Teleconsultation: Remote consultation between physicians that enables a professional to seek advice from colleagues with specific expertise based on available medical information.
- Telemedical cooperation: Assistance provided by a physician or other healthcare professional to a colleague engaged in a healthcare act, including consultation for emergency care providers.

Specialist Telemedicine may include Telemedicine Services in the Territory provided by General Practitioners (GPs) or Free Choice Pediatricians (FCPs).

Tele-Health

Tele-Health primarily focuses on primary care, connecting patients, especially those with chronic conditions, with physicians for diagnosis, monitoring, management, and empowerment. This system allows the physician, often in collaboration with a specialist, to interpret the necessary data for remote patient monitoring. The recording and transmission of data can be automated or managed by the patient or a healthcare operator. Telehealth involves active engagement of both the physician in patient management and the patient themselves in self-care, supporting therapeutic management programs and enhancing patient education and information for patient empowerment.

Tele-Assistence

Tele-assistence represents a socio-assistential system dedicated to caring for elderly or fragile individuals directly at home. This system utilizes alarm management, activation of emergency services and support calls from a service center. Although Tele-assistence primarily has a social dimension, the boundaries with the healthcare domain are blurred and it should integrate with it to ensure continuity of care.

3.3 Characterization and description of a Service

A Telemedicine service can be better understood through the attribution of certain characteristics and the description of the process.

Characteristics

- Territorial coverage: corporate, inter-corporate, regional, inter-regional, national, European, global, other.

- Community scope to which the service is addressed: citizens at home (at-risk patients, chronic patients, pediatric patients, elderly patients), citizens at dedicated care facilities, aircrew, detainees, military personnel, other.

Process descriptors

- Location of service utilization: home, dedicated care facilities or assisted living residences, territorial outpatient clinics, GPs and FCPs offices (with particular regard to aggregated facilities), pharmacy, hospital and care facilities, rescue vehicle, other.
- Location of service provision: hospital and care facilities, territorial outpatient clinics, GP and FCPs offices (with particular regard to aggregated facilities), specialized outpatient clinics, other.
- Mode (temporal mode in which the service is provided): real-time, deferred, mixed.
- Duration (temporal duration of the service): continuous, occasional, periodic.
- Clinical risk: emergency, urgency, control, acute, chronic.
- Professionals involved at the location of service utilization: GPs or FCPs, Specialist Physician, healthcare professionals in nursing and midwifery, rehabilitation professionals, healthcare professionals in the technical-diagnostic and technical-assistance areas, prevention healthcare professionals, pharmacist, other.
- Service providers: GPs or FCPs, Specialist Physician, healthcare professionals in nursing and midwifery, rehabilitation professionals, healthcare professionals in the technical-diagnostic and technical-assistance areas, prevention healthcare professionals, other.
- Other involved figures: caregivers, other.

Pathology
Identifies the pathology to which the service is addressed.
Measured Parameters/Treatment
Identifies the measured parameters, treatments performed, prescribed therapies.
Billing Methods
Describes the billing methods possibly adopted by the Servizio Sanitario Nazionale (SSN) for Telemedicine services, such as:

- Service packages/treatment paths

- Single-service contracts
- Other

3.4 Organization of a Service

Involved Actors

The actors involved in the provision of Telemedicine services are:

- Users: those who use the services, who can be patients, caregivers, or physicians. These users transmit health information and receive the outcomes of the services.
- Service Provider Center: authorized or accredited structures by the SSN, both public and private, that provide medical services through a telecommunications network. They receive health information from users and transmit the outcomes of the services.
- Service Center: a structure that manages and maintains the information system through which the Service Provider Center delivers the services. It deals with the installation and maintenance of tools, management of communication means and patient training. Some centers may perform both the functions of a Service Provider Center and a Service Center.

Technological Components

- Telecommunication infrastructure: essential for data transmission and communication among the involved actors.
- Interface: systems that allow access to the Telemedicine service network, including devices, web applications and dedicated portals.

Health Information

- Texts: demographic data, patient medical history.
- Images: digitized from analog sources or directly digital, such as X-rays or ultrasounds.
- Audio: sounds from medical instruments, such as a stethoscope.
- Other one-dimensional data: physiological signals such as those from an ECG.
- Video: images from endoscopy or video conferences.

Organizational Models
The development of organizational models that clearly delineate the relational dynamics involved is crucial to ensure accurate evaluation and better management of Telemedicine services. Classifying such models can significantly enhance the ability to objectively evaluate Telemedicine performance and the achievement of related objectives. There are several organizational models that can be identified based on the involved actors and the modes of service implementation.

- User-Patient or Caregiver - Service Provider Center relationship: with or without a Service Center, corresponds to Televisit and Telehealth services.
- User-Physician or other healthcare provider in the presence of the patient - Service Provider Center relationship: with or without a Service Center, includes Televisit, Telemedical cooperation and Telehealth services.
- Requesting Physician - Consulting Physician relationship: with or without a Service Center, corresponds to Teleconsultation services.

These actors are connected through the telecommunication infrastructure. The User and Service Provider Center are connected to the infrastructure through an interface.

3.5 Opportunities

The development of Telemedicine solutions offers new responses to traditional medical issues and opens up new opportunities to improve healthcare services through increased collaboration between healthcare professionals and patients.
The expected benefits guiding the development and adoption of Telemedicine techniques and tools include:

- **Equity of access to healthcare:** Telemedicine can enhance access to and availability of qualified healthcare in remote areas such as islands, mountainous regions and rural areas poorly connected to major cities. It can also improve healthcare in prisons, reducing costs and enhancing emergency management.
- **Continuity of care:** Telemedicine enables the provision of medical services directly to the patient's home, improving chronic disease management and enabling remote monitoring for early dehospitalization, freeing up hospital resources for more efficient utilization.
- **Increased effectiveness, efficiency and appropriateness:** Telemedicine contributes to improving the use of the healthcare system by supporting professionals

with technological tools. It promotes communication among healthcare actors, reduces hospitalizations, decreases waiting times and optimizes the use of available resources. Furthermore, it provides timely information to assess healthcare processes and improve drug therapy through devices that assist patients and reduce adverse events.

- **Access to specialist consultations:** Through Telemedicine, specialized professionals have the opportunity to collaborate more easily. This allows General Practitioners to consult specialists on specific clinical cases and patients to obtain consultations from specialists when necessary. Additionally, it enables hospitals lacking specific specializations to outsource evaluations to industry experts to ensure accurate and timely diagnoses. For example, small hospitals without cardiology departments can use Telemedicine to obtain consultations on ECG diagnosis from external specialists, thus facilitating appropriate management of clinical cases.

- **Patient empowerment:** One of the goals of Telemedicine is the active involvement of citizens in their own healthcare journey, fostering greater awareness of their health status. In an era characterized by high interconnectedness and growing expectations regarding care, technology plays a fundamental role, both as a communication tool and a source of information. Telemedicine facilitates more direct and accessible communication with the physician, offering the patient a sense of greater support and assistance.

- **Cost containment:** Telemedicine is considered a specialization within the broader scope of eHealth, which includes the use of ICT to support all healthcare sector functions and operational processes. The Electronic Health Record (EHR) represents the most advanced and innovative front that is gradually influencing European, national and regional realities. One of the advantages of new organizational models based on Telemedicine is the potential rationalization of socio-health processes, with a possible impact on containing healthcare costs and reducing the social cost of illnesses. Used correctly, Telemedicine services can contribute to transforming the healthcare sector and changing associated business models. The availability of Telemedicine services for disadvantaged areas or patients could lead to a decrease in expenses and an increase in system efficiency. Additionally, Telemedicine can support safe hospital discharge, reduce hospitalizations of chronic patients, decrease the use of nursing homes and reduce patient mobility.

- **Contribution to the economy:** Telemedicine and eHealth, along with technologies applied to medicine, represent one of the most innovative industrial sectors. The eHealth market is estimated to have a potential value of EUR 60 billion, of which Europe represents about a third. It is considered the second-largest healthcare industry after pharmaceuticals and medical devices. Therefore, the economic importance of Telemedicine extends beyond healthcare cost containment, significantly contributing to the economy by promoting the growth of European and national industries, including numerous small and medium-sized enterprises.

3.6 Main Areas

The management of chronic diseases and the continuity of care rely on the contribution of advanced technologies, including ICT, to create an operational network involving both institutional and non-institutional actors responsible for treating chronic illnesses. For example, Telemedicine and Teleassistance are tools that support the efficiency of new organizational forms of primary care physicians, enabling effective management of chronic conditions. Furthermore, specialized Telemedicine allows for the delivery of advanced care directly to the patient's home, especially in cases of severe chronic diseases.

Experiences of Telemedicine have been experimented with in numerous sectors of medicine and surgery, covering a wide range of pathologies, from cardiovascular and cerebrovascular diseases to respiratory diseases, from diabetes to mental health, from pediatrics to the frail elderly. The main objective is to improve the interaction between the community and the reference healthcare facilities, while simultaneously reducing the need for transfers for vulnerable and elderly patients.

Moreover, the use of Telemedicine in emergency-urgent services enables more efficient management of critical situations, providing real-time clinically relevant information for patient treatment.

Finally, the field of laboratory diagnostics and medical imaging has undergone significant reorganization through the implementation of initiatives aimed at ensuring interoperability of hospital systems and ASLs, with particular attention to Teleconsultation.

3.7 European scenario

The COVID-19 pandemic crisis and the European investment plan *Next Generation EU* have significantly hastened the process of digital innovation in the public sector. As early as 2014, the European Commission initiated a series of measures aimed at facilitating the development of a data-driven agile economy, including:

- Regulation on the free movement of non-personal data
- Cybersecurity regulation
- Directive on open data
- General Data Protection Regulation

In 2018, the Commission presented its first strategy for AI and coordinated a plan with the Member States, while on March 9, 2021, it outlined its vision and prospects for Europe's digital transformation by 2030.
In 2021, data shows that the European Union has experienced a consistent improvement in innovation performance, with an average increase of 12.5% since 2014 [8]. There is ongoing convergence within the EU, with countries with lower performance growing more rapidly than those with higher performance, thus narrowing the gap between them. As shown in ***Figure 3.2***, at the national level, Belgium, Denmark,

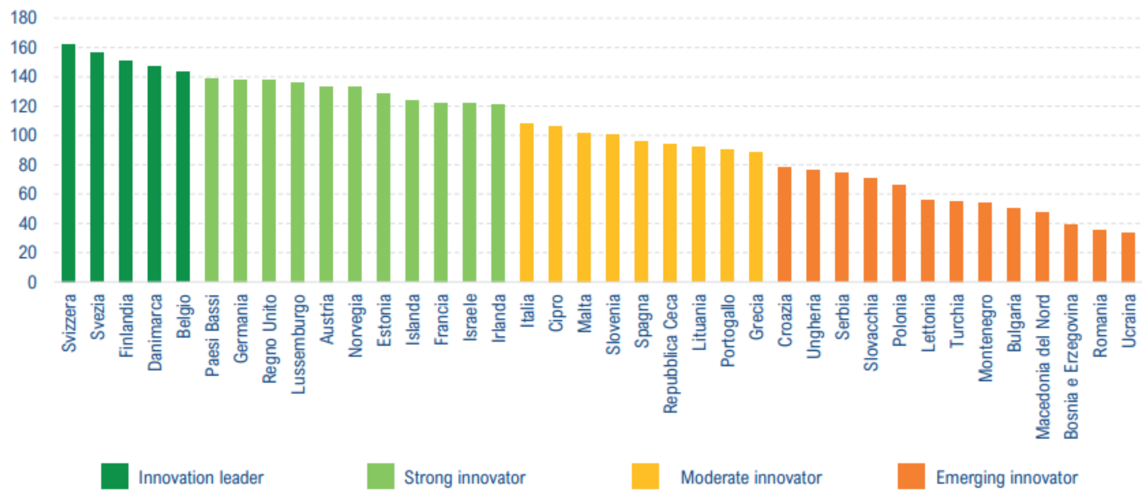


Figure 3.2: European Innovation Scoreboard 2021. *Source: The European House - Ambrosetti on European Commission data, 2022 [8]*

Finland and Sweden emerge as leaders in innovation, while Cyprus, the Czech Republic, Greece, Italy, Lithuania, Malta, Portugal, Slovenia and Spain report performance below the EU average. With the pandemic, new challenges have arisen and existing ones, such as climate change and growing inequalities, have been exacerbated. In this context, digitization and technological innovation emerge as crucial tools for containing the health crisis and its socioeconomic consequences.
Recently, the European Commission introduced the *European Health Data Space (EHDS)*, an initiative aimed at creating a European space for sharing health data,

with the goal of streamlining healthcare for citizens. In addition to simplifying access to and updating of health data, the EHDS aims to provide a coherent, reliable and efficient framework for the use of health data in research, innovation, policies and regulations, while fully respecting the EU's high data protection standards.

Among the project's objectives is to empower individuals through better digital access to their personal health data, thereby facilitating the availability of personal information. The EHDS also seeks to stimulate the data economy by promoting a single market for digital health services and products, in addition to establishing strict rules for the use of health data for research and other purposes.

Although the level of digitization in the healthcare sector varies from country to country, positive experiences emerge that can serve as examples for the digital transformation of healthcare.

Particularly, in the Nordic Countries, during the COVID-19 period, there has been a high adoption of Telemedicine, supported by reimbursements and guidelines geared towards the post-pandemic phase.

Analysis of the Telemedicine market highlights that in 2020, the value of the European market amounted to 6.53 billion USD, recording a Compound Annual Growth Rate (CAGR) of 29.4%. It is projected that by 2025, this value could increase to reach 20 billion USD. Regarding the market for video consultations, the CAGR increases to 41.2%, reaching a value of 8.43 billion USD by 2025. Remote patient monitoring, on the other hand, shows a slightly lower CAGR, with an estimated value of approximately 3.15 billion USD.

While investments in Italy have been limited or less significant, keeping the country among the last in this sector, some countries such as England, Belgium and the Nordic countries have benefited from significant investments, especially post-pandemic. The Telemedicine market continues to grow and it is expected to surpass 20 billion USD by 2025, with a CAGR of 29.4%, according to Frost&Sullivan's forecasts.

A recent report from the WHO, conducted across 47 European countries, provides a detailed overview of the digital healthcare landscape in Europe. The report highlights that electronic health records and electronic medical record systems have been adopted by 59% of European countries. Telemedicine, in particular, appears to be well-developed in the Nordic countries, where it has been utilized for many years due to historical, geographical and cultural reasons. For instance, 83% of countries utilize tele-radiology, while 72% engage in remote patient monitoring, both for curative and preventive purposes. Moreover, 62% of countries have specific policies aimed at promoting Telemedicine, representing a significant improvement compared to the 30% recorded in 2009.

The report reveals considerable progress, especially in recent years, but there is also an awareness that there is still much to be done to fully integrate these tools into the healthcare landscape. One of the main concerns relates to data security within e-Health and especially m-Health (mobile Health), where numerous cases of vulnerability have been documented. Ensuring the validity of e-Health systems is essential and it becomes urgent to establish oversight bodies in each country to guarantee the quality, safety and reliability of digital healthcare tools.

3.8 Italian scenario

The prospects and potential of digital transformation in the healthcare sector must be evaluated considering the specific characteristics of the territory and the socio-demographic context in which it operates. In Italy, the geographical landscape is characterized by a long and narrow peninsula, with a predominance of hilly (42%) and mountainous (35%) areas. This results in a situation where over half of the municipalities are located in internal areas that host about a quarter of the Italian population. Additionally, population aging is increasingly evident, with 23.5% of individuals over the age of 65, the highest percentage in Europe, but even higher figures in internal areas [8]. This leads to a higher prevalence of comorbidities and complications, increasing the demand for care and assistance.

The demographic evolution and the need to optimize resources have led the healthcare sector to revise its systems in a more sustainable way to meet the growing health needs. This has led to greater computerization of the healthcare sector, integration between healthcare and social care services and the adoption of new technologies such as Telemedicine. The digitalization of healthcare services presents an opportunity to address many of the challenges of the national healthcare system, reducing service fragmentation and increasing system efficiency and sustainability. Before the pandemic, the adoption of digital healthcare services was limited and uneven, but the crisis highlighted and pushed towards greater digitalization in the healthcare sector, especially regarding territorial assistance.

However, digital innovation in the healthcare sector faces some obstacles such as the lack of a uniform digital culture at the national level and a shortage of economic and human resources, both in terms of skills in the use of digital tools and the integration of computer systems, as the latter often have connectivity and interoperability issues. In the last 20 years, various governments have increasingly focused on digital transition, introducing terms like *"Digital Agenda"* and establishing bodies such as the *Agenzia per l'Italia Digitale* (AgID). This commitment materialized in the approval of the Digital Administration Code and the definition of strategies such as the *"Italian Strategy for*

Broadband" and the *"Digital Growth Strategy 2014-2020"*. The latter envisaged joint interventions by national, regional and local administrations to promote digital health, including initiatives such as the digitalization of the prescription cycle and the introduction of the Electronic Health Record (EHR).
In 2016, the State-Regions Conference approved the *Pact for Digital Health*, a programmatic document aimed at improving the efficiency, transparency and sustainability of the SSN through the use of digital innovation. This Pact promoted the implementation of tools such as the *Unique Booking Centers (CUP)* and telematic sick notes, as well as the strengthening of the EHR. The commitment to the digitalization of healthcare documents and the promotion of the use of the EHR continues with the *Three-Year Plan 2021-2023*. Within the framework of Mission 6 Health of the National Recovery and Resilience Plan (PNRR), Telemedicine plays a central role with specific intervention actions. This plan, aimed at reforming territorial healthcare, places the citizen at the center of their community, investing in the home as a privileged place of care and in the implementation of Telemedicine, in addition to enhancing all healthcare services. Digital solutions, in this context, can significantly contribute to reducing waiting times for appointments, improving access to healthcare services, optimizing professional and instrumental resources and increasing the overall efficiency of the healthcare system.
The minimum Telemedicine services included in the PNRR, aimed at ensuring uniform application throughout the national territory, include teleconsultation, telemedical advice, teleassistance, and telemonitoring, as established in the National Guidelines for the provision of Telemedicine services (State-Regions Agreement of December 17, 2020).
Furthermore, ministerial decrees have been issued to regulate the implementation of Telemedicine:

- Ministero della Salute Decree of April 29, 2022: approval of organizational guidelines for the *"Digital Model for the implementation of home care"*, to achieve the objectives of EU Milestone M6C1-4.
- Ministero della Salute Decree of September 21, 2022: approval of guidelines for Telemedicine services, defining fundamental requirements and service levels.
- Ministero della Salute Decree of September 30, 2022 (Attachment B): selection procedures for Telemedicine solutions, nationwide deployment, and evaluation of regional needs proposals, together with the adoption of Guidelines for Telemedicine services.

On April 1, 2022, investment 1.2.3 *"Telemedicine for better support for chronic patients"* was issued, articulated in two sub-interventions, Telematic Platform and Telemedicine

Services, whose implementation must comply with the two European targets:

- M6C1-8: at least one project per Region and Local Authorities on Telemedicine as a tool to support patient management.
- M6C1-9: at least 300,000 people assisted through Telemedicine tools by 2025.

The purpose of this investment is to establish a National Platform for Telemedicine services and finance projects aimed at enabling remote doctor-patient interactions, as well as research initiatives focused on digital technologies in the healthcare and assistance sector. This initiative focuses on the provision of Telemedicine services and aims to promote knowledge dissemination on this discipline and facilitate the match between supply and demand. Additionally, data collected during Telemedicine services will be used synergistically with other PNRR investments, such as the strengthening of technological infrastructure and tools for data management, analysis and simulation, with the aim of creating the National Telemedicine Platform. Telemedicine initiatives

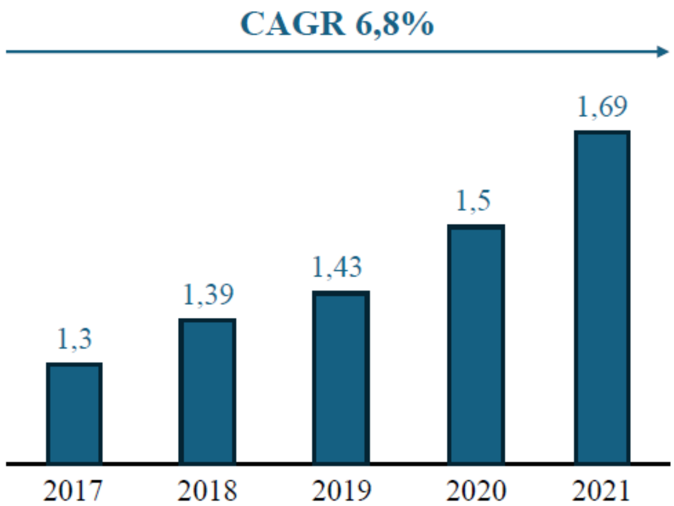


Figure 3.3: Evolution of digital healthcare expenditure (billions of Euros), 2017-2021. CAGR: Compounded Average Growth Rate. *Source: The European House - Ambrosetti on data Osservatorio Sanitá Digitale, Politecnico di Milano, 2022*

are broad and involve different levels, from national to local. With the aim of evaluating and monitoring the use of Telemedicine, several Italian regions, including Emilia Romagna in collaboration with Toscana, Liguria, Marche and Campania, and subsequently Veneto, Sicilia and Lombardia, established the *Osservatorio Nazionale e-Care* in 2007. This observatory aims to map e-Care networks, promote the exchange of best practices and related technologies to improve access and effectiveness of online services for citizens.

European e-health strategies and national health plan objectives are taken into account, with particular attention to the management of chronic and frail patients and to the continuity of care. Initially focused on home care, the Osservatorio is gradually expanding its scope to all Telemedicine sectors to define a national reference model.
Regarding the EHR, available in all Italian Regions and Autonomous Provinces, as of June 2022, there are 57.5 million active EHRs, with nearly 385 million digitized reports. Thanks to the PNRR, which allows for the automatic feeding of the EHR without requiring explicit consent from the citizen, the system's implementation has significantly increased in all regions, reaching 100% in eight of them. However, the usage and dissemination of the EHR among citizens and healthcare professionals show significant variability at the regional level: only in five Regions do all authorized doctors use the EHR, while only in four regions (Calabria, Emilia Romagna, Lazio and Lombardia) does the percentage of citizens who have used the EHR in the last 90 days exceed 50%. The pandemic has played a decisive role in the *"digital maturation"* of the population, also because in many cases access to the EHR allowed downloading the green pass or test results; according to the latest survey by the Digital Health Observatory of the Politecnico di Milano, 33% of citizens have used the EHR and 55% have heard of it (in 2019 they were only 6% and 21% respectively), while among chronically ill or disabled patients, usage and awareness levels increase to 54% and 82% respectively [8].
Despite the strategic importance attributed to digitalization for the country's development and the healthcare sector, Italy was lagging behind other European countries in digital transition when the pandemic arrived. This delay was evident, especially in computer infrastructures and the availability of broadband connections, thus limiting the application of digitalization even in the healthcare sector. The outbreak of the pandemic then accelerated the digital transition process, highlighting its importance and the need to evolve towards increasingly connected and patient-oriented care models. The PNRR contributed to this acceleration by increasing resources dedicated to digitalization and aiming to improve technological infrastructure, promote research and develop digital skills of healthcare personnel.

3.8.1 Utilization in the SSN

Aligned with the outlined relational organizational model, there are several crucial aspects to consider for the correct implementation and dissemination of Telemedicine within the SSN.
Information and Training
It is essential to adequately inform users about the procedures and methods of delivering Telemedicine services, as well as to train physicians and healthcare workers to

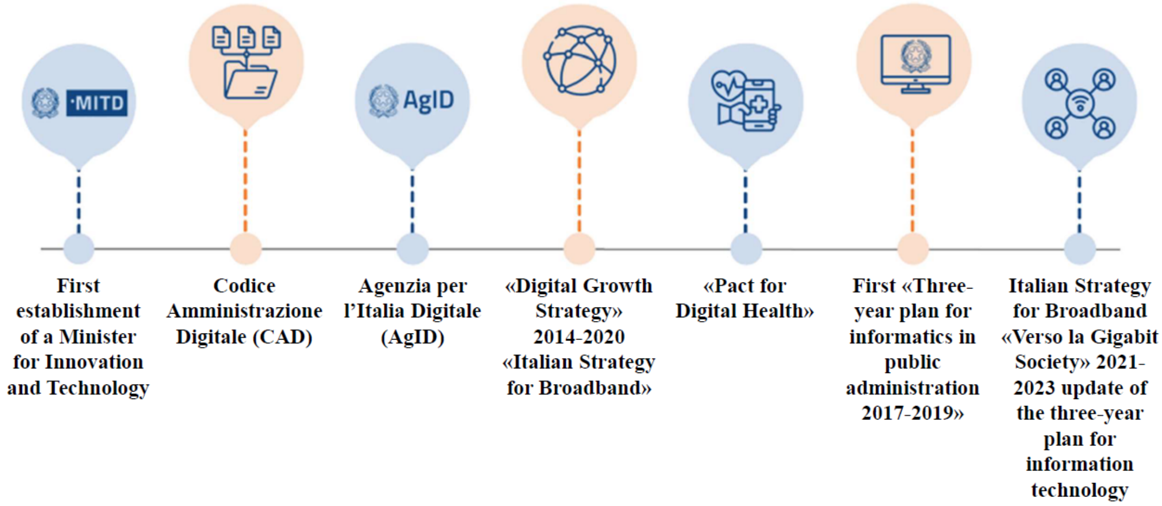


Figure 3.4: Main stages of Italian digitization. *Source: The European House - Ambrosetti on different sources, 2022*

ensure better understanding and acceptance of such methods.
To promote the widespread adoption of Telemedicine, it is essential to build trust in the new services and promote acceptance by healthcare professionals and patients. This involves two fundamental aspects: information and training [9].

- Information for Patients: Every healthcare act involving Telemedicine must respect standard rights and obligations, but also consider specific obligations, including patient information. It is important to inform patients about the opportunities and scope of Telemedicine services, the means used and data management, in compliance with current regulations. Furthermore, the increasingly widespread dissemination of such services raises new ethical issues regarding the relationship between patients and physicians. It is necessary to define these relationships to meet patients' needs, ensuring understandable, correct and reassuring information.

- Information for Physicians and other healthcare providers: Many physicians still have doubts about the impact of Telemedicine on their relationship with patients. It is important to provide them with more information on how Telemedicine can simplify and improve healthcare procedures, especially in monitoring chronic conditions and improving patients' quality of life.

- Patient Training and Empowerment: Despite efforts to make Telemedicine tools more accessible, patients often require training, especially if elderly or unfamiliar with new technologies. Training should focus not only on technological aspects but also on social and relational dynamics, the change in the physician-patient relationship and ensuring that, despite the distance, the patient will still receive care and assistance.

- Training and Updating of Healthcare Professionals: It is crucial to provide comprehensive training and regular updates to healthcare professionals to ensure they are ready for the correct and efficient use of Telemedicine technologies. This includes training on the use of new equipment and technologies, as well as the psychological approach necessary to maintain an empathetic relationship even at a distance.

- Training of other professionals and new professional profiles: In Telemedicine centers, it is crucial to also train technological and organizational professionals involved in service delivery. Training programs should be designed for them as well, considering the key role they play in Telemedicine.

Integration of Telemedicine into the SSN

In Italy, Legislative Decree No. 502 of December 30, 1992, *"Reorganization of the Health Discipline"*, together with its subsequent amendments and integrations, regulates within the *title II "services"* the methods by which structures providing health and social-health services enter the system. It particularly regulates the four distinct procedures provided:

- Authorization for the establishment of health and social-health structures
- Authorization to carry out health and social-health activities
- Institutional accreditation
- Contractual agreements

The issuance of authorization to operate is an essential requirement for anyone wishing to carry out healthcare activities, both in a private and public regime, and is subject to the possession of minimum requirements defined at the national level.

On the other hand, accreditation criteria, necessary to allow structures to provide healthcare services with public funding, are established by individual regions, in compliance with fundamental principles and essential levels defined by national legislation.

To provide services within the SSN framework, it is also necessary for the Region or the Azienda Sanitaria Locale (ASL) to enter into a contractual agreement with the providing structure, whether public or private.

The integration of Telemedicine into the SSN includes criteria for authorizing and accrediting Service Provider Centers for the provision of Telemedicine services, both in the private sector and within the SSN framework, as well as contractual agreements with the Servizio Sanitario Regionale (SSR).

Telemedicine is not considered a separate medical discipline but rather a tool that allows extending traditional medical practices beyond conventional physical boundaries. Framed within general regulations, Telemedicine is considered an alternative mode of delivering healthcare and social-health services and therefore follows current regulations with specific directives on implementation.

In the outlined regulatory framework, the concerned structures must meet certain requirements to provide Telemedicine services with public funding. These requirements include regional accreditation for the involved specialty disciplines and compliance with regional documents and standards related to Telemedicine. Additionally, it may be necessary to enter into specific contractual agreements with the Regions or ASLs to provide Telemedicine services.

Regarding accreditation procedures for Telemedicine, healthcare facilities also include medical practices, outpatient clinics and other forms of aggregation of GPs and Pediatricians in agreement with ASLs, as they may be involved in the provision of Telemedicine services.

Ethical aspects, personal data treatment and professional responsibility

These are crucial issues that must be addressed to ensure ethics, safety and responsibility in the use of Telemedicine. The latter raises significant ethical issues, as its nature directly impacts the interaction between physician and patient, influencing how citizens perceive healthcare and the protection of their dignity. It is essential to ensure that, despite the change in communication dynamics, the trust relationship between physician and patient can develop even in this new context. This requires a commitment to providing detailed information to the patient, going beyond informed consent and ensuring that questions and answers are understandable.

Furthermore, interesting perspectives emerge regarding the *"ethical certification"* of the quality and professionalism of physicians and care facilities, especially in the field of Telemedicine, to ensure maximum reliability for patients using such distance services.

In the context of personal and clinical data treatment through electronic tools, it is essential to comply with current regulations to ensure the confidentiality and security of information. This includes providing clear and consistent information to patients, obtaining their informed consent transparently and ensuring their rights to their personal data. It is also crucial to analyze and design healthcare processes to define responsibilities, tasks and functions in compliance with regulations and ensure data

availability only to authorized parties.
Cross-border Telemedicine, involving services performed by healthcare professionals and patients in different countries, falls within the objectives of numerous EU-related instruments. The European Commission, while recognizing the responsibility of Member States to ensure the spread of Telemedicine solutions, intends to provide clarity on how EU legislation can influence this sector, supporting national administrations and stakeholders involved.

3.9 Challenges

The rapid evolution of digital healthcare has introduced a new paradigm in healthcare delivery, with Telemedicine emerging as a transformative force. This mode of providing care leverages digital technologies to facilitate remote consultations, diagnostics and monitoring, promoting easier and more convenient access to healthcare services [10]. However, it is important to highlight that this transition presents significant challenges:

- **Digital divide and Accessibility:** despite technological advancements, a clear division in access to devices and reliable Internet connections persists, resulting in a digital divide among the population. This poses a significant challenge as populations with limited technological resources risk being excluded from the benefits of Telemedicine, exacerbating existing healthcare disparities.

- **Technological barriers and Health literacy:** the effective use of Telemedicine requires a certain level of technological proficiency and understanding of healthcare concepts. Some individuals, especially the elderly or those with limited exposure to digital tools, may encounter difficulties in interacting with Telemedicine platforms. Ensuring an intuitive user interface and providing adequate support is fundamental.

- **Regulatory and licensing issues:** Telemedicine services often face regulatory challenges related to licensing, reimbursement and cross-border healthcare delivery. Navigating complex regulatory frameworks and ensuring compliance with healthcare regulations in different jurisdictions is a significant obstacle to seamless Telemedicine implementation on a global scale.

- **Data Security and Privacy:** the remote nature of Telemedicine raises important concerns about the security and privacy of health data. Safeguarding sensitive patient information from cyber threats and ensuring compliance with data protection regulations, such as GDPR in Europe, are critical aspects.

- **Integration with existing Healthcare Systems:** many healthcare systems operate on legacy infrastructures and seamlessly integrating Telemedicine into these systems can be a complex task. Ensuring interoperability between EHRs and other healthcare IT systems is essential for a cohesive and efficient Telemedicine experience.

- **Resistance to change within Healthcare Culture:** the traditional healthcare culture may resist the adoption of Telemedicine alongside established practices, due to perceived disruption and replacement of these practices with new and innovative tools. Convincing healthcare professionals, institutions and patients to embrace Telemedicine requires a cultural shift and effective change management strategies.

- **Quality of Care and Diagnostic challenges:** Despite the valuable contribution of remote consultations, certain medical evaluations and diagnostic procedures may be challenging to perform remotely. The primary goal remains ensuring high standards of care and obtaining accurate diagnoses through virtual means, a concern that persists especially in certain medical specialties.

To address these challenges, various initiatives have been undertaken. For example, to overcome the disparity in access to digital technology, the promotion of subsidized devices, the expansion of connectivity infrastructure in underserved areas and the dissemination of digital literacy programs are advocated. Policymakers play a crucial role in facilitating the widespread adoption of Telemedicine through strategic regulatory reforms, including simplifying licensing procedures for Telemedicine professionals, updating reimbursement policies and establishing clear guidelines for cross-border Telemedicine services. On the other hand, to address concerns regarding data security and privacy, Telemedicine platforms must implement robust cybersecurity measures, such as end-to-end encryption, secure data storage and compliance with sector-specific data protection regulations, thereby building trust with users through transparent privacy policies.

For all this to be possible, it is essential for healthcare systems and providers to invest in the necessary infrastructure to support Telemedicine initiatives, through the updating of IT systems, the adoption of optimized EHRs and adequate training of healthcare personnel on Telemedicine technologies.

Furthermore, promoting a cultural change within the healthcare sector, which involves educating professionals about the positive impacts on patient outcomes and resource efficiency, is necessary.

Continuous research and development efforts are crucial for the advancement of telemedicine technology, including exploring new applications of emerging technologies, refining diagnostic tools and enhancing the user experience. Collaboration between technology developers, healthcare providers and researchers plays a fundamental role in driving innovation in the field of telemedicine.

4. ICT in the Digitalization of Healthcare Processes

Telemedicine services rely on the use of technological tools that facilitate communication among the various figures and structures involved. Therefore, it is essential to have robust ICT infrastructure to successfully implement Telemedicine services in the healthcare sector. The term Information and Communication Technology encompasses all technologies and methods that enable the transmission, reception, and processing of information, crucial for providing efficient and high-quality healthcare services.
Such applications require strong support from information systems that traverse all organizational levels of the healthcare sector, both at the managerial and operational levels. To address the challenges posed by population aging and the increase in chronic diseases, it is necessary to adopt new communication and healthcare welfare management systems. It is projected that by 2025, healthcare expenditure within the SSN will reach 11% of the national Gross Domestic Product (GDP), due to the aging population and the growing complexity of care pathways. [11]
The adoption of ICT technologies is essential to contain costs and ensure equitable access to care for the entire population. In Italy, there is a growing awareness of the role played by technologies, as the SSN is called upon to meet citizens' demands for quality and efficiency while simultaneously reversing the trend of healthcare expenditure growth. The implementation of ICT technologies leads to a restructuring of organizational processes, both at the decision-making level, enabling better resource allocation and cost reduction and at the operational level, improving personnel management and service quality. Additionally, it facilitates complete control of the patient care pathway and promotes an organizational culture oriented towards skills development to facilitate its dissemination.

4.1 Definition

The concept of ICT in the healthcare sector encompasses a broad array of technological tools and services aimed at prevention, diagnosis, treatment, monitoring and disease

management, as well as patient empowerment.
Commonly, the use of such technologies is referred to as e-Health, which encompasses all computer and telecommunication solutions applied in the healthcare sector.
According to the European Commission's 2004 definition, e-Health involves the application of ICT technologies involving various actors, including physicians, nurses, healthcare professionals, managers and patients. E-Health technologies can be categorized into three main categories:

- Tools for data management, transmission and storage
- Technologies for using data in the provision of healthcare services
- Technologies for remote assistance

These e-Health tools and solutions not only assist administrators and healthcare professionals in developing more efficient and accessible systems for prevention and care but also contribute to cost reduction, improved productivity and timely intervention.
The integration of these technologies requires organizational changes, a culture oriented towards digitalization and the development of new skills.
The adoption of ICT applications leads to a reduction in waiting lists, hospitalization days and medical errors, in addition to enabling faster and more accurate diagnoses. This translates into significant savings for the SSN and an overall improvement in efficiency and quality of care.
ICT tools represent a paradigm of innovation that integrates various disciplines, including computer science, medicine, statistics and business economics, facilitating the connection between new technologies and clinical and administrative healthcare processes.

4.2 Artificial Intelligence and Big Data

ICT technologies encompass devices that integrate Artificial Intelligence (AI) algorithms.
"AI can utilize sophisticated algorithms to *"learn"* features from a large volume of healthcare data and then use the insights gained to assist clinical practice. It can also be endowed with learning and self-correction capabilities to enhance accuracy based on feedback. An artificial intelligence system can aid physicians by providing up-to-date medical information from journals, textbooks and clinical practices to adequately inform the patient." [12]
These devices enable the acquisition and storage of data, facilitating the creation of

a comprehensive patient history. This promotes better communication and collaboration among healthcare providers and, consequently, more efficient practice and better patient care.
Data detection and collection are performed automatically through sensors, eliminating the need for manual input by healthcare workers. This allows for the efficient collection of a vast amount of data that can be processed and analyzed to support clinical practice and medical research.
These devices, equipped with AI algorithms, must be characterized by a rapid data collection system, memory for long-term storage, the ability to interact with the environment and other hospital tools, as well as integration with existing health information systems. Such integration maximizes benefits, supporting decisions and processes throughout the healthcare organization.
One of the main challenges encountered in hospital facilities concerns the management of data in digital form in most structures in Italy. This problem persists especially in southern Italy, where many facilities still operate in paper form through manual data entry, increasing the risk of errors in information digitization and the possibility of crucial information omissions, posing a risk of losing important data.

4.3 Health Information Systems

For digitalization to truly transform the organizational landscape of healthcare, it is essential that every facility has a homogeneous internal information system. Data management forms the basis of healthcare performance and organization, but handling large quantities of data, especially in sizable facilities, can be a daunting task. To improve both performance and organizational processes, more effective data management is essential, encompassing both storage and monitoring.
Interoperability of ICT systems is therefore essential, meaning that different systems must be able to communicate with each other and exchange data. Various actors are involved in the healthcare sector, including administrations, companies, enterprises, professionals and operators. Interoperability of ICT systems enables the exchange of data in different formats, facilitating electronic transmission of accounting data. This process leads to the dematerialization of paper-based information, reducing the risk of loss or difficulty in accessing information. However, the adoption of common standards in healthcare facilities could further improve the quality, accuracy, completeness and timeliness of data, transforming them into statistical resources of greater value and reliability.
In Italy, the lack of standards in information infrastructure is evident, with each hospital adopting a different information system. This leads to difficulties in communication

and information transfer between different facilities and within the same facilities. Device integration entails high costs, as it requires adapting and connecting devices in different ways to enable direct internal communication and necessitates a review of the entire structure.
Creating an electronic record that traverses horizontally across all information systems is a solution to obtain information in a single format accessible to all departments. This demonstrates how the electronic record is a prerequisite for integrating Telemedicine services.
To ensure effective integration of innovation in healthcare, cultural barriers must be addressed. Organizational inertia and resistance to change often hinder the diffusion of new technologies. It is crucial to develop soft skills, increase awareness of the potential of technologies and provide training to enable greater autonomy and responsibility in decision-making. Additionally, it is essential for decision-makers to recognize the benefits of digital solutions and disseminate this knowledge within the organization, breaking down old routines. The spread of digital skills is crucial to successfully integrate digital solutions into organizational processes.

4.4 Organizational Culture

For a revolution in organizational processes to occur, a cultural shift that fosters and guides change is essential. Often, despite the existence of technology, there is resistance to change due to fear of stepping out of the comfort zone and viewing technology as a threat to individual positions rather than as an opportunity. Consequently, despite efforts to adopt technology, it encounters obstacles in diffusion.
A cultural change is therefore necessary to promote the development of soft skills, enabling greater awareness of the problems and potential offered by technologies. This involves increased personal training and greater autonomy and responsibility in decision-making. The development of such skills is essential and includes:

- Understanding the impact of new technologies on healthcare processes
- Understanding the value generated by new technologies in healthcare processes
- Change management through training courses on new digital solutions
- Assuming greater decision-making autonomy based on data

Another barrier is the availability of financial resources: substantial investments are required to integrate innovation into the healthcare sector, as it is necessary to readapt and integrate the entire healthcare organization with the innovation. This process not

only entails obstacles in reorganizing processes but also resistance from the staff involved. Innovation also requires the introduction of new skills and a new commitment from decision-makers, who must be able to recognize the benefits and savings that could result from the integration of digital solutions and disseminate them within the organization, overcoming entrenched organizational routines.
It is therefore essential to promote the dissemination of digital skills, especially among managerial profiles in the healthcare sector and then extend and integrate them into lower operational levels. In summary, the main obstacles encountered in the introduc-

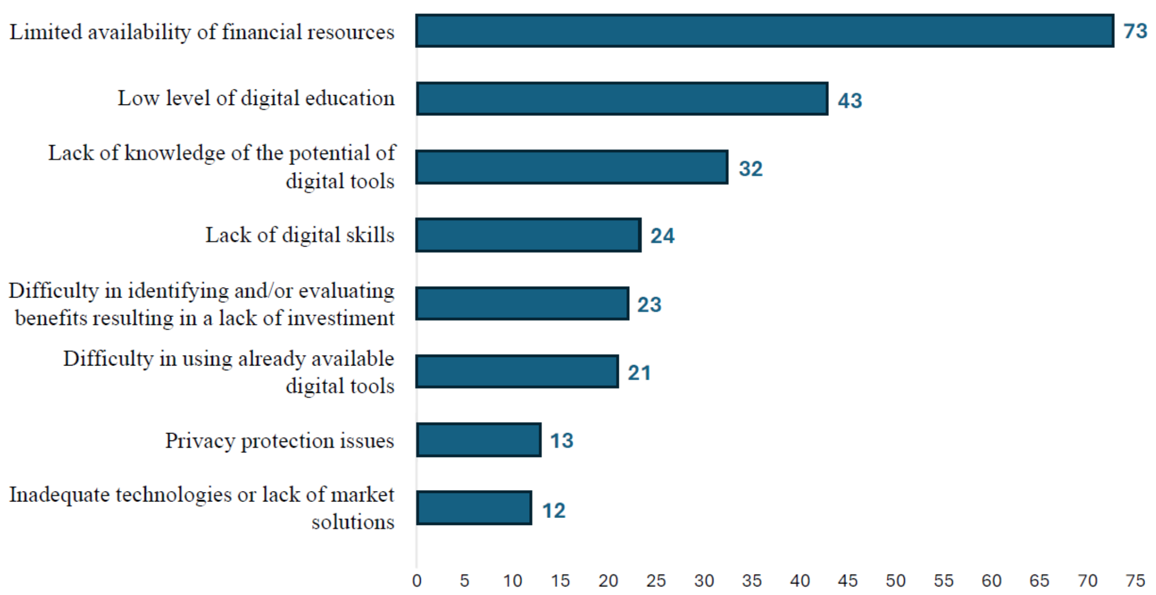


Figure 4.1: Barriers to digitization

tion of such new technologies, shown in ***Figure 4.1***, are [11]:

- Limited availability of financial resources
- Low level of digital education
- Lack of knowledge of the potential of digital tools
- Lack of digital skills
- Difficulty in identifying and/or evaluating benefits resulting in a lack of investment
- Difficulty in using already available digital tools
- Privacy protection issues
- Inadequate technologies or lack of market solutions

4.5 Digitalization in Italy: State of Art

In 2017, the Digital Innovation Observatory in Healthcare of the School of Management at Politecnico di Milano calculated a total expenditure of approximately EUR 1.3 billion for the digitalization of the Italian healthcare system. This figure represents about 1.1% of the total public healthcare expenditure, equivalent to around EUR 21 per inhabitant, marking a 2% increase compared to the previous year. This expenditure on digital healthcare was distributed among various actors within the SSN as follows [11]:

- EUR 890 million accounted for by healthcare facilities
- EUR 320 million directly spent by the Regions
- EUR 72.9 million spent by over 47,000 GPs
- EUR 16.7 million allocated for ICT expenditure by the Ministero della Salute

The investment efforts of past years in the healthcare sector have been accompanied by various plans aimed at guiding the sector towards digitalization. The objective has been to improve the organization of processes and healthcare services, optimize data management and utilize available resources more efficiently. The *"Patto per la Sanitá Digitale"* of 2016 emerged as a response to the growing awareness of the need to improve the quality of healthcare services and make healthcare systems more efficient. The priorities of this Pact include the widespread adoption of the Electronic Health Record (EHR), the adoption of solutions and services to ensure continuity of care between hospital and community settings, the development of Telemedicine to address chronic diseases requiring continuous monitoring and the promotion of solutions enabling interoperability of digital services. These actions focus on integrating the necessary networks among all professional figures involved in healthcare delivery, as well as making regional healthcare systems interoperable to facilitate communication between them.

Among all action plans, the EHR is widely adopted in Italy as it represents the key infrastructure enabling digitalization. Thanks to this, it is possible to manage a vast amount of patient data, essential for providing Telemedicine services. The EHR must be designed to ensure interoperability among different regions, facilitating data exchange between healthcare facilities in different regions and facilitating patient access to services. Currently, the situation sees each region managing its own system without national standardization. Only with the creation of interoperable EHRs will it be possible to overcome this fragmentation. In Italy, only 11 regions have adopted EHR

interoperability, highlighting a significant gap between the regions of Central-Northern and Southern Italy, with the exception of Puglia.
Compared to other nations, Italy is still lagging behind, both due to limited funding and the presence of inefficient healthcare structures and a lack of readiness to address digitalization. There is a clear lack of development of innovation-oriented skills. The spread of digital innovation should be preceded by a review of processes in healthcare companies to identify key issues and their impact on performance. This would allow for the automation of healthcare organizational processes, saving costs and improving service efficiency through incremental innovations.

4.6 Integrated Home Care

In recent years, many European countries have been facing significant challenges in the healthcare sector, such as the increasing prevalence of disabilities and chronic diseases, an aging population and a shortage of hospital beds. To address these challenges, the importance of decentralizing healthcare is increasingly being recognized as a shift from hospital-based to home-based care to reduce hospitalization costs and improve access to care. In this context, Integrated Home Care (IHC) emerges as a viable alternative

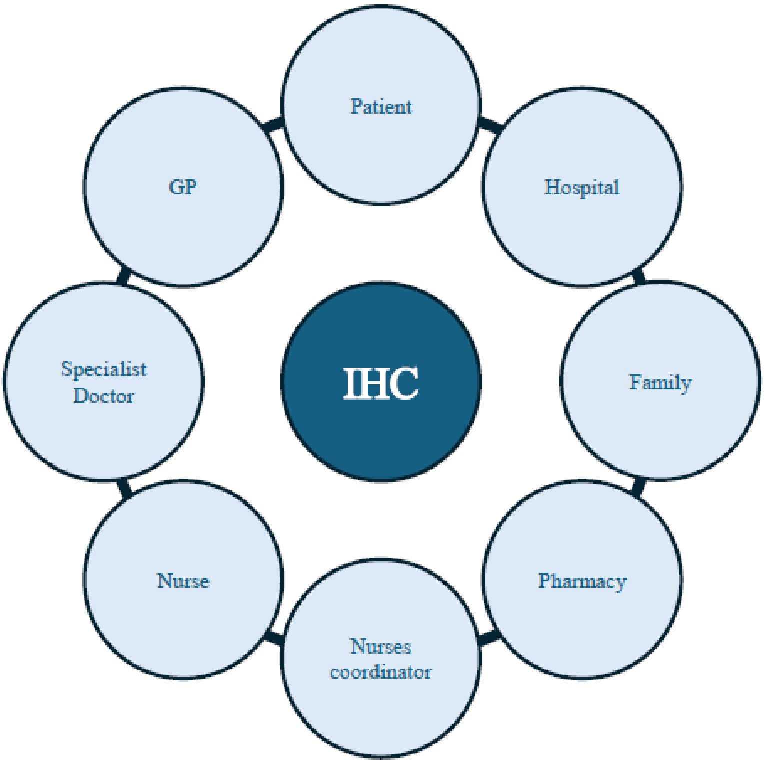


Figure 4.2: IHC actors

to provide healthcare and social assistance directly at the patient's home. However, despite the research efforts made in this field, the complexity of the sector requires further investigation.

As shown in ***Figure 4.2***, the network of actors involved in IHC includes decision-makers such as hospitals and general practitioners, organizers responsible for materials and medications, as well as actors directly involved in providing home care, such as nurses and those who follow up with the patient daily, such as family members and caregivers [13]. Most of the patients assisted in this context are elderly individuals over 65 years old affected by chronic diseases or disabilities and hospitalization often becomes impractical and extremely costly for the SSN. Therefore, decentralizing care by transferring it directly to the patient's home becomes a necessity.

IHC allows patients to receive a wide range of services in their familiar environment, which can be preventive, acute, rehabilitative or palliative. These services include healthcare and social assistance for non-self-sufficient elderly individuals, post-hospitalization patients, individuals with disabilities or chronic diseases. It is thus configured as a care pathway involving primary care, hospital services and social services, executed by a multidisciplinary team at the patient's home. However, currently, there is a lack of uniform definition and a standard model of home care, with services offered varying from country to country and even within the same country. This lack of precision and variety in approaches has contributed to low levels of coordination and integration, especially in countries like Italy.

ICT tools present themselves as a solution to these problems in the context of IHC, capable of improving efficiency, quality and service integration. However, the real issue is not the lack of ICT but rather how to best leverage them in the context of IHC. Therefore, it is essential for the operators of this field to fully understand the IHC process before developing and implementing ICT solutions.

In the field of IHC, integrating healthcare processes and adopting ICT-based solutions represent a fundamental area of research and development. However, to effectively address the complexity of a multidisciplinary and multidimensional process like IHC, it is necessary to adopt a Business Process Modeling approach that highlights interactions and promotes coordination among the various actors involved, thus providing a solid foundation for the development of ICT solutions integrated into the IHC sector [13].

Currently, coordination in IHC presents challenges related to extracting information from heterogeneous sources, often paper-based. Communication occurs through documents such as requests for home care, therapeutic plans and medical records, which are shared among different professionals and locations, such as hospitals, medical offices and patients' homes. This communication takes place asynchronously, with documents dispersed among various individuals and locations.

The use of ICT technologies can improve this communication, allowing more efficient access to care and facilitating optimal follow-up. ICT also allows for the integration of logistical and clinical processes in IHC, combining patient demographic and clinical information with administrative and accounting systems to track resources and manage materials and supplies.

In Italy, a significant number of patients, especially the elderly, receive home care, with a considerable portion affected by chronic skin wounds. These wounds affect a large portion of the population and represent a significant cost for the SSN, both in direct terms and in terms of days of work lost by patients and their families providing home care.

The Wound Care sector is a challenging field with significant costs from both a healthcare and an assistance perspective. These types of wounds, which can be treated at the patient's home as part of a planned care pathway, mainly include pressure ulcers, vascular lesions and diabetic foot ulcers.

While vascular lesions and diabetic foot ulcers have defined hospital care pathways and specialized reference centers, pressure ulcer management remains a less defined area, involving a wide range of professionals without a clear intervention protocol.

These lesions are common and cause pain, disability and a significant reduction in the quality of life for patients, requiring considerable human and material resources for management.

In Italy, the prevalence of patients with pressure ulcers is high, both in hospitals and among home care patients, with percentages ranging from 8% to 13.2% in hospitals and up to 20%-66% in intensive care units [14]. Prevention is crucial, with regular patient mobilization and personalized rehabilitation plans aimed at maintaining or improving mobility.

To improve the management of patients with chronic wounds, it is essential to create integrated care pathways between hospital facilities and the community, involving a wide range of professionals such as general practitioners, specialists, home care nurses, physiotherapists and podiatrists. The activation of home care services occurs at the request of the general practitioner, with an intervention plan defined based on the patient's needs.

However, there are limitations in the current system, including contractual constraints affecting the delivery of care and the use of medical devices (MDs). Telemedicine and the use of ICT technologies represent a potential solution, allowing for immediate communication and better patient involvement in their own care plan.

5. Wound Viewer

Elderly individuals requiring Integrated Home Care often face significant challenges, especially when it comes to managing skin ulcers. One of the main difficulties is the complexity in coordinating wound care and IHC. Currently, the most pressing issue concerns the optimal management of patients with skin ulcers requiring constant monitoring and treatment. This difficulty directly impacts the well-being of patients, as delayed wound healing increases the risk of serious complications such as limb amputation or even death.

To address this challenge, the start-up Omnidermal Biomedics was established in 2017 by a research group for the development of medical devices based on Artificial Intelligence formed at the Politecnico di Torino, in Turin. The aim was to improve and simplify the management of skin lesions. This condition affects a wide range of the elderly population, with 2 million cases in Italy, 10 million in Europe and 80 million worldwide [11]. Considering the aging population and the constant increase in the percentage of elderly individuals, it is expected that the number of cases will continue to rise over time. For example, the percentage of the population aged over 65 is steadily increasing, reaching projections of up to 34.5% of the entire population by 2050 [15]. The start-up has developed an innovative device called Wound Viewer, which inte-

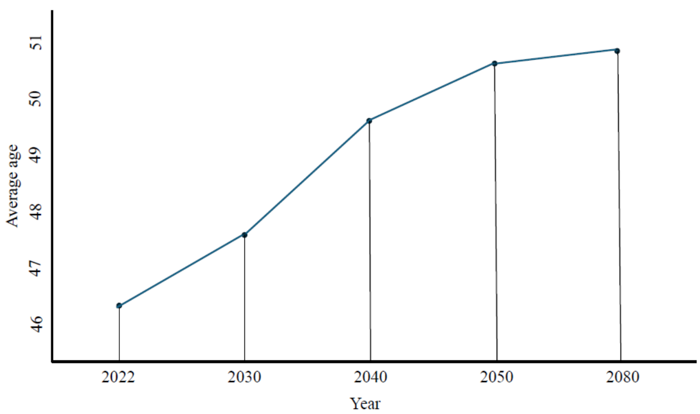


Figure 5.1: Forecast of the average age of the population in Italy: *source ISTAT*

grates an AI algorithm to assist healthcare personnel in the diagnosis, monitoring and management of skin ulcers. This tool not only helps collect and manage patient in-

formation but also optimizes healthcare service organization. Omnidermal's main goal is to improve the interaction between the doctor and the patient, making the doctor's work more efficient and the patient's healing process more comfortable.
Currently, the methods used during medical visits for assessing and monitoring the wound are often rudimentary, invasive and painful for the patient.
Moreover, the limited accuracy of such instruments results in a high rate of diagnostic errors, leading to incorrect medication prescriptions and prolonged healing times. This delay can lead to serious consequences, such as limb amputation or even the patient's death.

5.1 Technical Features

The Wound Viewer (WV) is the first technology developed by Omnidermal Biomedics and it is a class IIa medical device certified under the European MDR regulation that came into effect on May 25, 2017. It is a device intended for use by healthcare professionals, enabling a comprehensive and automatic assessment of the evolution of skin wounds in a few seconds.
The device is equipped with 16 depth infrared (IR) sensors and a CMOS camera through which raw photos are acquired with the support of 4 white LEDs. After the acquisition and saving of the lesion photograph, the skin ulcer analysis algorithm, implemented within the device, applies a Discrete Time Cellular Nonlinear Network (DT-CNN) computing architecture to identify the wound within the acquisition and provide relevant measurements of it.
In this way, the device can automatically return to the user all the essential clinical parameters necessary to evaluate and monitor the pathological status of the lesion: from tissue segmentation and classification of the skin ulcer to the area, volume and depth of the wound, based on the international Wound Bed Preparation Score (WBP) protocol. The WBP Score, shown in ***Table 5.2*** allows for the classification of the skin ulcer based on the composition of the wound bed tissue and its exudate, providing an objective assessment of the current status of the lesion [16].
In addition to the WBP Score, the device also allows for wound classification using the TIME and TEXAS scales.

- *TIME Scale:* Developed to facilitate the wound bed preparation essential for the healing of skin ulcers, it involves controlling exudate and edema, reducing bacterial load, promoting healthy granulation tissue and removing necrotic tissue. Wound classification is based on the type of tissue composing the wound bed at the time of the visit, the degree of infection assigned by the operator, the amount

Class	Description
A	The wound is composed of 100% granulation tissue
B	The wound consists of more than 50% but less than 100% granulation tissue. Neither eschar nor necrotic tissue is present.
C	The wound is composed of less than 50% granulation tissue. Neither eschar nor necrotic tissue is present.
D	Presence of eschar or necrotic tissue.

Figure 5.2: WBP Score

of exudate emitted by the wound and the wound edge.

- *TEXAS Scale:* Applicable only to wounds with a "Diabetic Foot" etiology, it classifies wounds based on two parameters: Grade and Stage.

After the examination and any dressing, the data acquired through the medical device and those manually entered by the user are automatically saved in an organized manner in the patient's clinical folder, where it is possible to additionally view through graphs the trend over time of the patient's disease status under treatment. Through the collection of patient's clinical data, the Wound Viewer system ensures uniformity and standardization of data, especially in the wound evaluation phase.

Furthermore, technology integrated with internal information systems allows clinical operators and nurses to obtain a comprehensive, objective, standardized and automatic assessment of the fundamental clinical parameters of the skin ulcer in a few seconds, shortening the wound measurement time and making the results independent of possible interpretation by the clinical operator. In addition to reducing the visit time, digital and automatic wound measurement overcomes the limitations of traditional manual measurement, which is performed using tools that can cause discomfort or even pain to patients with injured skin. Moreover, since wounds often present irregular shapes, they cannot be accurately measured through analog measurement, leading to measurement errors that can exceed 30% [17], as shown in ***Figure 5.3***. Performing digital acquisitions, on the other hand, yields more precise results that are transferred directly into the patient's clinical folder, avoiding potential data loss in manual transcription and enabling continuous and comparative follow-up of the healing evolution of the skin ulcer, alerting operators to the risk of clinical complications.

Saving data on a cloud platform allows for easier sharing of health data and greater cooperation among operators, improving their daily activities, the quality of patient visits and ensuring a reduction in costs for home care.

Thanks to the Wound Viewer, diagnostic accuracy of up to 94% can be achieved, with specific results including [11]:

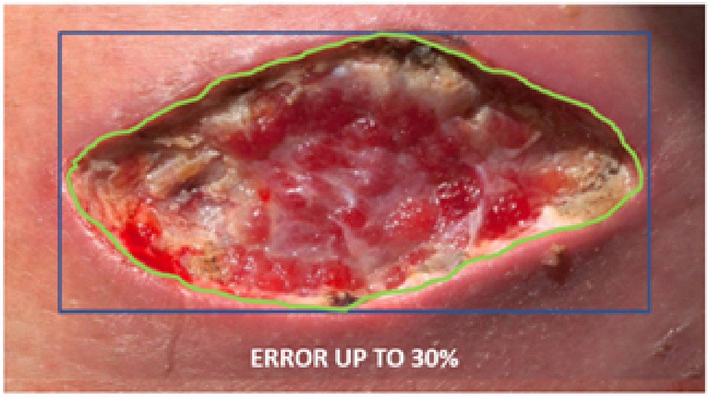


Figure 5.3: Traditional measurement vs Automatic measurement with WV

- 94% precision in calculating wound area, detecting variations up to 0.2 cm^2
- 99% precision in calculating wound granulation
- 94% precision in calculating wound depth, detecting variations up to 1 mm

The device consists of both hardware and software components, together offering significant advantages in distinct processes:

- *Clinical Process:* The Wound Viewer captures images of skin ulcers through appropriately designed sensors. Subsequently, using an AI algorithm, it compares patient clinical data with an extensive database, analyzing wound morphological parameters stored in a cloud platform. The device provides crucial information to the physician such as area, depth, type of ulcer tissue, and detection of any infections. This approach enables more accurate diagnoses, reducing diagnostic errors by up to 40%. Moreover, thanks to the Wound Viewer, specialists can avoid the use of invasive and rudimentary tools, reducing discomfort for patients and obtaining quantitative data rather than just qualitative. The use of the device significantly reduces visit times, from 20 to just 3 minutes, improving the productivity of medical and nursing staff and reducing waiting lists.

- *Management Process:* The Wound Viewer facilitates the collection and organization of clinical data for each patient, storing them in digital clinical folders. This allows for a complete tracking of the patient's care process, monitoring the frequency of visits, treatments administered and facilitating decision-making. Data collection complies with data protection laws such as HIPAA and GDPR, with highly encrypted data transfers and secure storage on AWS servers. In case of device loss, the application automatically logs out after a period of inactivity to ensure data security. Communication between the external camera and the mobile application occurs through a secure communication channel (HTTPS).

Digitizing clinical folders allows for quicker access to patient information, reducing the risk of misplacing paper documents and enabling precise monitoring of treatments and visits.

Hardware Component
The device, which can be likened to a tablet, consists of several key elements: a rear camera for capturing detailed images of chronic lesions, light sources arranged around the perimeter to illuminate the ulcer and detect any shadow areas caused by skin irregularities and a screen for displaying wound morphological parameters and accessing the patient's digital clinical folder. The Wound Viewer also offers the option to be connected to a remote control device, such as a smartphone, tablet, or PC, or it can be used autonomously, without the need for external connections.
Software Component
The software integrated into the Wound Viewer device is based on an algorithm called *"Cellular Automaton" (CA)*, a particular type of algorithm that manages the evolution of internal states of a set of elements, called cells, arranged on a regular grid with finite dimensions. This type of algorithm draws inspiration from various evolutionary phenomena observable in nature. By associating these cells with pixels of a digital image, circuits can be designed or algorithms implemented capable of processing images or recognizing them. The algorithm used by the WV analyzes the photograph of the wound, recognizing its three-dimensionality thanks to variations in shadows generated by its structure.

5.2 Telemedicine Platform

Data acquisition and storage have always posed significant challenges in healthcare. Today, more and more companies offer platforms capable of managing, storing and organizing data efficiently. So far, all patient information has been primarily stored in paper documents, accessible only to healthcare professionals responsible for patient care. The transition to digitization is not only crucial for the industry but also represents an essential step in ensuring accessible, protected, clear and consistent data that respect privacy and are characterized by standardized processes.
The software used by the Wound Viewer allows for the creation of a complete electronic medical record for each patient, including all relevant information about the patient, their injuries and the visits conducted. The data are securely stored and protected in the cloud, an online storage environment accessible remotely with different levels of authorization for doctors and specialists. Every piece of data saved on the device is synchronized and immediately available to authorized users, thus eliminating issues

related to loss or unexplained absence of documentation, which often cause delays in defining care plans and increase the risk of wound chronicity. Thanks to the presence

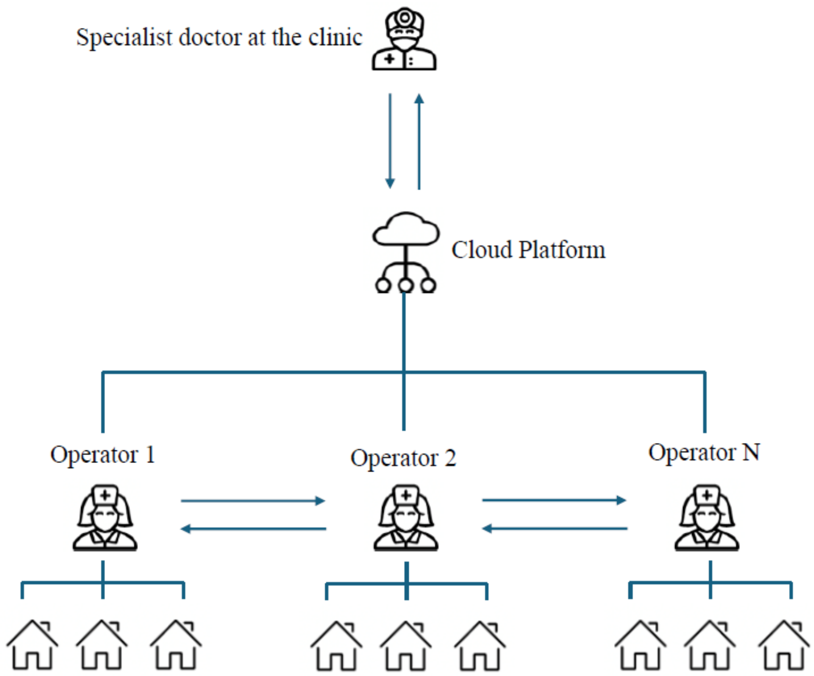


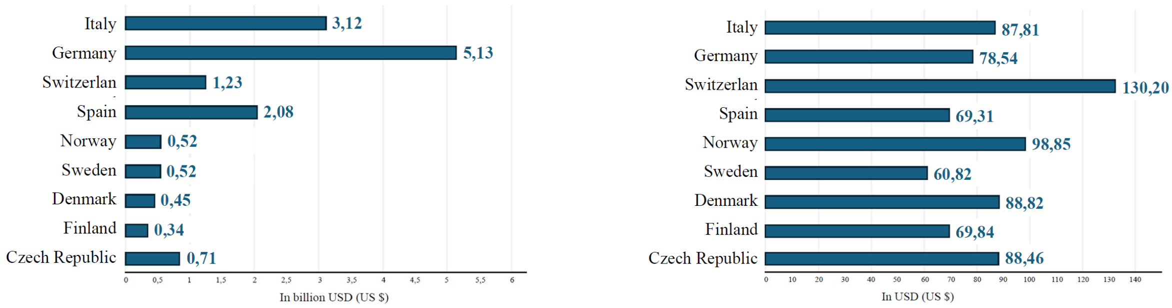
Figure 5.4: Home assistance

of an online data repository, it is possible to track the evolution of injuries over time: after each visit, the wound image is captured and stored, allowing professionals to assess the effectiveness of prescribed therapies and make any necessary adjustments in real-time.

The Wound Viewer has been designed to be used both in hospitals and in patients' homes or care facilities, resulting in significant savings in terms of hospital costs and working hours for wound care specialists, as shown in ***Figure 5.4***. A nurse can perform the examination directly at the patient's home and the data are transmitted in real-time to the doctor, enabling immediate exchange of information and feedback. This not only optimizes costs but also the time required to provide care, since the application of the Wound Viewer for home care enables constant communication between nurses and doctors.

5.3 Study on the Wound Viewer introduction in Italy and other European Countries

In the context of introducing a new technology for wound care such as the Wound Viewer at a national level, an analysis of the telemedical environment was conducted, focusing specifically on the wound treatment sector, in various European Countries including Switzerland, Germany, Spain, the Czech Republic, Norway, Finland, Sweden and Denmark, where Omnidermal Biomedics s.r.l. contacts were present. A preliminary research was conducted using the *Statista* platform regarding the size of the digital health market in Italy and the previously mentioned countries. The research results highlighted that the digital health market in Europe has been steadily growing since 2017, with a forecasted compound annual growth rate (CAGR) of 6.36% for the period 2024-2028, reaching a market volume of 46.36 billion dollars by 2028.



(a) Total revenue **(b)** Average revenue per user

Figure 5.5: Digital Health Market in 2023. *Source: STATISTA*

Moreover, in terms of specific market segments, the *"Digital Treatment & Care"* sector is estimated to be the largest in the current year, with a total revenue value of 15.84 billion dollars.

The data related to the digital health market for each analyzed countries are illustrated in ***Figure 5.5***, highlighting Germany as the leading Country in the development and adoption of health technologies, based on the per-user data shown in ***Subfigure 5.5b***.

The analysis conducted on the European digital health market has highlighted an environment that is extremely conducive to the adoption and investment in new technologies aimed at healthcare, with a growing awareness of the importance of technological innovation in managing and improving both individual and collective health. The increasing interest and financial and regulatory support thus outline solid foundations for the development and widespread adoption of innovative digital solutions in the healthcare sector.

Considering the application context of the Wound Viewer technology for managing patients with skin ulcers, the primary focus of the investigation was on nursing homes, where the majority of the affected population resides. This population mainly consists of individuals over 65 years of age, often suffering from pre-existing conditions and/or bedridden for extended periods.

For each country included in the analysis, as shown in ***Figure 5.6***, both the population over 65 residing in the territory and the amount of annual public expenditure dedicated to elderly care facilities were recorded.

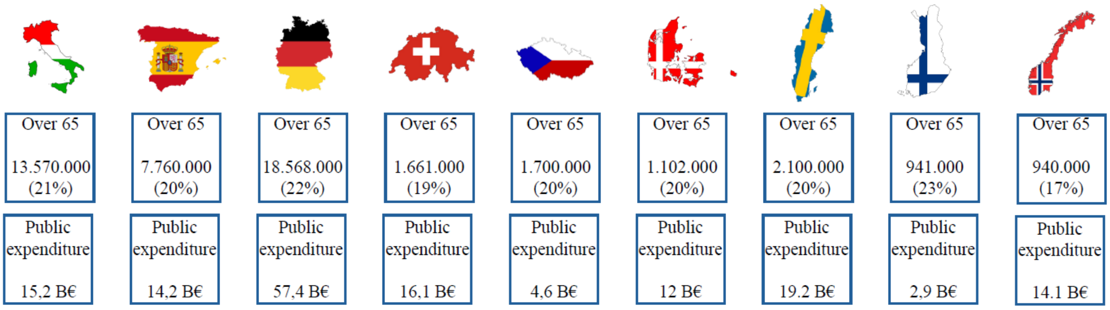


Figure 5.6: Public expenditure on nursing homes in 2023. *Source: STATISTA*

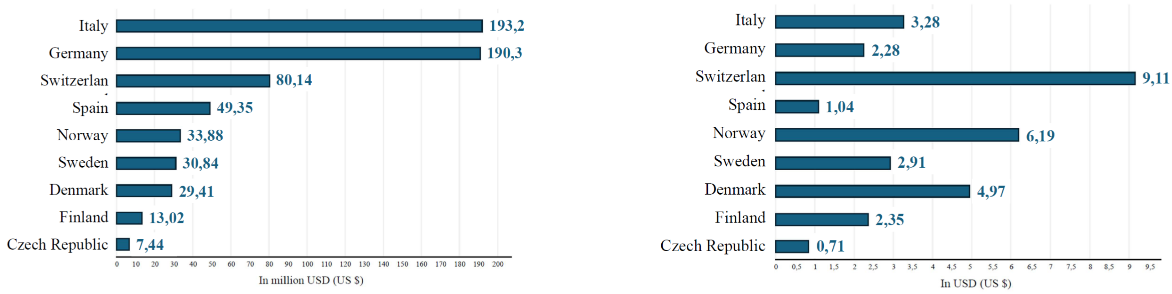
At a later stage, several nursing homes were contacted in all the considered Countries, conducting a survey on the incidence of skin ulcers in patients hosted within the facilities and on the adoption of innovative technologies for their management. This survey highlighted a significant incidence of this pathology among nursing home residents, accompanied by a shortage of healthcare providers able to provide necessary care and frequent complexity in managing the patient's clinical picture and coordinating with specialists in the field of wound care. From this, a marked interest in the implementation of telemedical solutions emerged, which allow for more efficient management and facilitate communication and collaboration with specialist physicians operating in the country's hospitals.

The data on the elderly population, the opinions gathered through contact with nursing homes, along with information on the annual expenditures dedicated to funding public nursing homes and the size of the digital health market in the analyzed Countries, outline a favorable context for the introduction of the Wound Viewer device in nursing homes. The adoption of such a device would facilitate communication among nurses who alternate daily in caring for patients within the facilities and with external experts to improve the accuracy in wound assessment and the formulation of treatment plans. As a telemedical device, this technology would be able to connect the entire territory, facilitating access to care and coordination between caregivers and doctors in a field such as wound care, which sees a significant number of new patients each year and a shortage of experts in their management.

5.3.1 Impact on National Wound Care Market

Finally, a study on the wound care market was conducted to assess the economic impact of introducing an innovative telemedical device, the Wound Viewer, at a national level for the evaluation and monitoring of skin ulcers. The introduction of this device was examined in European Countries where a significant market for digital healh

and chronic wound care has been identified, indicating a higher incidence of this issue and/or greater attention to this field of care compared to other countries.
The data collected on the total market size for wound care are illustrated in ***Subfigure 5.7a***, while ***Subfigure 5.7b*** shows the per capita investments for each Country analyzed. From these data, it emerges that Italy and Germany have the largest markets for wound care in terms of total expenditure. However, considering the population size and therefore the per capita expenditure, Switzerland, Norway and Denmark are the European countries, among those analyzed, with the highest per capita investment.



(a) Total revenue **(b)** Average revenue per capita

Figure 5.7: Wound Care Market in 2023. *Source: STATISTA*

To estimate the impact on care costs in the field of wound care resulting from the use of the Wound Viewer at a national level, data collected during a study conducted at the ASL Hospital in Asti, following the adoption of the device in 2018 as an evaluation and monitoring tool for patients with skin ulcers treated at the facility, were used [17]. On that occasion, 850 new patients with chronic wounds were registered over the course of a year and the care costs were compared between the year before and the year after the device's implementation. Thanks to the Wound Viewer and its ability to transmit the information amongst the operators directly into the patient's Electronic Medical Record (EMR), the wound care specialists were able to administer the most appropriate therapy for each patient according to their overall clinical condition. Additionally, it was possible to make general patient management operations more efficient, allowing healthcare providers to focus on those patients who required more attention and treatment, lowering the number of visits to the ones that were going through a correct healing process. From those logical actions taken by the hospital through the use of this device the total cure cost for the hospital was reduced by 9%, while the per patient cure cost reduced by 14% [17].
The percentage of cost reduction for wound care, recorded at the Asti Hospital between 2018 and 2019, was used to estimate the economic impact of introducing the Wound Viewer on a national level in Italy and other European countries. This analysis considered, for each Country, a 9% reduction in the total annual expenditure for wound care

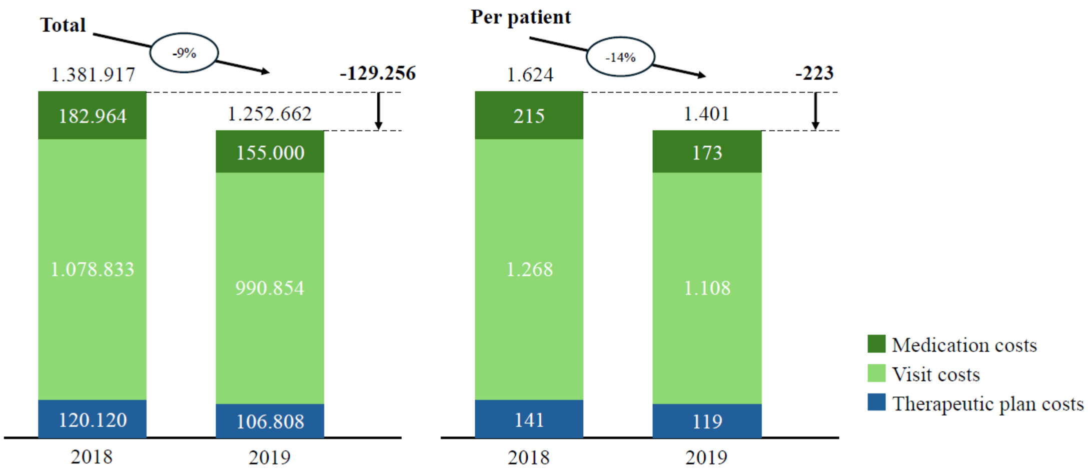


Figure 5.8: Reduction of cure cost for wound care for a patient population of 850 (total and per patient). The values reported in the Figure are in Euros. *Adapted from [17]*

that was recorded over the course of 2023, resulting in the outcomes shown in ***Figure 5.9***,

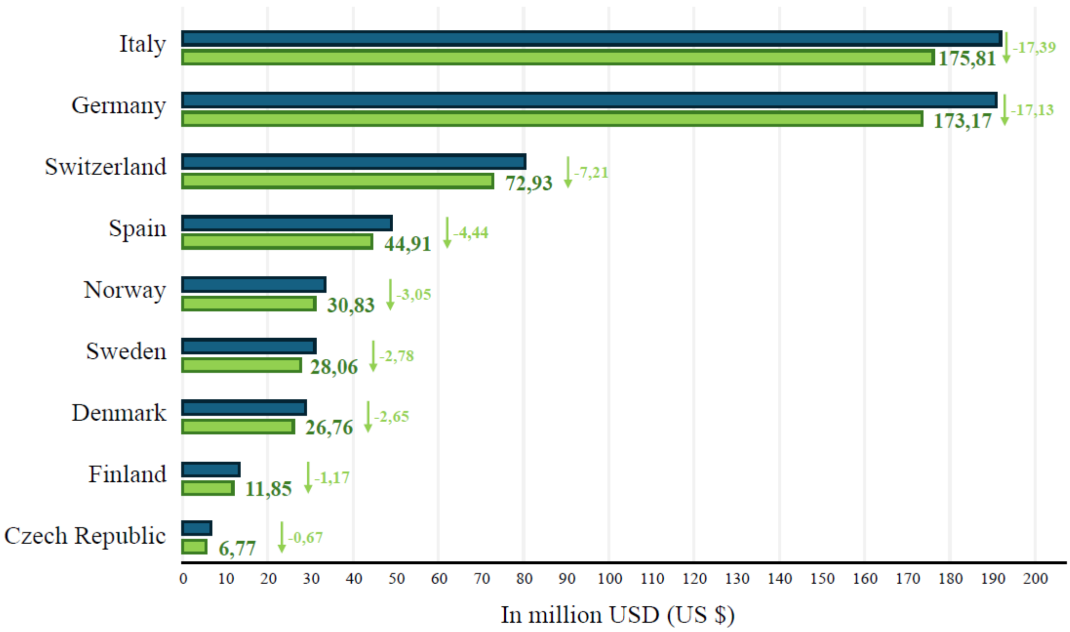


Figure 5.9: Estimated national cure cost for wound care reduction using telemedical procedures through the WV implementation

The hypothesis formulated regarding the potential nationwide introduction of the Wound Viewer has shown a significant reduction in the annual expenditure dedicated exclusively to wound care, amounting to millions of dollars. The Wound Viewer thus presents itself as a valuable telemedical tool for optimizing the management processes of patients with chronic wounds, with a significant impact on the wound care market. The calculations made represent an approximation of real costs and an estimate of

the impact of using a device like the Wound Viewer, based on an observational study conducted at the ASL Hospital in Asti, during which a reduction in the management and treatment costs of patients with such conditions was effectively recorded.
The nationwide adoption of the Wound Viewer could further enhance this positive impact by facilitating the exchange of information among healthcare providers across the country, improving the monitoring and definition of treatment plans, accelerating management processes and optimizing the use of expert medical personnel. All this inevitably leads to a significant reduction in wound care costs, as estimated numerically during the current study.

5.3.2 Denmark case

In the Danish context, the field of skin ulcers has traditionally been rooted in nursing and continues to represent the predominant practice. However, in recent decades, there has been a growing interest from physicians, particularly surgeons, leading to the development of specialized interdisciplinary centers for ulcer treatment. The establishment of such centers has contributed to increasing national attention on the prevention and treatment of skin ulcers, fostering awareness that risk factors should be assessed and that, in most cases, such injuries are preventable.
The first Scandinavian society dedicated to wound management, the *Danish Society for Wound Care*, was founded in 1992 by pioneers comprising both doctors and nurses. Since then, there has been a consistent focus on the topic, with the development of specialized interdisciplinary wound care centers in various Danish regions and the presence of nurses with specialized wound care skills in all hospitals in the country.
According to current national and local guidelines, patients at risk of developing pressure ulcers should be evaluated for their risk factors and, if necessary, provided with preventive aids. In the event of pressure ulcer occurrence, these should be treated with a moist environment and appropriate dressings to promote healing. More complex pressure ulcers will be referred to local surgeons or specialized interdisciplinary centers.
As an illustrative example of hospital organization in Denmark within the field of wounds, the organization of ulcer management in the Zealand region is presented. In this region, a central ulcer committee has been established, composed of specialist nurses, doctors and hospital administrators. This committee coordinates directives for the prevention and treatment of all ulcers in hospitalized patients in the region. Committee activities include the preparation of local directives, planning of staff training, monitoring the frequency of pressure ulcers, establishment of central contact networks and collaboration with primary care. In each hospital ward in the region, there is a

wound care expert nurse whose responsibilities include coordinating the ward, training new staff and ensuring the availability of necessary dressings. Two coordinating nurses work as an interface between the central committee and local specialized nurses, ensuring that all hospitals in the region adhere to the same standards and develop evidence-based knowledge, such as through e-learning programs.

All hospital care in Denmark for skin ulcers is publicly funded and in municipalities, nurses working in home care services and nursing homes are primarily those dealing with ulcers, collaborating with general practitioners or hospital specialists.

During the contacts established with the *Dansk Selskab for Sarheling (DSFS)* association in Denmark, the existence of a telemedical platform specifically dedicated to managing and acquiring data related to individuals affected by skin ulcers across the entire Danish territory emerged, called *'plaja.net'*. This solution appears particularly suitable for the introduction of a device such as the Wound Viewer, which would be capable of synergistically integrating with the existing platform in Denmark. This integration would facilitate the collection of necessary data for the continuous monitoring of patients suffering from skin ulcers, enabling comprehensive supervision in any context, whether it be hospital-based, home care or residential and fostering smoother collaboration among the specialist doctor and healthcare professionals operating in the territory.

6. Compressed Sensing paradigm in Medical Imaging

6.1 Introduction

The advent of digital innovation has played a crucial role in various sectors, with the pandemic significantly accelerating the digital transition in healthcare. The pervasive diffusion of new technologies and the explosion in data generation have made digital technology an essential component of everyday life. Today, healthcare plays a prominent role in the data economy, extensively employing enabling digital technologies such as High Performance Computing, Cloud, Internet of Things (IoT), Big Data analytics and AI in an increasingly interconnected and dynamic world. The WHO has also underscored the strategic importance of digitalization in improving the efficiency and sustainability of healthcare systems, while ensuring equitable access and more effective treatments to enhance citizens' health and quality of life.
Italy's digitalization journey, closely intertwined with the healthcare sector, is a central theme in the Next Generation EU investment framework. Health and digitalization represent fundamental strategic levers for the country's growth and sustainable development, as confirmed by investments outlined in the National Recovery and Resilience Plan (PNRR). Digital healthcare has numerous areas of application, with one of the most debated in recent years being the realm of Connected-Care, where data and information management plays a fundamental role. The experiences of leading countries in healthcare digitalization, such as Finland, Estonia and Israel, highlight the importance of having a national digital strategy and a well-structured digital healthcare ecosystem involving the entire value chain, with investments in infrastructure and digital skills for both healthcare professionals and citizens.
The integration of digital technology with healthcare offers greater possibilities for collecting and interpreting healthcare data, enabling the delivery of more effective and personalized services. In particular, the expansion of healthcare services into the digital realm offers two significant advantages: reaching populations with limited access

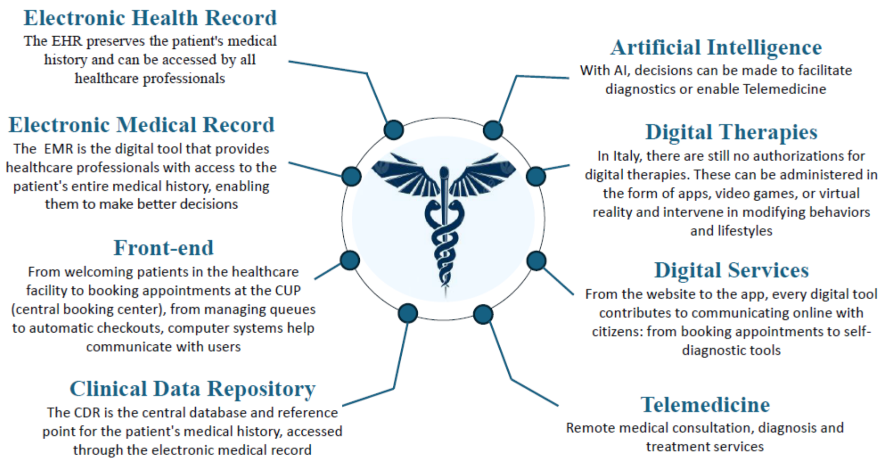


Figure 6.1: Digital Healthcare and Connected-Care

to traditional healthcare services and providing additional services, thanks to their increased ability to monitor or predict individuals' health status. Wearable devices play a crucial role in tracking individual health parameters. Furthermore, digital transformation allows for a greater emphasis on home care over hospital care, enabling more efficient resource allocation and greater control over the quality and effectiveness of services provided. This approach places the patient at the center and provides support to healthcare personnel in all stages of patient management.
In essence, the primary goal of digital healthcare is not simply the transition from paper-based to electronic records or the replacement of in-person activities with remote ones, such as Telemedicine or Teleconsultation. Rather, the goal is to improve the quality and effectiveness of healthcare by enhancing physicians' decision-making processes through the dissemination of scientific knowledge and the use of data-driven support tools.
According to the recent study *"Digital Health2030 - Verso una trasformazione Data-Driven della Sanitá"*, the healthcare sector has become the leading source of data generation globally, representing 30% of the global volume. It is projected that by 2025, the compound annual growth rate of healthcare sector data will reach 36% [8]. Healthcare activities generate large amounts of data that grow rapidly over time and traditionally healthcare organizations have struggled to deal with the increasing data volume due to the limitations imposed by the infrastructure used for data transmission. Furthermore, with the evolution of intelligent networks such as the Internet of Things (IoT), network sizes expand and network environments become increasingly complex, posing a significant challenge for network communication. The issue of energy saving, transmission efficiency and data security has gradually been emphasized. In this context, the implementation of data compression methodologies plays a fundamental role

in managing and transferring healthcare information, given the significant amount of data generated daily in the contemporary digital context. Data compression aims to reduce the space occupied by data without compromising its integrity, thereby reducing costs and making transmission more efficient. This is crucial in a context where the amount of data to be managed is constantly increasing and the costs associated with their transmission are significant.

The use of compression methods, resulting in reduced data volume, can lead to several advantages, such as:

- more efficient use of storage resources
- reduction in costs for purchasing and maintaining storage infrastructure
- reduction in transmission times
- reduction in transmission costs

However, it is essential to ensure that data compression does not compromise the integrity of information, especially in a healthcare context. This implies the use of robust and reliable compression algorithms that minimize the loss of relevant information.

Starting from this intrinsic need to reduce the volume of data transferred and stored in the clinical setting, a new and innovative data compression method has been experimented with.

In the specific context of the Wound Viewer device, an algorithm based on the principle of Compressed Sensing (CS) has been evaluated and implemented. The goal is to reduce the weight and therefore the cost of storing and transmitting images produced by the device itself and subsequently archived in the Cloud platform, while maintaining the fundamental features for the detection and automatic classification of acquired wounds.

CS emerges as a solution to simultaneously address the three fundamental issues in intelligent network communication and transmission of personal data:

- Energy saving
- Transmission efficiency
- Data security

In the context of CS, a smaller number of samples is required to reconstruct sparse or compressible signals, thus overcoming the limitations imposed by the traditional Nyquist-Shannon Sampling Theorem.

6.2 Compressed Sensing Theory

Compressed Sensing represents a new area of research with various applications in signal processing, medical imaging, seismology and communications. This methodology ensures effective data compression and faithful reconstruction by reducing the number of linear measurements required compared to the original data size [18].
CS addresses the challenge of managing the large volume of collected data, which is exponentially increasing every year. It originated as a paradigm based on signal reconstruction using fewer samples than traditional data acquisition methods. This approach not only solves the data storage problem but also offers other advantages, such as more efficient signal sampling compared to the established Shannon-Nyquist Sampling Theorem, according to which, in order to be correctly reconstructed, a signal must be sampled at a sampling frequency of at least

$$f_{sampling} = 2 \cdot B$$

B represents the upper limit of the signal bandwidth.
CS utilizes advanced techniques from applied mathematics, particularly linear algebra, to solve underdetermined linear equations. The methodology involves acquiring a limited number of data samples followed by reconstructing the original signal using specific algorithms. The most effective strategy for CS signal reconstruction is to solve an L0-norm minimization problem.
Recent studies have demonstrated that CS and sparse reconstruction techniques are competitive compared to other traditional algorithms like JPEG in image compression and reconstruction.
The applications of CS are numerous and include improving the quality of voice recordings, compressing medical images and various IoT applications [19, 20, 21]. The block

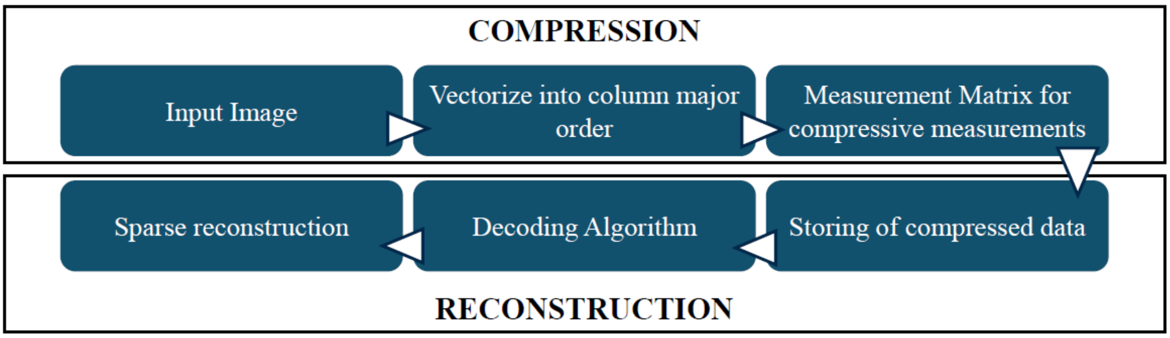


Figure 6.2: Block diagram of CS model

diagram in ***Figure 6.2*** describes the process underlying image compression and reconstruction using the Compressed Sensing method. After data collection, the digital image is vectorized following the column major order. The creation of the measurement matrix is the next step, based on algorithms such as Discrete Fourier Transform (DFT), Discrete Cosine Transform (DCT) or Discrete Wavelet Transform (DWT) and other probabilistic methods to obtain Compressed measurements. These matrices, structured to allow for quick implementation with low computational cost, facilitate the reconstruction of sparse signals through random measurements, resulting in efficient and stable algorithms with a reduced number of samples. The results obtained with these matrices are stored and subsequently used in the process of decoding Compressed data. The reconstruction process of sparse signals is carried out using algorithms such as Least Squares Method (LSM), Basis Pursuit (BP), Orthogonal Matching Pursuit (OMP) and the fusion of BP and OMP.

Suppose that x is a discrete signal which is transformed into y by multiplying it by a matrix Φ with MxN dimensions. The CS process can be expressed as:

$$y = \Phi x, \tag{6.1}$$

where $M<N$, $y \in \mathbb{R}^M$, and Φ is called *measurement matrix.* From ***Equation 6.1***, signal x with N dimensions is compressed into signal y with M dimensions and x is unsolvable by y because the number of equations is less than that of the unknows. The precondition of solvability for x is that x be sparse or that x be sparse on some orthogonal bases, that is:

$$x = \Psi s, \tag{6.2}$$

where Ψ is an orthogonal matrix with NxN dimensions, which satisfies the conditions that $\Psi\Psi^T = I$ and $\Psi^T\Psi = I$. The Ψ is the *sparsity matrix* and s is a sparse vector. When K values of s are non-zero and other N-K values are zero ($K << N$), we call the vector s *K-sparse*. Common sparsity matrices are DFT, DWT and DCT matrices. Combining ***Equations 6.1*** and ***6.2***, we obtain that

$$y = \Phi x = \Phi\Psi s = \Theta s, \tag{6.3}$$

where $\Phi\Psi$ is the *sensing matrix.* To construct x from y, sensing matrix must be in accordance with the restricted isometry property (RIP):

$$1 - \delta_k \leq \frac{\|\Theta v\|^2}{\|v\|^2} \leq 1 + \delta_k, \tag{6.4}$$

where $\delta_k \in (0, 1)$, v is an arbitrary sparsity signal. The process of reconstruction can be described as a convex-optimization problem.

CS theory has been widely studied with different applications. This theory is composed of two important parts, sensing and reconstruction. The sensing part needs a sensing matrix that satisfies certain conditions to obtain a sparse signal. There are

many classical sensing matrices, such as the random (e.g. Gaussian and Bernoulli ones), deterministic (e.g. polynomial and chaotic ones) and structured random (e.g. Toeplitz and Hadamard ones) matrices. While for the reconstruction step it is required a measurement vector and CS algorithms to reconstruct the original signal. There are many types of reconstruction CS algorithms, such as the convex-optimization, greedy and Bayesian algorithms.
Regarding CS applications it can be utilized in many different domains such as data compression, image encryption and cryptography [22] [23].

6.3 Compressed Sensing for image encryption

CS has been widely applied in data compression, image encryption, cryptography, complex network reconstruction, channel estimation, analog-to-information conversion, channel coding, radar reconstruction, radar remote sensing and digital virtual-asset security and management [24]. ***Figure 6.3*** presents an exemple of a data-encryption transmission system based on CS.

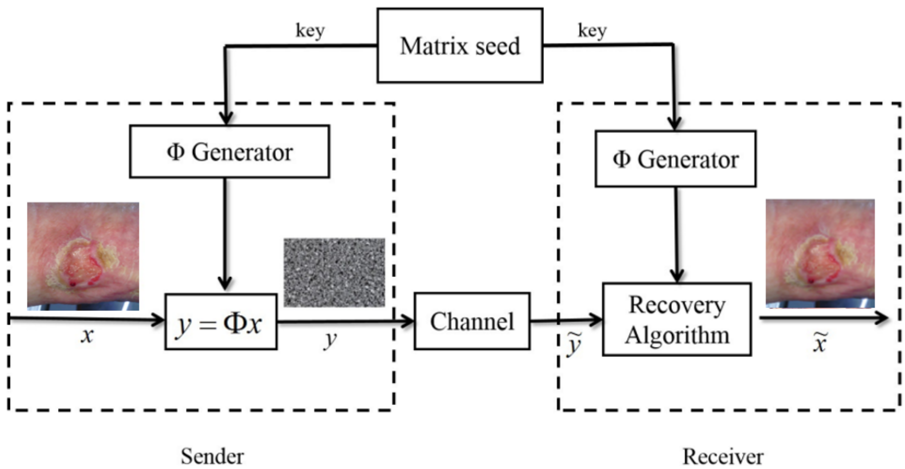


Figure 6.3: Data-encryption transmission system based on CS, wich can simultaneously realize data encryption and compression. *Adapted from [24].*

The choice to adopt CS as a method of encoding for medical images holds significant relevance in the context of transmitting such sensitive data. These images are invariably associated with patients' personal information, subject to stringent data protection and cybersecurity regulations, such as GDPR in Europe or HIPAA in the United States. In this context, the use of CS not only significantly reduces transmission and storage costs but also provides an additional level of security and privacy.
CS allows for the reduction of image data size while maintaining its integrity and clinical relevance. Furthermore, it enables the secure transmission of Compressed images

through vulnerable or potentially insecure networks. Without the correct decryption key, which is only obtainable during image encoding, the image remains unreadable and inaccessible to anyone attempting to intercept or manipulate it. This ensures additional protection for patient data during transmission, which becomes selective and controlled, limiting access to only interested parties.
On the other hand, the transfer of smaller file sizes allows for shorter transmission times and more efficient use of storage resources. This is particularly advantageous in environments where bandwidth is limited or where there is a need to transfer large amounts of data quickly, such as in emergency situations or rural areas.
Essencially, CS is naturally advantageous in image encryption, thanks to the sparsity of data characterizing images under specific bases or dictionaries. Orsdemir et al conducted a verification of the effectiveness of the CS-based image encryption scheme, demonstrating its resilience to noise [25]. They examined the model's security against both brute force and structured attacks. Furthermore, CS is widely used in the creation of various cryptographic schemes. Addressing the primary challenges of image authentication, namely tamper detection, localization and recovery, Du et al proposed an image authentication method based on CS, known as semifragile authentication [26]. Similarly, Hu et al presented a scheme for image reconstruction and identity authentication based on CS, implemented in the context of cloud computing. Their approach involves transferring complex reconstruction operations to the cloud server, while simultaneously ensuring the protection of the image's private information [27].

6.4 GDPR and image encryption

The GDPR represents a comprehensive set of regulations for data protection, establishing a series of principles governing the collection, use and processing of personal data, including health-related data, which are crucial within the Telemedicine context. The key pillars of data protection under GDPR include:

- **Legality, correctness and transparency:** Personal data must be collected and processed lawfully, fairly, and transparently. Individuals must be clearly informed about the purpose and legal basis of data collection and processing, as well as their rights and how their data will be used.

- **Purpose limitation:** Data must be collected and processed only for specific, explicit and legitimate purposes, avoiding use for incompatible purposes.

- **Data minimization:** Personal data must be adequate, relevant and limited to what is strictly necessary for the purpose, avoiding excessive collection and processing.

- **Accuracy:** Data must be accurate and up-to-date, ensuring periodic verification of their accuracy and correction or deletion of inaccurate or outdated information.
- **Storage time limitation:** Data must be stored only for the time necessary for the purposes for which they are processed, with an obligation to delete or anonymize data no longer needed.
- **Integrity and confidentiality:** Data must be processed securely to protect them from unauthorized access, loss or damage, by adopting appropriate technical and organizational measures to ensure security.
- **Accountability:** Organizations must demonstrate compliance with the GDPR, adopting suitable policies and procedures to ensure compliance with regulations and data protection.

In the telemedical context, these principles imply that personal data, including health-related data, must be processed transparently, securely and in compliance with the GDPR. Operators are required to implement appropriate measures to protect the processed data, provide clear information to patients about the use of their data, and ensure that data are processed only for legitimate purposes. By adhering to these principles, Telemedicine services can ensure patient privacy and data security while leveraging the benefits of remote healthcare.
In light of this, selecting a Telemedicine service provider that retains personal data within the EU/EEA and does not transfer them outside this area is crucial to ensure GDPR compliance and protect the confidentiality of personal information.
The GDPR imposes strict restrictions on the transfer of personal data outside the EU/EEA, especially to countries without adequate data protection regulations. This is because such transfers can increase the risk of unauthorized access, loss or improper use of data.
To address this situation, some Telemedicine providers have adopted measures such as data localization, encryption and anonymization to protect patient information and ensure GDPR compliance.
Within this regulatory framework, the approach to Compressed Sensing, as a system of image encryption, emerges as a significant opportunity to ensure data security in case of theft or manipulation, as the stolen data would be unreadable to anyone, while manipulation would be detected during the image reconstruction process.
One possible strategy is to store the image decryption key in a look-up table stored on a server physically located in a different location from the Wound Viewer data storage Cloud. This approach ensures that in case of unauthorized access to the Cloud, the images remain encrypted and therefore inaccessible. Furthermore, the key to encode

and read the images remains accessible only to a limited number of users, ensuring the security of compressed data transmission even through insecure networks.
This solution ensures full compliance with the GDPR, addressing the issue of data transfer outside the EU/EEA. Since the decryption key is stored in a separate location, data transmitted outside the EU/EEA are rendered unreadable without the reconstruction matrix, providing an additional level of security and data protection.

6.5 Compressed Sensing on Wound Viewer Images

It was therefore decided to apply a CS algorithm to the images acquired through the Wound Viewer to allow for a more efficient and secure transmission of medical images without losing the fundamental information necessary for wound classification following the image reconstruction.
In particular, for this application it has been implemented the Block Compressed Sensing (BCS) that is the most appropriate approach when dealing with high-dimensional images [28].
Furthermore, an overlapped technique has been adopted. It has been demonstrated that patch-based redundant representation is significant to achieve high recovery quality [29].
This method involves dividing the image into many small patches and operating on each image patch separately during measurement and reconstruction, which reduces computational complexity and greatly saves sensing matrix storage space. The measurement value of each image patch can be independently sent after being obtained and the receiver can reconstruct the image patch according to the data and realize real-time performance.
Considering a I_rxI_c image with a total of $N = I_r I_c$ pixels, the image is divided into blocks of BxB dimensions and sampled with the same sensing matrix. As shown in ***Figure 6.4*** the vectorized signal of each i-th block is detoned as x_i and

$$y_i = \Phi_B x_i, \tag{6.5}$$

where Φ_B is an n_BxB^2 matrix and $n_B = \frac{nB^2}{N}$.
Then, measurement matrix Φ can be represented as:

$$\Phi = \begin{pmatrix} \Phi_B & & \\ & \ddots & \\ & & \Phi_B \end{pmatrix}, \tag{6.6}$$

where Φ is a block diagonal matrix. This ***Equation 6.6*** demonstrates that BCS is storage-saving, as it requires to store only the n_BxB^2 matrix Φ_B rather than an nxN

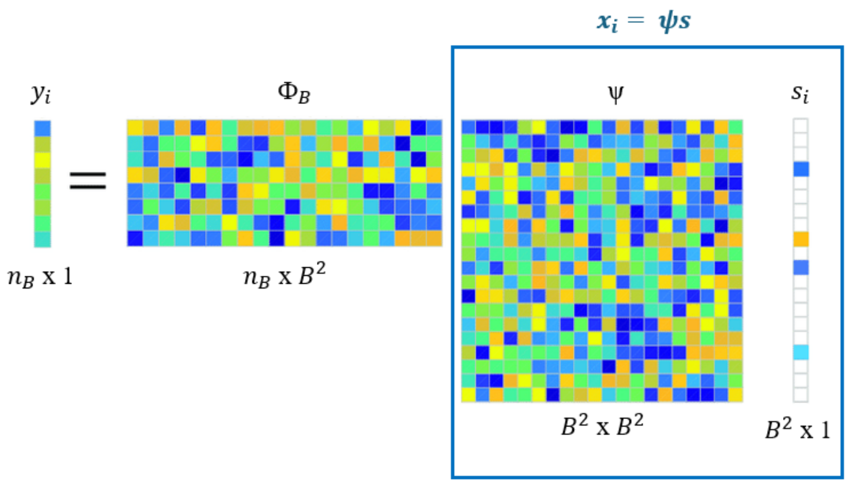


Figure 6.4: CS process for each block. *Note: s, sparse vector of x; y, measurement vector; ΦΨ, sensing matrix; M<N*

matrix.
To obtain the sparsity coefficients, the Discrete Cosine Transform (DCT) frequency based technique was used.
The most common DCT definition of a 1-D sequence of length N is:

$$Y[k] = C[k]\sum_{n=0}^{N-1} X[n]cos[\frac{(2n+1)k\pi}{2N}], \tag{6.7}$$

where k = *0,1,...,N-1*. Similarly, the inverse DCT transformation is defined as:

$$X[n] = \sum_{k=0}^{N-1} C[k]Y[k]cos[\frac{(2n+1)k\pi}{2N}], \tag{6.8}$$

where n = *0,1,...,N-1*.
In both ***Equations 6.7*** and ***6.8*** $C[n]$ is defined as:

$$C[n] = \begin{cases} \sqrt{\frac{1}{N}}, & \text{for n = 0} \\ \sqrt{\frac{2}{N}}, & \text{for n = 1,2,...,N-1} \end{cases} \tag{6.9}$$

The 2-D DCT is a direct extension of the 1-D case and is given by:

$$y[j,k] = C[j]C[k]\sum_{m=0}^{N-1}\sum_{n=1}^{N-1} x[m,n]cos[\frac{(2m+1)j\pi}{2N}]cos[\frac{(2n+1)k\pi}{2N}], \tag{6.10}$$

where j,k = *0,1,...,N-1* and the inverse DCT is defined as:

$$x[m,n] = \sum_{j=0}^{N-1}\sum_{k=1}^{N-1} C[j]C[k]y[j,k]cos[\frac{(2m+1)j\pi}{2N}]cos[\frac{(2n+1)k\pi}{2N}], \tag{6.11}$$

where m,n = 0,1,...,N-1 and $C[n]$ is as it is as in 1-D transformation.

The algorithm used for WV images compression and reconstruction can be described by the following steps of encoding and decoding using the DCT and inverse DCT technique.

Encoding System. To encode and compress the image four steps were conducted:

Step 1. The image is divided into blocks of BxB pixels, considering an overlap percent between blocks. Here *B=8* and *overlap = 0.25*

Step 2. Working from left to right, top to bottom, the DCT is applied to each block computing DCT coefficients, while the IDCT (Inverse Discrete Cosine Transform) is applied to compute the bases matrix.

Step 3. DCT coefficients are sorted in descending order. The values of the first k coefficients are stored as they are while the others are stored as zero in a vector. Here different sparsity levels of 0.05, 0.1, 0.2 and 0.3 (corresponding to Compression Ratio values of 13, 12, 11 and 10 respectively) were tested.

Step 4. The array of Compressed blocks that constitute the image is stored in a drastically reduced amount of space.

Essencially, the input image is broken into small BxB blocks, then DCT is applied on each block. After that DCT coefficients are quantized to reduce the storage space. This step is lossy step and to quantify the loss of information the Mean Square Error (MSE) has been computed: the higher the MSE value, the greater the information loss.

Deconding System. It's the reverse process of encoding. There are two steps for reconstruct the original image from Compressed image:

Step 1. Each block is reconstructed multiplying its DCT coefficient with the basis matrix obtained during the encoding process.

Step 2. The blocks are combined into an image reconstructing the original one.

CS is a lossy technique so the output image is not the exact copy of the original one. This process' efficiency is measured by the Compression Ratio (CR) value that is defined by ratio of storage bits of original image and storage bits of Compressed image:

$$C_r = \frac{n_1}{n_2}, \tag{6.12}$$

where n_1 is the number of bits to store the original image and n_2 is the number of bits to store the Compressed one.

On the other side, loss of information is measured by MSE between reconstructed image and original image, as

$$MSE = \sum_{i=1}^{M}\sum_{j=1}^{N}(x(i,j) - x'(i,j))^2, \tag{6.13}$$

where MxN is the dimension of the image, $x(i,j)$ is the pixel value of (i,j) coordinate of the original image, while $x'(i,j)$ is the reconstructed image's pixel value.
If MSE of reconstructed image to original image is greater than the information lost is more.

(a) Original (b) CR = 10 (c) CR = 11 (d) CR = 12 (e) CR = 13

Figure 6.5: Wound Viewer image compression and reconstruction with different CR values

Four different compression modes were tested with different sparsity levels and for each mode the MSE between the reconstructed image and the original image was calculated, using the image shown in ***Figure 6.5*** as reference.

CR	MSE Original – Reconstruction	Total MSE Original – Zero Image
10	756.426.350	$1{,}48 * 10^{15}$
11	855.978.543	
12	1.149.909.992	
13	2.025.743.717	

Figure 6.6: MSE of output images with different CS values

Table 6.6 shows the information loss with different CR while the third column shows total MSE of the original image with a zero image, so that it is possible to analyze how many percentage of information it is loss out of total information. Where the zero image is obtained initializing an MxN matrix of zeroes.

6.6 YOLOv8 for skin ulcers detection and classification according to WBP Score

After reconstructing the images from the extracted DCT coefficients in the frequency domain and the DCT basis matrix, wound classification was performed using a pre-trained Convolutional Neural Network (CNN) on the original image dataset to detect and classify skin ulcers according to the WBP scale. The images in the dataset were compressed and reconstructed at various CR values to assess the neural network's ability to extract relevant features at different levels of compression.
To perform classification, the YOLO (You Only Look Once) network with a detection task was employed. This neural network is characterized by layers for feature extraction

that perform convolution operations between a kernel and a portion of the image. Convolution is a mathematical operation used in image processing, which, given two functions, produces a third function that is calculated as follows:

$$(f * g)(t) = \int f(\tau)g(t - \tau)d\tau, \tag{6.14}$$

where, f and g represent two discrete-valued functions on limited domains.
When referring to images of $M\text{X}N$ pixels of dimensions, the previous equation can be reformulated as:

$$(f * g)(x, y) = \sum_{i=0}^{M}\sum_{j=0}^{N} f(x, y)g(x - i, y - j), \tag{6.15}$$

For feature extraction purposes, convolution is performed between the input image and an odd-sized kernel whose central point is aligned with a pixel of the image. The values of the kernel are multiplied by the corresponding pixel values in the image and the resulting values are summed to obtain a single number that will populate the new output matrix from the convolutional layer, called *Feature Map*.
The parameters that characterize a convolution kernel are:

- **Size:** the size is defined by height and width.
- **Coefficient values:** each value in the kernel specifies how much weight to assign to neighboring pixels in the input image during convolution calculation.
- **Padding:** it involves adding zero-valued pixels around the edges of the input image before applying convolution. This is necessary to control the behaviour of convolution at the image edges.
- **Stride:** it refers to the number of pixels shifted each time the kernel is applied to the input image during convolution.

The kernel has variable sizes among the layers composing the network to allow feature extraction at different levels of the image. It is applied across all 3 RGB channels of the image and from each section within the kernel, features are extracted for the detection and classification of objects of interest. Subsequently, the convolutional layer is followed by a max pooling layer, which executes the pooling operation to reduce the dimensions of the input matrix. Specifically, max pooling involves sliding a window of specified dimensions along the matrix and retaining only the maximum value from each section within the kernel. This process yields an output matrix with reduced dimensions.
Lastly, a SiLu activation function is applied to the values of the matrix, resulting in an

output matrix of the same dimensions but with different values. The SiLu activation function is defined as:

$$SiLu(x) = x * sigmoid(x) = x * \frac{1}{1 + e^{-x}}, \tag{6.16}$$

These sub-layers of alternating convolution, pooling and sigmoid function are repeated across all layers of the network to enable feature extraction, gradually transitioning from low-level to high-level features, relevant for the established task.

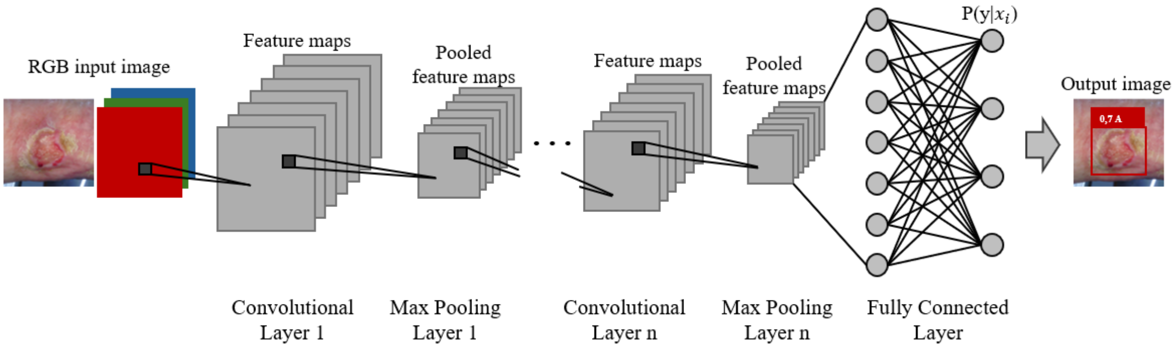


Figure 6.7: CNN architecture

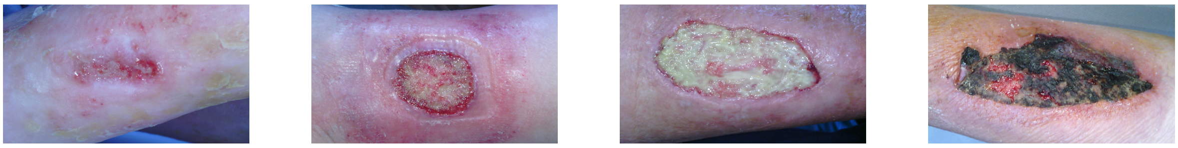
The network architecture is shown in ***Figure 6.7***.
The last layer is a Fully Connected, meaning that all the output neurons are connected to all the neurons of the previous layer and vice versa. The output neurons are numerically equal to the number of object classes to be recognized, which is four, corresponding to the number of wound classes according to the WBP scale. At the output of the network, each output neuron will be associated with the probability of the detected object belonging to each of the object classes $P(y|x_i)$, where y is the output values vector and x_i is the i-th object class.

6.6.1 Dataset

A dataset containing **446** skin ulcer images acquired through the Wound Viewer device and associated with their respective class according to the WBP scale assigned by the clinician was used. For the training step, a balanced Training Set consisting of **200 images** (50 per class) was created, while a Validation Set of **119 images** was used for performance evaluation and a Test Set of **127 images** was used for the inference. Class D wounds, being associated with the presence of eschar and/or necrotic tissue, were the least represented among the available images. To increase the number of examples of wounds in this class for the network training, data augmentation was preliminarily performed by applying simple transformations such as mirroring and rotation to the

available Class D images.
The creation of five different datasets was then carried out, using original images and reconstruct images after compression at different CR:

- **Dataset I:** Original Images
- **Dataset II:** Reconstructed Images with CR = 10
- **Dataset III:** Reconstructed Images with CR = 11
- **Dataset IV:** Reconstructed Images with CR = 12
- **Dataset V:** Reconstructed Images with CR = 13



(a) Class A **(b)** Class B **(c)** Class C **(d)** Class D

Figure 6.8: Dataset I images from each class

For training and validating the network, manual segmentations of all images in the dataset were performed to obtain binary masks, to which class labels were assigned. These masks were then converted into text files containing the object classes and the coordinates of bounding boxes, required as input for the network during training, resulting in a supervised dataset.

6.6.2 Training

The training of the network was subsequently performed on all datasets using pre-saved weights from a training process carried out on the COCO (Common Objects in Context) dataset containing 80 object classes.
Furthermore, the network perform data augmentation importing the *albumentation* library and applying the following transformations on the original images:

- Blurring with a Low Pass Filter (LPF)
- Blurring with a Median Filter
- From RGB to Grayscale
- Contrast Limited Adaptive Histrogram Equalization (CLAHE)

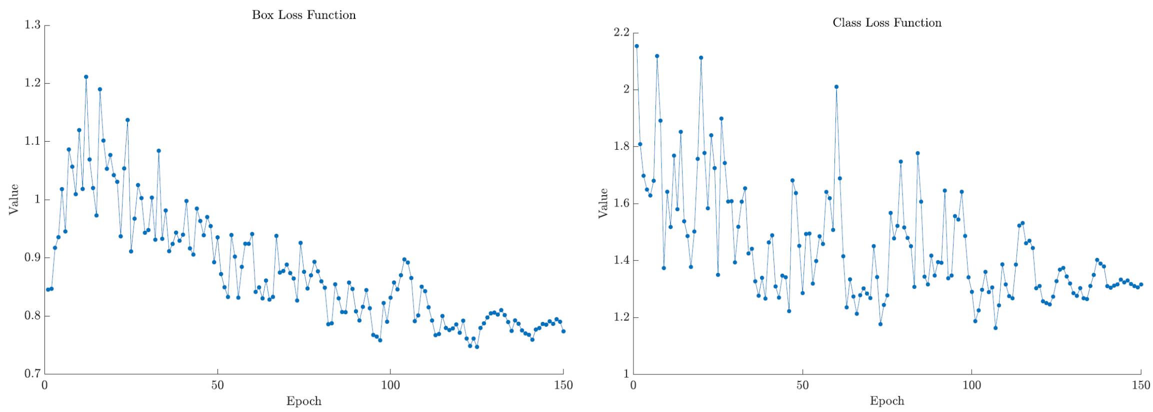
The *albumentation* library is closed during the last 10 training epochs, stopping the data augmentation.

During training, the network aims to minimize a loss function, which is a measure of the error between the network's estimation and the supervised output. The loss function used consists of two components to be minimized: the loss on bounding boxes, given by the accuracy with which the coordinates of the box containing the object are detected and the loss on class, given by the correct recognition of the class to which the detected object belongs. ***Table 6.9*** shows the main training parameters of the network.

n_epochs	imgsz	patience	batch	box	cls
200	640	30	16	2.5	5.5

Figure 6.9: Network training parameters

Several values were preliminarily tested as number of epochs for the training, identifying 200 as the best compromise between computational cost and network improvement, by visually assessing the box and class loss functions trend during the network training computed on Validation Set images of Dataset I.



(a) Bounding Box Loss Function

(b) Object Class Loss Function

Figure 6.10: Loss function trend on Validation Set

Figure 6.10 shows box and class components of the loss function during the training epochs. It was observed that between 150 to 200 epochs, the graph reached a plateau beyond which there was no significant improvement in performance. It was then decided to set the number of training epochs to 200 to prevent overfitting on the Training Set images.

- **Imgsz** indicates the image dimensions for resizing, which the network automatically applies for processing and feature extraction.

- **Patience** indicates the number of epochs to wait without improvement in validation metrics: if the metrics do not improve for more than 30 training epochs, the training terminates. This parameter prevents overfitting of the network on the training images.
- **Batch** indicates the size of the training batch, i.e., how many images are processed before the internal parameters of the network are updated.
- **Box** indicates the weight of the bounding box loss component in the loss function, influencing the importance attributed to accurate prediction of bounding box coordinates.
- **Cls** indicates the weight of the classification loss in the total loss function, influencing the importance of correct class prediction relative to other components.

7. WBP Classification on skin ulcers images after Compressed Sensing

The objective of this work was to demonstrate the feasibility of a precise classification according to the WBP scale, commonly used in clinical settings to evaluate skin ulcers, applied to images of lesions with reduced weight compared to the originals acquired through the Wound Viewer. The aim was to obtain lighter images to facilitate data transmission, reduce storage costs and potentially develop a method for encrypting images to enhance data security and protection, limiting the access only to authorized users with the decryption key.

Furthermore, by comparing the classification performance before and after the CS, it is possible to use the latter as a numerical estimate of the image reconstruction quality.

For image compression, an algorithm based on Compressed Sensing theory was used, as previously described, with the goal of achieving effective compression while maintaining the essential features necessary for automatic lesion classification. A study was conducted to assess the impact of compression on classification accuracy, testing four different compression levels. Naturally, as the compression level increases, the resolution of the reconstructed image decreases, affecting the image features crucial for classification.

The graph in ***Figure 7.1*** illustrates the relationship between the weight of the reconstructed image and the RATIO value set for compression. The maximum compression tested corresponded to a RATIO value of 0.05 that corresponds to a sparsity level of 3 non-zero elements for each block, to avoid excessive loss of wound characteristics essential for recognition and classification, resulting in a reconstructed image weight equivalent to 1/13 of the original one.

To perform automatic wound classification, the Yolov8 network was trained by setting the parameters as described in the previous chapter, using all five training sets.

Specifically, weights obtained after the network training on original images were used as starting point for the training on the images after CS.

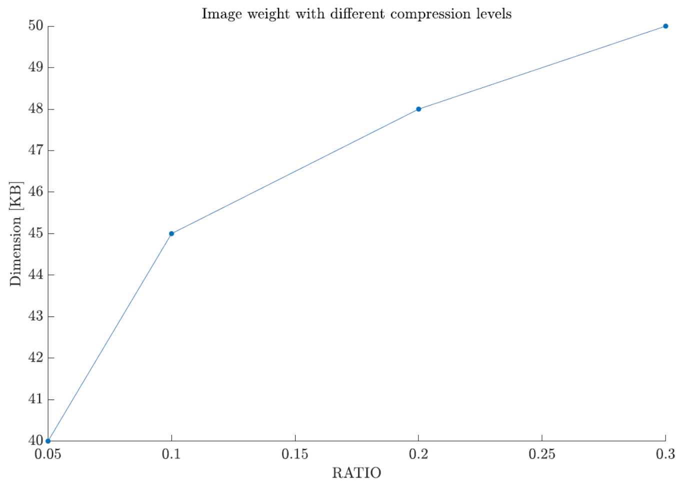


Figure 7.1: Relationship between image dimensions and level of compression applied

The training of the network involves the gradual fine-tuning of internal parameters, such as neuron weights, based on the detection and classification performance achieved on the Validation Set, aiming to minimize the loss function composed of three components:

- Loss on bounding boxes
- Loss on the identified object class (label)
- Focal loss of the distribution

The network trained on balanced Training Sets was employed to perform inference on the Test Sets, using the corresponding weights obtained during training on sets with different compression levels.
Inference was thus executed on all the five Datasets to assess the correlation between the degree of image compression and the network's ability to extract relevant features for classification. The goal was to find the optimal compression level capable of achieving a significant reduction in image transmission and storage costs while maintaining high detection and classification performance of the wound.
Figure 7.2 and ***Figure 7.3*** show the Confusion Matrices obtained during the inference conducted on the various Test Sets, using the weights that achieved the best performance during the five training sessions carried out. On the diagonal of the matrix, in green, the number of wounds correctly identified and classified for each class is reported, while in red, the images misclassified are indicated. In orange, finally, the images in which the model was unable to detect the wounds are highlighted, with a loss of recognition among class A and B wounds, which are minor, while all class C and D wounds are detected. Overall, there is a high number of class C wounds correctly

		True class			
		A	B	C	D
Predicted class	A	19	0	2	0
	B	5	20	8	0
	C	2	5	54	0
	D	0	0	2	5
Not classified		4	1	0	0

Figure 7.2: Classifier Confusion Matrix on original images (Dataset I)

		True class			
		A	B	C	D
Predicted class	A	19	0	2	0
	B	5	17	8	0
	C	2	8	54	0
	D	0	0	2	5
Not classified		4	1	0	0

(a) Dataset II

		True class			
		A	B	C	D
Predicted class	A	19	2	4	0
	B	5	15	8	0
	C	2	8	52	0
	D	0	0	2	5
Not classified		4	1	0	0

(b) Dataset III

		True class			
		A	B	C	D
Predicted class	A	17	2	6	0
	B	6	16	9	0
	C	2	7	49	1
	D	0	0	2	4
Not classified		5	1	0	0

(c) Dataset IV

		True class			
		A	B	C	D
Predicted class	A	21	3	9	0
	B	3	13	9	0
	C	2	8	47	1
	D	0	0	1	4
Not classified		3	2	0	0

(d) Dataset V

Figure 7.3: Classifier Confusion Matrix on reconstructed images

recognized, partly due to the majority of images with wounds belonging to this class in the Test Set. Additionally, there is a particular ability of the network to recognize class D wounds, although it should be noted that this class is poorly represented in the Test set as in clinical reality it is rarer to find such injuries.

To evaluate the classification performance on each class, three different metrics were calculated using the Confusion Matrices obtained to assess the classifier's effectiveness in recognizing and classifying wounds, according to WBP score, from reconstructed images after compression. Specifically, Precision (or Positive Predicted Value), Recall (or Sensitivity) and F1 Score were calculated for each i-th class, as

$$Precision_i = \frac{TP_i}{TP_i + FP_i}, \tag{7.1}$$

$$Recall_i = \frac{TP_i}{TP_i + FN_i}, \tag{7.2}$$

$$F1_i = 2 * \frac{Precision_i * Recall_i}{Precision_i + Recall_i}, \tag{7.3}$$

where $i = class\ A,\ class\ B,\ class\ C,\ class\ D$, TP_i (True Positive) indicates the number of wounds from the i-th class correctly classified, FP_i (False Positive) the number of wounds from other classes misclassified as i-th class and FN_i (False Negative) the

number of wounds from the i-th class misclassified. These metrics have been calculated by category to evaluate the performance of each particular class and to know how well the classifier can distinguish a specific class from the others. Furthermore, it is a more reliable measure when you deal with imbalanced classes, as in this case.
In addition, to obtain a summary measure of the overall classifier performance across all classes, Precision, Recall and F1 Score were calculated instead, using macro-averaging, along with Accuracy, as

$$Precision = \frac{Precision_A + Precision_B + ... + Precision_N}{N}, \tag{7.4}$$

$$Recall = \frac{Recall_A + Recall_B + ... + Recall_N}{N}. \tag{7.5}$$

$$Accuracy = \frac{CorrectPredicions}{AllPredictions}, \tag{7.6}$$

where, in this case, $N = 4$.
All the metrics have values ranging between 0 and 1.
It was decided to use these metrics because they could be useful in evaluating performance in multi-class classification problems. Specifically

- ***Precision*** for a particular class in multi-class classification indicates the fraction of instances correctly classified as belonging to a specific class out of all instances the model predicted to belong to that class. In other words, Precision measures the model's ability to identify instances of a particular class correctly.

- ***Recall*** for a particular classi in multi-class classification indicates the fraction of instances in a class that the model correctly classified out of all instances in that class. In other words, recall measures the model's ability to identify all instances of a particular class.

- ***F1 Score*** combines Precision and Recall scores and assesses the predictive skill of the model by elaborating on its class-wise performance.

- ***Accuracy*** measures the proportion of correctly classified cases from the total number of objects in the the dataset. However, it's important to consider that accuracy provides an estimate of the overall model quality, but it disregards class balance and the cost of different errors. That's why other metrics that evaluate performance on each individual class as well have been used.

Tables 7.4 show the values of Precision, Recall and F1 Score obtained for each object class on the different dataset tested.

	Precision	Recall	F1
A	0,905	0,633	0,745
B	0,567	0,654	0,608
C	0,844	0,818	0,831
D	0,714	1	0,833

(a) Dataset II

	Precision	Recall	F1
A	0,760	0,633	0,691
B	0,536	0,577	0,556
C	0,839	0,788	0,813
D	0,714	1	0,833

(b) Dataset III

	Precision	Recall	F1
A	0,680	0,567	0,618
B	0,516	0,615	0,561
C	0,830	0,742	0,783
D	0,667	0,800	0,727

(c) Dataset IV

	Precision	Recall	F1
A	0,636	0,724	0,667
B	0,520	0,500	0,510
C	0,810	0,712	0,758
D	0,800	0,800	0,800

(d) Dataset V

Figure 7.4: Classifier performance on reconstructed images

The results obtained are in line with expectations, indicating a loss of relevant characteristics for classification as the level of compression applied to the images increases, resulting in a decrease in the classification performance of the network. Overall, the model demonstrates high precision in recognizing the most severe class, namely class D wounds with necrotic tissue. This is particularly important, as class D ulcers require specific and timely intervention and represent a more significant alarm bell compared to other classes. Conversely, there is a more pronounced decrease in the recognition of class A ulcers as the level of compression applied to the images increases. This is probably because class A wounds are generally smaller in size compared to other classes and therefore more difficult to identify in low-resolution images, such as those obtained after compression. Overall, it was observed that both in the original and reconstructed images, the greatest classification error occurs with class B wounds, which exhibit characteristics intermediate between class A and class C, making them difficult to discriminate even for experienced healthcare professionals in the field of skin lesions.

	Precision	Recall	F1 Score	Accuracy
Original	0,774	0,810	0,784	0,772
CR = 10	0,757	0,776	0,766	0,748
CR = 11	0,712	0,749	0,730	0,716
CR = 12	0,673	0,681	0,677	0,677
CR = 13	0,691	0,684	0,687	0,669

Figure 7.5: Overall classifier performance across all classes on reconstructed images

The overall performance of the classifier on all classes to be identified was then

calculated. A decrease in precision was observed with increasing image compression levels, while recall remained significantly high. This indicates that the network tends to be less conservative, generating a high number of false positives and, conversely, a low rate of false negatives. This latter aspect, considering the values obtained previously for individual classes, can be attributed to the network's significant ability to recognize class C and D wounds, achieving higher recall values as well as a very low number of false negatives. Of note is the case of Dataset III, where the recall calculated for class D reached the maximum value of 1, indicating that all class D wounds were identified, albeit with a precision value slightly lower than 1, suggesting that some wounds not belonging to class D were mistakenly classified as such. Regarding the F1 score, obtained as the harmonic mean of precision and recall, it remained almost constant across all tested datasets. Finally, the Accuracy, which effectively measures the model's accuracy in correctly classifying the classes, experienced a slight decrease with increasing image compression levels, but remained sufficiently high even on the dataset to which compression with $k = 0{,}05$ was applied with a value of 0,685.
Based on the results obtained from the various datasets, it can be concluded that the compression applied to dataset V is acceptable in terms of extracting useful features for the classification of the images to which such compression is applied. It is essential to emphasize that the training of the network was conducted on a limited set of images available for the present study. Expanding the available dataset opens up broad and realistic opportunities for improvement.

7.1 Impact on transmission infrastructures and storage platforms

Applying the theory of Compressed Sensing, we managed to obtain reconstructed images with sizes up to 13 times smaller than the original images. This reduction in image size, without loosing significant features for skin ulcers classification has a considerable impact on Telemedicine applications, where efficient transmission and storage of medical images are crucial. This study aims to highlight the opportunity of significantly decrease the bandwidth required for transmission over networks, making it easier to share images between healthcare facilities, specialists and remote locations. Additionally, smaller image sizes result in decreased storage requirements, reducing storage costs and allowing to store a larger volume of patient data without investing in additional storage infrastructure.
In evaluating the potential reduction in image transmission costs when adopting the

Compressed Sensing technique, it was considered that each patient with a skin ulcer, monitored through the Wound Viewer technology, requires an average of 5 images of the lesion during the evaluation and treatment period, to monitor its evolution, healing or possible worsening. A single image acquired through the device weighs approximately 530 KB. Using these values, the transmission costs per patient were calculated, assessing the extent of cost reduction when transmitting compressed images and evaluating separately the different levels of compression tested.
The reduction percentage was calculated as:

$$R_{\%} = \frac{A - B}{A} * 100, \tag{7.7}$$

where A is the original image weight and B is the reconstructed image weight.

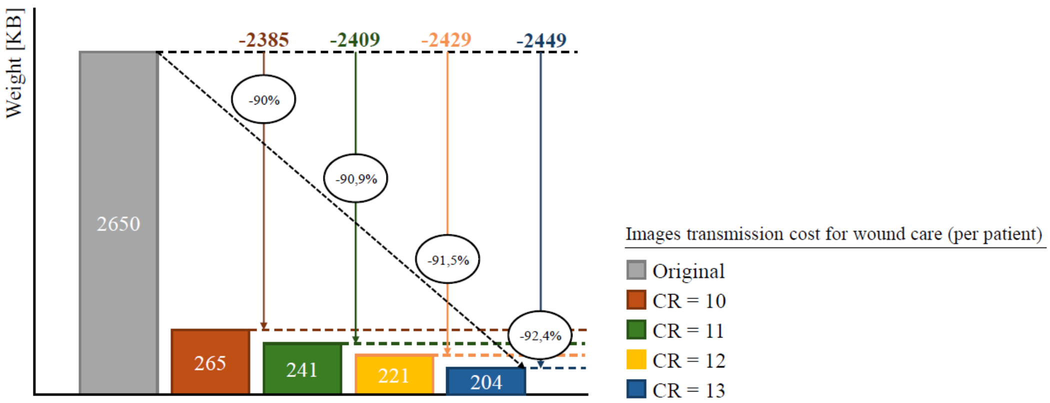


Figure 7.6: Images transmission cost per patient. The values reported are in KB

As shown in ***Figure 7.6***, there is a reduction in the transmission costs of such clinical data up to a 92.4% in the case where a CR equal to 13 was tested, still achieving promising classification performance despite the high level of image compression.
Considering the substantial number of patients affected by skin ulcers each year and the images produced for each of them, this reduction in transmission and storage costs can lead to substantial cost savings for healthcare providers while improving overall patient care through enhanced accessibility to these medical imaging data.

7.2 ASL Asti case

In a hospital in Italy, ASL Asti, the WV was uptaken and a comparison was conducted between data regarding the cost of cures recorded in the year prior to and the year following the adoption of the technology [17]. It turns out that ASL Asti, has approximately 850 new patients affected by skin ulcers each year. This prevalence was used in the current study to analyze the images transmission cost and the extent of its

reduction in a real-world application of the device in a hospital, in this case in Italy, over the course of a year.
Considering that the evolutionary history of the ulcer must be constantly monitored in order to carry out a specific treatment or medication, an average of 5 images acquired per patient was estimated. In this scenario, we obtain 4250 images acquired, archived and potentially transmitted every year, with an approximate cost of 2.25 GB. The graph in ***Figure 7.7*** illustrates the extent of the average reduction in transmission and storage costs calculated.

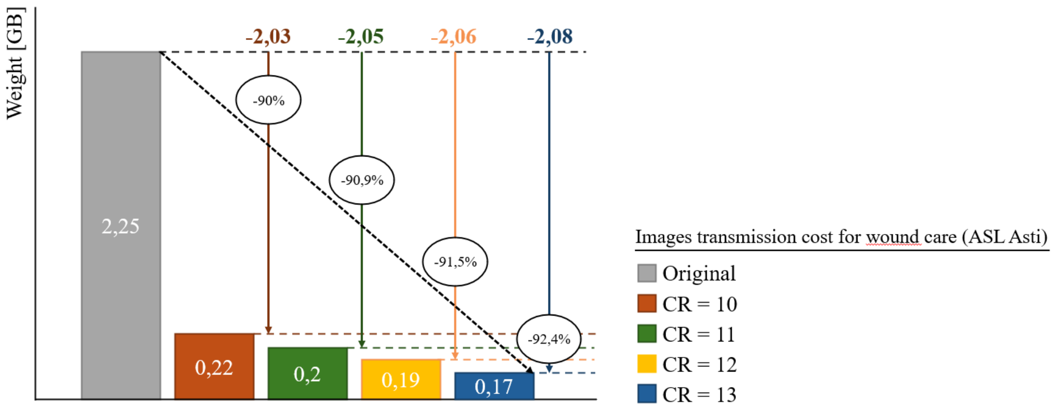


Figure 7.7: Images transmission cost per year (ASTI). The values reported are in GB

7.3 European Countries case

The percentage of transmission weight reduction calculated for a single individual was used to estimate the national impact, considering the average number of new ulcer patients recorded each year in Italy and in the other European countries included in the study (1% of the total population).
Given the promising performance obtained for all tested compression levels, a national-level analysis was conducted considering the transmission weights of images with a CR of 13, which have the maximum impact on transmission networks and storage platforms. The numerical results obtained considering one year of WV usage are shown in ***Figure 7.8***.
This study was conducted to analyze the alleviation of infrastructure burdens for image transmission and storage, in the event of nationwide adoption of the Wound Viewer. This integration is already underway in Denmark, where the integration of the telemedical device with the existing Pleje.net platform for national data sharing in the field of wound care is being evaluated.
Considering the number of people affected by this condition each year and the number

	Germany	Italy	Spain	Czech Republic	Sweden	Denmark	Finland	Norway
Population (millions)	83,3	58,9	47,4	10,5	10,5	5,9	5,6	5,4
Estimated ulcer population	833.000	589.000	474.000	105.000	105.000	59.000	56.000	54.000
Current transmissi on costs [TB]	2,207	1,561	1,256	0,501	0,501	0,156	0,148	0,143
Updated transmissi on costs [TB]	0,168	0,119	0,095	0,038	0,038	0,012	0,011	0,0109

Figure 7.8: Images transmission cost per year

of images that need to be produced for each of them for lesion evaluation and monitoring, the reduction in transmission and storage weights hypothesized in the case of using compressed images results in a significant impact.

8. Conclusions

Skin ulcer is a condition that affects a portion of the global population that cannot be neglected and is characterized by an evolution that is sometimes unpredictable and difficult to assess. For this reason, early diagnosis and assessment of the condition are crucial to define the correct therapeutic plan and bring the lesion to healing. Otherwise, the affected skin tissue undergoes necrosis, leading in the worst cases to an avoidable need for amputation of the affected limb. Furthermore, the field of wound care has been considered a second-tier medical specialty over the years, not receiving the necessary attention it requires. This results in a scarcity of healthcare professionals experienced in the diagnosis, assessment and treatment of the condition, especially when it comes to home care or care in nursing homes where the majority of the over-65 population, who are most susceptible to developing skin ulcers, reside.

From the idea of introducing a non-invasive tool capable of automatically assessing the wound, the Wound Viewer was born, a telemedical device designed to support healthcare workers dealing with this condition by creating a bridge between frontline workers and this field specialists.

In addition to this, through the acquisition of images of the lesion and extraction of area and depth parameters, it is possible to constantly monitor the evolution of the wound and promptly intervene in case of deterioration by adjusting the therapeutic plan. This allows for continuity in the care of patients affected by this condition, providing nurses who alternate in wound care with a comprehensive overview of each patient under their care.

In recent years, Telemedicine has emerged as a fundamental tool for optimizing the efficiency of the healthcare system, especially in a post-COVID-19 context that has highlighted deficiencies in healthcare delivery. This tool provides quicker and more convenient access to healthcare services, enabling remote monitoring and medical consultations, reducing the need for travel and lowering the risk of contagion. In the context of wound care, the use of telemedical devices is particularly beneficial, ensuring greater assistance to elderly residents in nursing homes or at home, avoiding contact with hospital environments where there is a high incidence of healthcare-associated infections, especially in elderly individuals already weakened by underlying conditions.

Throughout this study, it has been examined the impact from various perspectives of introducing a telemedical device such as the Wound Viewer at a national level, with a focus on specific European countries where a significant wound care market is observed and where the integration of WV has shown a hypothetical impact, based on a previous study conducted at the ASL Hospital of Asti, which is significant.
However, the significant proliferation of new technologies and the transition to digital in healthcare have led to an explosion in data generation, often incompatible with the transmission and storage infrastructures available today. This has gradually emphasized issues regarding energy saving, efficiency in data transmission and storage and data security. For this reason, it was decided to test a new data compression method based on Compressed Sensing theory, originally developed for signal acquisition at a lower sampling frequency than traditionally established by the Nyquist Theorem for the correct reconstruction of the acquired signal.
The CS technique was adopted for its intrinsic feature of potentially performing image encryption simultaneously with compression, which in a context such as healthcare becomes of significant relevance and interest, as personal data subject to stringent GDPR directives are handled.
The CS was performed on images at various compression levels, followed by automatic lesion classification using a CNN, aiming to assess the extent to which the image could be compressed without losing excessive features necessary for clinical lesion evaluation with sufficient accuracy. The decrease in classification performance as the level of sparsity applied to the images increased during the CS phase was also used as a quantitative measure to assess the loss of information and the quality of the compression performed.
In light of the results obtained in the classification of images at various compression levels compared to the performance in classifying the original images, compression via CS in the Discrete Cosine Transform domain emerges as a valid method for significantly reducing image transmission and storage costs while retaining relevant features for lesion classification through the WBP scale used in clinical settings.
These findings present promising opportunities and perspectives for introducing a device like the WV on a national scale, substantially reducing costs for wound care with minimal impact on clinical data transmission and storage infrastructure, while simultaneously introducing a method for image encryption capable of enhancing data protection by limiting its sharing to authorized individuals.

Bibliography

[1] Gianluca Zoppo, Francesco Marrone, Monica Pittarello, Marco Farina, Alberto Uberti, Danilo Demarchi, Jacopo Secco, Fernando Corinto, Elia Ricci. AI technology for remote clinical assessment and monitoring. *Journal of Wound Care*, 29(12):692–706, 2020.

[2] Ministero della Salute. Infezioni correlate all'assistenza: cosa sono e cosa fare, 2022. Available from: https://www.salute.gov.it/portale/malattieInfettive/dettaglioContenutiMalattieInfettive.jsp?lingua=italiano&id=648&area=Malattie%20infettive&menu=ica.

[3] World Health Organization (WHO). Global strategy on human resources for health: workforce 2030, 2023. Available from: https://www.who.int/publications/i/item/9789241511131.

[4] S. K. Patel, S. M. Surowiec. *Venous Insufficiency*. 2024. Available from: https://www.ncbi.nlm.nih.gov/books/NBK430975/.

[5] R. G. Frykberg, J. Banks. Challenges in the Treatment of Chronic Wounds. *Advances in wound care (New Rochelle)*, 4(9):560–582, 2015. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4528992/.

[6] Consiglio Regionale del Piemonte. Ulcere cutanee, cure piú facili, 2024. Available from: https://www.cr.piemonte.it/cms/articoli/comunicati-stampa/ulcere-cutanee-cure-piu-facili.

[7] Sara Becchi and Rosanna Cavazzana. Tecnologia e wound care: Woundviewer heal faster, live better, 2023. Available from: https://www.ilditonellapiaga.it/2023/11/17/tecnologia-e-wound-care-woundviewer-heal-faster-live-better.

[8] Meridiano Sanitá Sicilia. Digital health2030 - verso una trasformazione data-diven della sanitá, 2022. Available from: https://d1zl7bkpoemuu6.cloudfront.net/wp-content/uploads/2022/11/sanita-digitale-Digital-Healthcare-2030.pdf.

[9] A. Haleem, M. Javaid, R. P. Singh, R. Suman. Telemedicine for healthcare: Capabilities, features, barriers, and applications. *Sensors International*, 2:100–117, 2021. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8590973/.

[10] M. X. Jin, S. Y. Kim, L. J. Miller, G. Behari, R. Correa. Telemedicine: Current Impact on the Future. *Cureus*, 12(8), 2020. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7502422/.

[11] Alessandra Campanella. *Analisi dei processi di digitalizzazione nella sanitá: Il caso Wound Viewer*. Politecnico di Torino, Torino, 2019.

[12] Fei Jiang, Yong Jiang, Hui Zhi, Yi Dong, Hao Li, Sufeng Ma, Yilong Wang, Qiang Dong, Haipeng Shen, Yongjun Wang. Artificial intelligence in healthcare: past, present and future. *Stroke Vasc Neurol*, 2(4):230–243, 2017.

[13] V. Russo, M. Ciampi, M. Esposito. A Business Process Model for Integrated Home Care. *Procedia Computer Science*, 63:300–307, 2015. Available from: https://www.sciencedirect.com/science/article/pii/S1877050915024825.

[14] ServiceMed. Il Wound Care a domicilio: un percorso integrato per la gestione delle lesioni da pressione. Available from: https://www.servicemed.it/academy/.

[15] Istat (Istituto Nazionale di Statistica). Il paese domani: una popolazione piú piccola, piú eterogenea e con piú differenze, 2023. Available from: https://www.istat.it/it/files/2023/09/Previsioni-popolazione-e-famiglie.pdf.

[16] R. G. Sibbald, J. A. Elliott, R. Persaud-Jaimangal, L. Goodman, D. G. Armstrong, C. Harley, S. Coelho, N. Xi, R. Evans, D. O. Mayer, X. Zhao, J. Heil, B. Kotru, B. Delmore, K. LeBlanc, E. A. Ayello, H. Smart, G. Tariq, A. Alavi, R. Somayaji. Wound Bed Preparation 2021. *Advances in Skin and Wound Care*, 34(4):183–195, 2021. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4528992/.

[17] Jacopo Secco. Imaging and Measurement. 2017.

[18] S. Belgaonkar, V. Singh. Image Compression and Reconstruction in Compressive Sensing Paradigm. *Global Transitions Proceedings*, 3, 2022. Available from: https://www.sciencedirect.com/science/article/pii/S2666285X22000322.

[19] Y. Sun, J. Liu, K. Yu, M. Alazab, K. Lin. PMRSS: privacy-preserving medical record searching scheme for intelligent diagnosis in IoT healthcare. *IEEE Trans. Ind. Inf.*, 18(3):1981â1990, 2021.

[20] Lakshminarayana M, Mrinal Sarvagya. MICCS: a novel framework for medical image compression using compressive sensing. *International Journal of Electrical and Computer Engineering (IJECE)*, 8(5):2818–2828, 2018.

[21] Xun Wang, Hongbin Chen. A survey of compressive data gathering in WSNs for IoTs. *Wireless Communications and Mobile Computing*, 14, 2022.

[22] Z. Zhang, N. Zhou, B. Sun c, S. Banerjee, J. Mou. Multimedia healthcare cloud personal archives security system based on compressed sensing and multi-image encryption. *Journal of Franklin Institute*, 361(8):106844, year =.

[23] J. Liang, H. Peng, L. Li, F. Tong, S. Bao, Lanlan Wang. A secure and effective image encryption scheme by combining parallel compressed sensing with secret sharing scheme. *Journal of Information Security and Applications*, 75:103–487, 2023. Available from: https://www.sciencedirect.com/science/article/pii/S2214212623000716.

[24] Y. Fang, L. Li, L. Liu. Overview of Compressed Sensing: Sensing Model, Reconstruction Algorithm, and Its Applications. *Applied Sciences*, 10, 2020. Available from: https://www.researchgate.net/publication/343897062_Overview_of_Compressed_Sensing_Sensing_Model_Reconstruction_Algorithm_and_Its_Applications.

[25] A. Orsdemir, H.O. Altun, G. Sharma. On the security and robustness of encryption via compressed sensing. *In Proceedings of the IEEE Military Communications Conference*, pages 1–7, 2008. Available from: https://ieeexplore.ieee.org/document/4753187.

[26] L. Du, X. Cao, W. Zhang. Semi-fragile watermarking for image authentication based on compressive sensing. *Sci. China Inf. Sci.*, 59:1–3, 2016. Available from: https://link.springer.com/article/10.1007/s11432-016-5542-8.

[27] G. Hu, D. Xiao, T. Xiang, S. Bai, Y. Zhang. T. A compressive sensing based privacy preserving outsourcing of image storage and identity authentication service in cloud. *Information Sciences*, 387:132–145, 2017. Available from: https://www.sciencedirect.com/science/article/abs/pii/S0020025516309628.

[28] L. Li, Y. Fang, L. Liu, H. Peng, J. Kurths, Y. Yang. Overview of Compressed Sensing: Sensing Model, Reconstruction Algorithm, and Its Applications. *Applied Sciences*, 10(17):5909, 2020. Available from: https://doi.org/10.3390/app10175909.

[29] J. Zhang, C. Zhao, D. Zhao, W. Gao. Image Compressive Sensing Recovery Using Adaptively Learned Sparsifying Basis via L0 Minimization. *Signal Processing*, 103:114–126, 2014. Available from: https://www.sciencedirect.com/science/article/pii/S0165168413003873.