NOVA SCHOOL OF SCIENCE & TECHNOLOGY

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Bachelor of Science in Biomedical Engineering

MEDICAL DEVICES INFORMATION SYSTEMS IN PRIMARY CARE

MASTER IN BIOMEDICAL ENGINEERING

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Abstract

People who suffer from chronic diseases are becoming more involved in remote monitoring processes each year. The market acceptance of remote care programmes, connecting patients through medical devices as part of the treatment regime, is spreading worldwide. Healthcare providers use medical devices to monitor, in various ways, the chronically ill population, namely people with diabetes and hypertension. However, most hospital and service provider information systems do not conform to the same important data standards, making interoperability and information sharing difficult.

In this sense, the Multimorbidity Health Information System (METHIS) project is a multidisciplinary, goal-oriented, design-science-based intervention aiming to improve physician-patient communication and patient engagement. It focuses on multimorbidity and ageing, encompassing patients with more than one chronic disease and over 65 years old. The proposed solution is a Clinical Medical Devices Information (CMDI) system and data model which contains standardised information about chronic patients, medical devices and other data sets to be included in the METHIS System. With this framework, the system can perform consistently and reliably while meeting all relevant regulatory requirements or standards. Based on this dissertation and the METHIS project's complementary work, implementing the CMDI in various Family Health Unit (FHU) in Portugal will make it possible to combat the diversity and loss of telemonitoring information.

Keywords: Primary Health Care, Medical Devices, Digital Transformation, Health Information System

Resumo

A cada ano, os doentes crónicos estão mais envolvidos em processos de telemonitorização. A aceitação pelo mercado de programas de cuidados à distância, ligando doentes através de dispositivos médicos como parte do regime de tratamento, está a espalhar-se por todo o mundo. Os prestadores de cuidados de saúde utilizam dispositivos médicos para monitorizar, de várias formas, a população cronicamente doente, nomeadamente as pessoas com diabetes e hipertensão arterial. No entanto, a maioria dos sistemas de informação dos hospitais e prestadores de serviços não estão em conformidade com as mesmas normas, o que dificulta a interoperabilidade e a partilha de informação.

Neste sentido, o projeto METHIS é uma intervenção multidisciplinar, baseada em *Design Science*, que visa melhorar a comunicação entre médico e doente e o envolvimento do mesmo. Tem como foco a multimorbidade e o envelhecimento, englobando doentes com várias doenças crónicas e com idade superior a 65 anos. A solução proposta é um sistema e o correspondente modelo de dados CMDI que contém informação padronizada sobre doentes crónicos, dispositivos médicos e outros conjuntos de dados a serem incluídos no Sistema METHIS. Com este modelo de dados, o sistema possui a informação para poder funcionar de forma consistente e fiável, cumprindo todos os requisitos ou normas regulamentares relevantes. Com base nesta dissertação e no trabalho complementar do projeto METHIS, a implementação da base de dados CMDI em vários Unidades de Saúde em Portugal tornará possível combater a diversidade e a perda de informação na telemonitorização.

Palavras-chave: Cuidados de Saúde Primários, Dispositivos Médicos, Transformação Digital, Sistema de informação sobre saúde

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Abbreviations

ADA American Diabetes Association 5

BGM Blood Glucose Monitor 26–28

CE Conformitè Europëenne ix, 10, 12, 13, 29
CGM Continuous Glucose Monitor 26–28, 53
CMDI Clinical Medical Devices Information iv, v, ix, 31, 34, 35, 42, 44, 47, 51, 52, 55–62
CPU Central Processing Unit 14

DGS *Direção Geral da Saúde* 6
DH Digital Health 6, 7
DSRM Design Science Research Methodology ix, 3, 30, 35

EC European Commission 29
EHR Electronic Health Record 6, 22, 61
EMA European Medicines Agency 10, 12, 62
EU European Union ix, 10–12, 24, 28, 29, 47
EUDAMED European Database for Medical Devices 28, 29, 47

FDA Food and Drug Administration 11, 47, 49, 52, 62
FHU Family Health Unit iv, 33, 52, 56–60

GDPR General Data Protection Regulation 34, 42

HCIS Health Care Information System 6

ICD International Classification of Diseases 44

ICD-10-CM International Classification of Diseases, 10th Revision, Clinical Modification 44, 45

ICD-10-PCS International Classification of Diseases, 10th Revision, Procedure Coding System 44–46

ICD-9-CM International Classification of Diseases, 9th Revision, Clinical Modification 44, 45

ICT Information and Communication Technologies 1

IoT Internet of Things 7, 36

IS Information Systems 30, 59

ISO International Standards Organization 12, 13, 42–44, 47, 49–52, 62

IT Information Technology 19, 59

IVD In Vitro Diagnostic Medical Device 9, 11, 12, 23, 29, 35, 47

MCS Mental Component Summary 38, 39, 41, 54

MDR Medical Devices Regulation 12, 13

METHIS Multimorbidity Health Information System iv, v, 2, 31, 33–36, 56, 57, 59–62

NCDs Noncommunicable diseases 3, 4

PCS Physical Component Summary 38, 39, 41, 54

PHC Primary Health Care 3, 31, 34, 55, 56

PII Privacy and Personally Identifiable Information 19, 59

SF-12 12-Item Short Form Survey 37, 38, 76

SF-36 36-Item Short Form Survey 37

SIDM *Sistema de Informação para Dispositivos Médicos* 28, 29

SNS *Serviço Nacional de Saúde* 7, 43, 44, 52, 62

SONHO *Sistema Integrado de Informação Hospitalar* 38

UDI Unique Device Identifier ix, 47, 48, 53, 62

USA United States of America 11, 24, 44

WHO World Health Organization 8, 43, 44, 51

1 Introduction

The introductory chapter views the global analysis and context of the field of study in question. To better understand this study, we present below this dissertation's motivation and main goal.

1.1 Motivation

Health systems face two significant challenges, the digital transformation of supply to increase access and to tackle the ageing of populations: the longer people live, the more medical resources must be committed to sustaining their healthy lifestyles, which increases costs. Health systems are seeking to reduce the demand for hospital beds by shortening the lengths of hospital stays and offering more health care outside the acute sector. The critical area may also be geographically concentrated in larger cities, which increases the potential demand for primary health care services [2].

The healthcare industry has encountered significant problems related to health efficiency that require proper solutions. These difficulties are due to increasing costs, systematic process failures, poor quality of care, and a lack of patient-specific treatment. The lack of healthcare staff and resources has often resulted in longer work hours and burnout among healthcare professionals [3].

The digital transformation of health services is not an easy task. It requires a proper organisation of health services to respond to citizen demand, especially regarding Universal Healthcare Coverage Primary Health Care. The use of Information and Communication Technologies (ICT) shows considerable growth in the health sector. ICT applications include devices and equipment that have software. Originally, ICT was mainly used in larger healthcare organisations, but nowadays is found in all healthcare sectors. Applications and devices that use many information and communication technologies, including embedded software, are now widely available in hospital clinics and the homes of patients and clients.

Therefore, healthcare providers are starting to use medical devices to monitor, in various ways, the chronically ill population or even to monitor, at the patient's home,

the evolution of some acute conditions or in post-operative follow-up. Today, many patients are advised to monitor, for example, their blood pressure and glucose level with the help of medical devices in their houses [4]. Citizens are challenged to be active and interested partners in what concerns them, and it is within their power to do so. The role of technology is increasingly relevant in helping to transform for the better the ability to diagnose and treat many diseases, reducing rehabilitation times and also the respective costs. Biomedical Engineers are among the significant professionals responsible for their design, development, regulation, assessment, and training in their use [5].

1.2 Main Goal

This study proposes a model for developing a medical device information system architecture and the corresponding data model to improve communication between patients at home and medical staff. This work is part of the METHIS Project, which will be further explored in chapter 5.

It is essential to mention that, even though the described topic may be studied in the management field, interpreting it from the perspective of Biomedical Engineering through Hospital Management will provide significant advantages to both the system and the patient.

2

Theoretical Concepts

This section discusses the related work and the theoretical foundation required for the thesis. This will be used as input for the formulation of the solution's objectives, design and development, and DSRM demonstration processes.

2.1 Primary Health Care

Primary Health Care (PHC) focuses on persons rather than diseases and covers physical, psychological, and social well-being. It is the initial step in a continuous process of putting health care as close to people's homes and workplaces as feasible, as it provides promotional, preventative, curative, supporting, and rehabilitative services. By providing therapy in and through the community, PHC addresses personal and family health issues, the more significant public health problem, and the needs of specified groups [6, 7].

2.1.1 Chronic Diseases

Noncommunicable diseases (NCDs), also referred to as chronic diseases, are caused by a combination of genetic, physiological, environmental, and behavioural variables. NCDs are classified into four main types [8]:

- Cardiovascular diseases;
- Cancers;
- Chronic respiratory diseases;
- Diabetes.

Many other conditions of public health importance are closely associated with the four major noncommunicable diseases, such as [9]:

- Other noncommunicable diseases (renal, endocrine, neurological, haematological, gastroenterological, hepatic, musculoskeletal, skin and oral diseases and genetic disorders);

- Mental disorders;
- Disabilities, including blindness and deafness;
- Violence and injuries.

NCDs affect people of all ages, from all sorts of backgrounds, and all countries. These diseases are usually connected to the elderly. However, data indicates that more than 15 million NCDs-related deaths occur between 30 and 69. It is estimated that 85% of premature deaths occur in low and middle-income countries. Children, adults, and the elderly are all vulnerable to the risk factors contributing to NCDs, such as poor food, inactivity, cigarette smoke exposure, and excessive alcohol usage [8].

High blood pressure, high blood glucose, high blood lipids, and obesity can all be caused by a poor diet and insufficient physical exercise. These metabolic risk factors can contribute to cardiovascular disease, the leading cause of mortality. Metabolic risk factors cause four significant metabolic abnormalities that enhance the risk of NCDs:

- High blood pressure;
- Overweight/obesity;
- Hyperglycemia (high blood glucose levels);
- Hyperlipidemia (high levels of fat in the blood).

Increased blood pressure is the most significant metabolic risk factor in attributable fatalities worldwide, followed by overweight and obesity and elevated blood glucose [8].

2.1.2 Reference Values

A reference range or reference interval in health-related professions is the range or interval of results judged normal for a physiological measurement in healthy people. It serves as a reference point for a physician or other health professional interpreting a collection of test findings for a specific patient.

When blood pressure is measured, it is assigned two numbers: a top and a bottom. The first is systolic blood pressure, the maximum amount of blood pressure reached when the heart is pumping and forces the blood around the body. The other one is diastolic blood pressure, the lowest blood pressure level while the heart relaxes between pulses. Millimeters of mercury is used to measure blood pressure (mmHg). If the first number is 120 and the second is 80, this is expressed as 120/80mmHg, often known as ”120 over 80” [10].

- **140/90mmHg or over** – the threshold for detecting hypertension (high blood pressure). This is the stage at which the danger of severe health problems increases. Physicians may prescribe medication and advise patients to make lifestyle changes, like practice more physical activity.

- **120/80mmHg up to 140/90mmHg** – pre-hypertension, often known as high-normal blood pressure. This indicates the patient may develop high blood pressure in the future, even though it is still not considered hypertension.
- **90/60mmHg up to 120/80mmHg** – normal blood pressure. At this level, it is very difficult for the patient to develop heart disease and stroke.
- **90/60mmHg or lower** – low blood pressure. Sometimes the patient may feel dizzy and it can be a sign of other health problem. But usually it is not a problem [10].

The majority of blood glucose monitors uses mg/dL. The normal values for a person without diabetes are [11]:

- **70-99 mg/dL (3.9–5.5 mmol/L)** - when fasting.
- **Less than 140 mg/dL (7.8 mmol/L)** - 2 hours after eating.

The Official American Diabetes Association (ADA) recommendation for non-pregnant adults with type 1 or type 2 diabetes [11]:

- **80-130 mg/dL (4.4–7.2 mmol/L)** - when fasting.
- **Less than 180 mg/dL (10.0 mmol/L)** - 2 hours after meals.

2.2 Health Systems

Health systems include all associations, institutions, and resources committed to producing health actions. An endeavour to enhance health, whether via personal health care, public health services, or intersectoral activities, is classified as a health action [12].

Although the primary goal of a health system is to enhance health, other inherent goals include being responsive to the people served. This responsiveness is influenced by how individuals are treated and the environment where they live, and it should guarantee that the financial responsibility of paying for health care is spread. National health system efficacy, efficiency, and equity are significant determinants of population health status [13].

Several variables determine how health care systems effectively accomplish good health. These determinants include the competence of persons and organisations within health systems, the capacity to grab chances, and contextual qualities like path-dependency, socio-cultural views, economic set-up, and the country's history. However, establishing a connection between optimal health and effective healthcare systems, differentiating health systems from other health determinants, and understanding how health systems are linked to good health have proven challenging. Another problem is determining how to bring innovations into healthcare systems successfully and how these innovations interact with healthcare system characteristics to impact health outcomes [14].

2.3 Health Information Systems

A ”system” is a connected whole or an ordered process that works together to achieve a mutual goal. In the case of health information systems, the goal is to improve health care administration by providing appropriate information assistance. ”Information” is defined as a collection of facts or data. Most national health information systems lack such cohesiveness, having evolved gradually in response to administrative, economic, regulatory, or donor demands, and are generally exceedingly complicated [15, 16].

Processes, people, and information technology work together and make a Health Care Information System (HCIS) to give health-related information to a health care organisation. Computer applications are required in health care companies to assist both clinical and administrative procedures. An Electronic Health Record (EHR) system integrating clinical and administrative applications is central to HCIS in hospitals and most physician office-based practices [17].

Good management is required to improve the efficiency of healthcare services. The need to achieve more with less is especially pressing in the health sector, dealing with ever-increasing demands while getting static or falling resources. The challenge for health systems is to maximise service delivery management to avoid ineffectiveness losses [16].

The health information systems consist of four core functions: data creation, compilation, analysis, communication and usage. The health information system collects data from the health sector and other professional fields, analyses it to ensure quality, applicability, and availability, and translates it into information for health-related decision-making [18].

2.3.1 Standardisation

The first and most crucial stage in developing a HCIS is standardisation to enable information to be shared effectively and efficiently. Any National HCIS Strategy success relies on deploying information standards. A standardised information system performs consistently and reliably while meeting all relevant regulatory requirements or standards.

Standardised information is of crucial importance in the use of EHR. Most hospital and service provider information systems do not adhere to the same standards, making interoperability and information exchange hard. Health authorities record and process the same data differently because there is no national framework for defining and adopting information standards. Different health systems must record data in the same manner since the nature of health information is very diverse [19].

2.4 Digital Health

Digital Health (DH) is a term that refers to the junction of healthcare and digital technologies [20], and it is used to improve healthcare organisations and provides a new type of care services with more efficiency and quality. The *Direção Geral da Saúde* (DGS) of

Portugal, for example, developed the *Serviço Nacional de Saúde* (SNS) 24 application to provide consumers with digital health information and services such as vaccines and medication subscriptions [21].

We can divide DH into digital patients, devices, and clinics. Digital patients use mobile health devices to change and sustain their behaviour, including telemedicine, patient self-measurements, and digital retention [22]. Digital devices, which range from telehealth and telecare systems to patient portals and personal health records, mobile health applications, and other online platforms and devices, aid in the resolution of clinical problems [23–25]. The digital clinic aspect focuses on generating mHealth data, analysing it clinically meaningful, and incorporating it within clinical workflows [22].

2.5 Internet of Things

The Internet of Things (IoT) is defined as "the network of physical objects which are supported by embedded technology for data communication and sensors to interact with both internal and external objects states and the environment" [26]. IoT has become almost ubiquitous, in our homes, in every shopping center, motorways and our cars, using both the fiber-network and the mobile network.

The benefits and beneficial impacts of the IoT in healthcare are numerous socially and financially accessible [27]:

- Patient comfort increases, which leads to improved patient satisfaction and shorter recovery times.
- IoT healthcare devices, wearable technology, and data access enable physicians to better monitor patients and provide more informed therapy.
- IoT security technologies make patients, physicians, and employees safer.
- UV light sanitation systems assist in keeping surroundings clean and people healthy.

We will see healthcare facilities becoming more advanced as IoT increases and devices continue to evolve, allowing better health results, improved patient and visitor experiences, and improved working conditions for professionals [28]. Indeed, while technology cannot prevent population from ageing or completely eradicate chronic diseases, it can make healthcare more socially and financially accessible [27]. Therefore, the healthcare services can improve the access to care by leveraging the IoT network.

2.6 Medical Devices

In an era of information, medical devices are becoming a vital part of Health Systems and include all health technology used for medical reasons [29, 30]. They're an essential element of the healthcare and medical industries because they're utilised to diagnose,

prevent, and treat various diseases and disorders. They can also support chronic disease monitoring [30, 31]. Without medical devices, normal medical operations would not be possible, from bandaging an injured ankle to measuring blood glucose levels, implanting an artificial hip, or any surgical intervention [31].

An estimated two million different types of medical devices are on the market today, divided into over 7,000 different generic device groupings (Figure 2.1) [31]. The World Health Organization (WHO) classifies medical equipment into the following categories:

- Single-use devices (e.g. syringes or catheters);
- Implantable (e.g. pacemakers);
- Imaging (e.g. ultrasounds);
- Medical equipment (e.g. haemodialysis machines);
- Software (e.g. computer-aided diagnostics);
- In vitro diagnostics (e.g. glucometer);
- Personal protective equipment (e.g. mask and gloves);
- Surgical and laboratory instruments;

The construction and design of medical equipment are critical for patient safety [29]. By utilising sensors with higher precision, lower power consumption, and digital output, they are becoming smaller, more intelligent, accessible, and produced at cheaper costs.

Sensors included in medical devices improve patient comfort, enhance the effectiveness of healthcare personnel, and save healthcare costs. Pressure, force, airflow, oxygen, pulse oximetry, temperature, and barcode sensing are the most common sensors found in medical equipment [27].

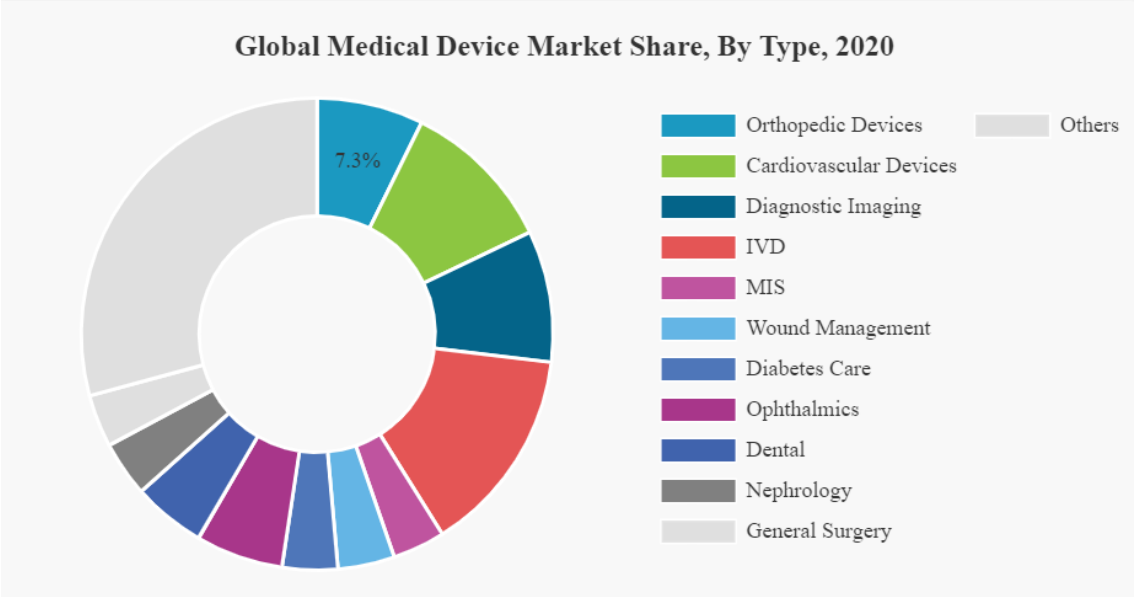

Figure 2.1: Global medical devices market [32].

2.6.1 In Vitro Diagnostic Medical Devices

In Vitro Diagnostic Medical Device (IVD) is a medical device that, individually or in combination, is designed by the manufacturer for the in vitro analysis of samples generated from the human body to give information for diagnostic, monitoring, or compatibility reasons [33].

Furthermore, they enable the rapid examination of biological products, like blood, urine, or saliva. The findings are shown in minutes via a simple interface, eliminating the need for costly equipment or costly maintenance or accreditation processes.

The risk categorisation of IVD is based on a risk to both individual and public health, taking into account:

- The specific disorder, condition, or risk factor of interest that the IVD is intended to detect or define;
- The intended user;
- The importance of the information to disease diagnosis, screening, monitoring, or staging [33];

For example, a continuous glucose monitor is a Class C IVD which gives a glucose reading to the patient every 5 minutes. The device consists of a sensor, a transmitter, and a receiver. The sensor, generally a tiny wire or filament with a glucose oxidase coating on one end, is inserted under the patient's skin and the interstitial glucose level is measured. When the glucose oxidase combines with the glucose in the interstitial fluid, an electrical signal is produced. This signal is transmitted to a phone or receiver, and an

alert will sound if the blood sugar level (high or low) has to be corrected. Furthermore, the continuous glucose data may be kept on the cloud, allowing a patient or caregiver to undertake a visual pattern analysis to evaluate insulin quantity modifications for the patient [34].

2.6.2 Wearables

Wearables are health-related devices, real-time and non-invasive, used in direct contact with the body and allows the continuous monitoring of an individual's activities without interrupting or limiting the user's motions, providing clinically relevant data, like heart rate, oxygen levels, and blood pressure [35].

These devices have sensors and send data to smartphones or other devices via a wireless connection. They are being employed in the healthcare business to help clinicians collect, evaluate, and leverage patient data for clinical trials while enhancing patient care and overall quality of life [36]. In addition, it allows health care providers to monitor patients after therapeutics or treatments.

Wearable biosensors are biological sensors connected to a person's body and provide a function that sets them apart from existing technologies regarding mobility, convenience of use, and environmental adaptation [37–39]. They include watches, clothing, bandages, glasses, contact lenses, and rings. They have evolved in accessories, integrated clothes, body attachments, and body insertions [40, 41].

2.6.3 Classification

Before applying for Conformitè Europëenne (CE) marking certification, a medical device manufacturer must identify the class of its medical device technology to establish the applicable requirements. European Union (EU) categorises devices based on their duration, the extent of contact with the body while in use, and whether they are "active". It also distinguishes devices used in the central cardiovascular and central nervous systems from other devices because they may be riskier [42].

Applying all medical equipment to the most stringent CE certification requirements is impractical. This classification offers the advantage of arranging devices based on the likelihood that they may cause harm [43]. As a result, device classification reflects the number of possible hazards of a device, and its objective is to direct the device into the appropriate evaluation method for approval.

In the EU, within European Medicines Agency (EMA), medical devices are classified into the following classes: I, IIa, IIb, and III, based on their intended use and inherent dangers (Figure 2.2). Furthermore, Class I devices can be separated into Is – sterile state, Im – measurement function, and Ir – reusable surgery [44].

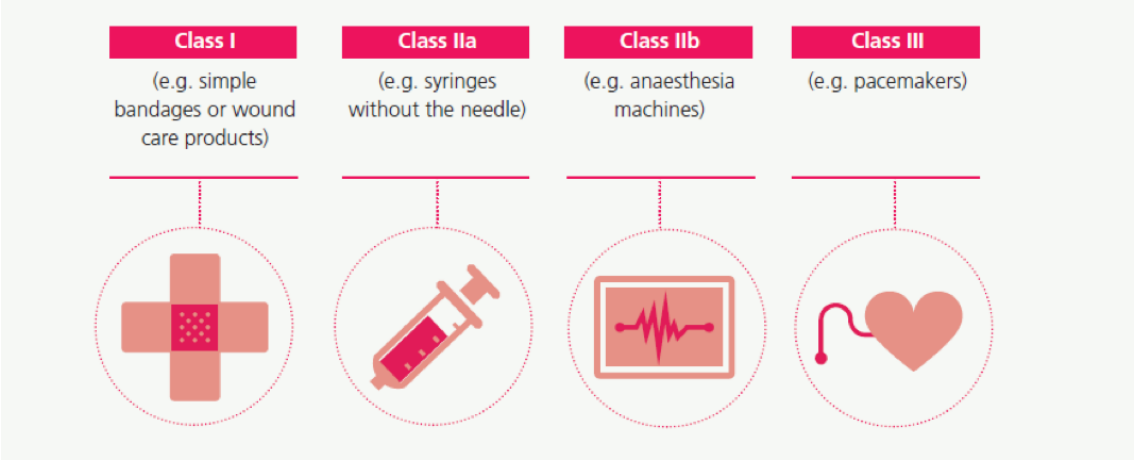

Figure 2.2: Medical device classification in the EU [45].

IVD are categorised into classes A, B, C, and D, considering the intended purpose of the devices and their inherent dangers, as shown in Figure 2.3 [44].

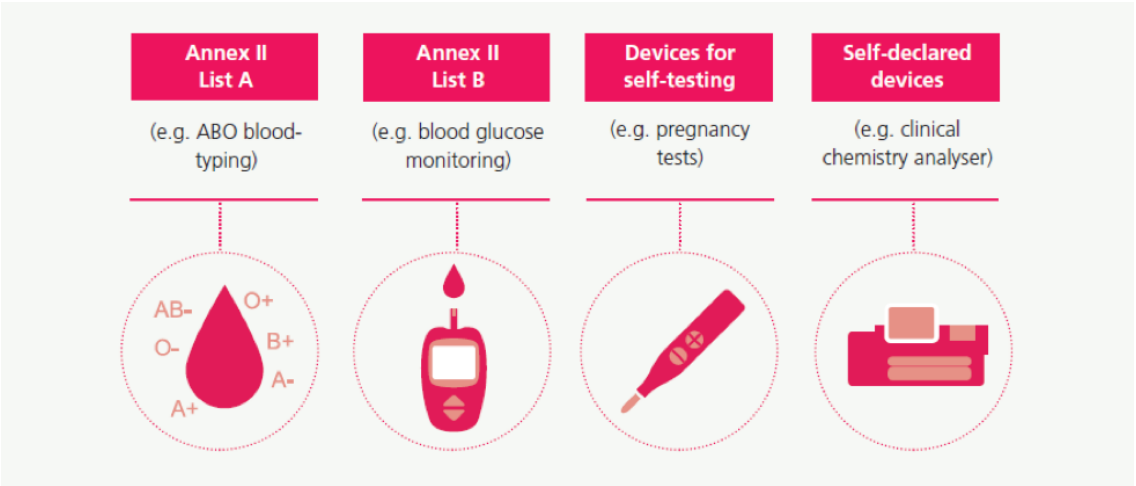

Figure 2.3: In vitro diagnostic medical device classification in the EU [45].

For example, Class IIb includes all the medical equipment for continuous monitoring of vital physiological parameters under anaesthesia, intensive care, or emergency care. In contrast, class IIa is intended for medical devices used in routine checks or self-monitoring. Respiration, heart rate, brain functioning, blood gases, blood pressure, and body temperature are all vital physiological processes and characteristics.

On the other hand, in the United States of America (USA), medical devices are regulated by the Food and Drug Administration (FDA). Those not approved for sale could be used for clinical research in the USA under the Investigational Device Exemptions regulation. The FDA divided medical devices into Class I, Class II, and Class III classes. The risk decides which categories the medical device gives to the patient and the level of regulatory control necessary by the FDA to market the device legally [46].

2.6.4 Regulation

Medical devices are regulated at the EU Member State level, but the EMA is involved in the regulatory process. The Medical Devices Regulation (MDR) (EU 2017/745) and IVD Devices regulation (EU 2017/746) changed the European legal framework for medical devices, introducing new responsibilities for EMA and competent national authorities in the assessment of specific categories of the medical device [47]. According to the MDR, medical equipment may only be sold on the European market if they have the CE mark (Figure 2.4). CE means the product complies with European legislation applicable to that specific product group. To receive a CE mark for a medical device, the manufacturer or developer must demonstrate that the standards of European medical device legislation, known as the MDR, are satisfied. The MDR, for example, specifies the device's and its manufacturing processes' safety and performance standards. The medical device maker or developer must have suitable quality assurance methods, such as a quality management system. This process involves the EMA [48].

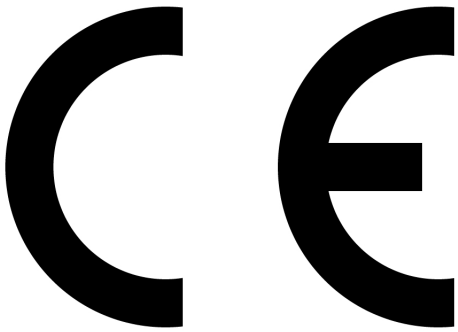

Figure 2.4: CE marking [49].

International Standards Organization (ISO) 13485 is an international standard for medical device makers, suppliers, and distributors. It establishes a quality management standard and is meant to meet the legislative requirements for medical devices. Overall, ISO certification demonstrates that a company can continuously assess and improve its processes, goods, and services. ISO certifications are only valid at the organisational level, not at the product level (whereas the CE mark applies at the product level). To achieve ISO certification, the organisation must fulfil all of the ISO standards. Because ISO certification is optional, acquiring an ISO 13485 certification is not required to comply with the MDR. It may, however, help comply with it [50].

The MDR's primary criteria are that the manufacturer builds and maintains a quality management system. This is necessary for the medical equipment manufacturer to get CE marked finally. A quality management system of this sort, which must be adequate and proportionate to the risk categorisation and type of medical equipment, guarantees that

the device, design, and manufacturing procedures are high quality. Although ISO 13485 certification is not required, following this standard is advised to verify that the quality management system is adequate. The producer must undergo a conformity assessment procedure to comply with the MDR standards and get a CE mark for the medical device. This approach requires self-certification (Class I) or examination by an independent third party: a Notified Body, depending on the risk class of the medical device (Class IIa or higher). The European Commission has selected notified organisations to carry out MDR conformity evaluations. Following the successful completion of such a procedure, the medical equipment conforms with European rules and regulations and may be supplied on the European market with a CE mark [51].

2.7 Sensors

A sensor is a device that detects and responds to a signal or stimulus with an electric signal. There are different types of sensors that range from applications in medicine to fire detection. Medical sensors are used to diagnose, monitor, or treat disorders in the medical area. For example, in blood pressure measurement, a pressure sensor, mainly used in the oscillometric method, can determine the pressure in the cuff using the air as a medium for pressure transmission [52].

2.7.1 Constitution

The main components of a sensor node are a microcontroller, transceiver, external memory, power source and one or more sensors. Sensor nodes employ their sensors to detect changes in current circumstances in their surroundings. The ADC unit converts these measurements into relative electric signals, which the node's processor then analyses. The node wirelessly sends the data through its transceiver to other nodes or a base station. From this point, it may transfer any necessary information to an external database or a cloud storage provider [53, 54].

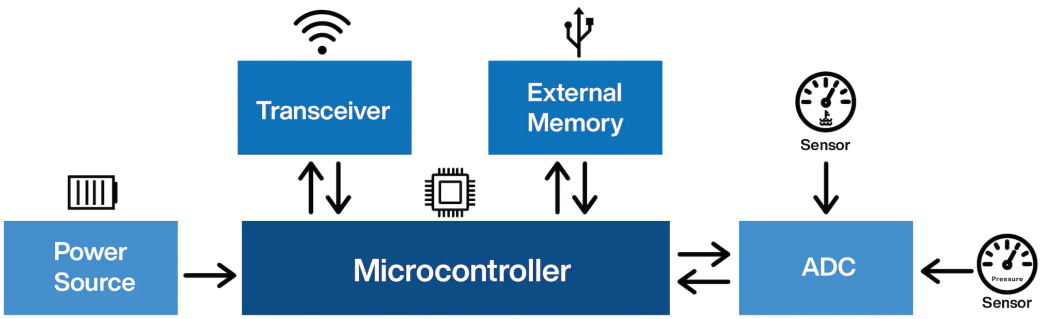

Figure 2.5: Architecture of a sensor node [55].

A microcontroller is an integrated circuit that includes a processing core, memory, and related circuitry and regulates various operations of electronic devices or systems. It is responsible for processing data and regulating the activities of the other components in sensor nodes. They must include an appropriate instruction Central Processing Unit (CPU), with minimal power consumption to ensure quick processing time, several hardware interfaces, memory, and a wake-up time [56].

To keep prices low and prevent additional components from being added to the already constrained area, the maximum number of possible interfaces must be on a microcontroller. Its power operation is low, in the house of milliwatts, and can enter standby mode. These microcontrollers are expected to reach nanowatts, considering them ideal for applications where a low power consumption requirement is a decisive factor [57].

A transceiver is a radio transmitter-receiver that uses many of the same components for a node to receive and send data from another node as needed. It has four operating states: transmit, receive, idle, and sleep. In the idle state, the node is waiting for a signal, but it does not receive any. Transceivers are classified into radio-frequency, fibre-optic, ethernet and laser. These are different, but the functioning remains the same. Each type has its characteristics, like the number of ports accessible for connecting the network [58]. Since one of the major faults with sensor nodes is energy consumption, the laser is a popular alternative because it consumes less power, does not require an antenna, and is secure. However, the simplest to utilise is RF, which requires an antenna [57].

One of the most pressing concerns confronting sensor networks is power usage. Communication needs a more significant amount of electricity than sensing or computation. Because it would be hard to change the battery in a hostile environment, two types of batteries are employed, chargeable and non-chargeable [57]. There are several different types of batteries available for wireless sensor nodes. Several parameters should be addressed while evaluating different battery technologies. Some examples are the energy density, cycle life, environmental effect, safety, cost, available supply voltage, and charge/discharge characteristics [59].

A recent study compared various types of batteries, as next demonstrated [60]. Nickel-cadmium batteries deliver strong currents at a reasonably constant voltage and can withstand high discharge rates without sacrificing battery capacity. The critical distinction between nickel-metal hydride and nickel-cadmium batteries is that the former keeps its characteristics after several recharges. It may also be employed in high-temperature environments because of its wide working temperature range. Alkaline batteries are the most commonly used in wireless sensor networks because they are inexpensive, readily accessible, and excellent for low current applications at room temperature. Their service life, for example, is 5 to 6 times that of zinc-carbon batteries. Lithium batteries are a newer technology with high specific energy, long cycle life, and no memory effect. They have been widely used in electronic devices, including mobile phones, hearing aids, and laptop computers. These batteries have greater voltages and larger flat areas at all discharge rates. Furthermore, it was discovered that the thermal effect of increased discharge rates

on lithium batteries is minimal, making them the optimum choice for these applications [59, 60].

An operating system must control processor time to ensure that each program receives its fair share. Multiple activities concerning each other may occur concurrently in a sensor network node [61]:

- Sensor readings are collected from onboard sensors.
- They are processed by the microcontroller and possibly stored in secondary storage before being transmitted over the communication device.
- Communication from neighbouring nodes is received and forwarded to other nodes.
- Timed events occur.

The operating system must manage this concurrency in a way that is both resource-efficient and simple for the system developer to grasp. In order to reduce power consumption, when no application is active, the CPU goes into sleep mode. The operating system must handle the limited resources effectively while offering a programming interface, allowing system developers to construct resource-efficient software [61].

Several operating systems have been created in the sensor network research community, each presenting a unique solution to the fundamental challenges. TinyOS and Contiki are two of the most well-known operating systems. TinyOS's programming language, nesC, is an extension of the C programming language. Contiki, on the other hand, uses conventional C [61].

The most utilised communication in sensor networks are ZigBee, Wi-Fi, and Bluetooth 4.0 [62]. ZigBee is a specification for high-level communication protocols based on an IEEE 802 standard. Because of its speedier, more flexible, and scalable networking characteristics, a sensor network equipped with an IEEE 802.15.4 Zigbee radio protocol is superior to Bluetooth with an IEEE 802.15.1 radio protocol. The most important aspect is that Zigbee uses less energy, processing, and memory resources [63]. It also benefits from its ultra-low power sleep mode and short wake-up periods [64].

The IEEE 802.15.4 standard, which specifies the physical and MAC layers for low-cost, low-rate personal area networks, is the foundation for ZigBee. ZigBee defines network layer standards for the star, tree and mesh topologies and provides an application layer framework for programming. In the star topology, for example, communication is established between devices and a single central controller, called the PAN coordinator. The PAN coordinator may be mains powered, while the devices will most likely be battery powered [65].

2.7.2 Characteristics

In this subsection, a set of sensor specificities are presented:

- Accuracy is a sensor's capacity to deliver a correct measurement, i.e., the most significant difference between the actual value and the displayed value at the sensor's output. It can be stated as a percentage of the full scale or in absolute terms and is influenced by a combination of systematic and random influences, contributing to the overall measurement error [66]. It is the degree of closeness of the measurements to the target.

- Precision is often referred to as repeatability and reproducibility error, which is the degree of closeness of the measurements with each other. Repeatability measures a stage's ability to position itself consecutively to the same objective value. In other words, it is the capacity to deliver a consistent output when there is a constant input [67].

- Reproducibility is a measure of whether the findings in a study can be replicated by another research team using the same procedures [68].

- Linearity refers to how closely the sensor's response curve resembles a straight line. The more linear the sensor's output, the easier it is to calibrate, and the less uncertainty there is in its output scaling [69].

- The sensor's sensitivity is defined as the slope of the output characteristic curve or, more broadly, the minimal physical parameter input required to produce a discernible output change. The sensitivity of various sensors is defined as the change in input parameters necessary to create a standardised output change. Others describe it as a change in output voltage for a given change in the input parameter.

- Environmental changes might influence a sensor's performance and accuracy. Some sensors, for example, are susceptible to temperature, humidity or pressure [70]. In this sense, defining the threshold values for the device's proper functioning is necessary.

2.8 Digital Transformation

Digital Transformation is incorporating digital technology into all business domains and adopting digital solutions over manual solutions, significantly changing how value is operated and supplied to customers [71]. This transition necessitates organisations to manage their evolution, engage with people, and alter how employees work and think [72]. In summary, Digital Transformation can be defined as "a process that aims to improve an entity by triggering significant changes to its properties through combinations of information, computing, communication, and connectivity technologies" [72]. In order to put this transformation into practice, the Momentum Framework is explained below.

2.8.1 Momentum framework

Telehealth is becoming increasingly important as technology progresses. However, most existing healthcare systems are not yet ready to include telemedicine in regular care. In this sense, the Momentum Framework is a Digital Transformation framework designed to aid the introduction. This framework outlines a set of rules for developing an action plan to assist in implementing telehealth in existing systems, encompassing the Context, People, Plan, and Run areas [73]. Aside from these fields, the Momentum may be divided into four categories: strategy, organisation, legal and security, and technology.

The following paragraphs list the eighteen essential success elements, split by their domains [73]. Because the Context domain is the most important of the four regions, it should be the first thing to come to mind. It discusses the context in which the telemedicine service will be integrated and everything associated with it. The Context area consists of the following factors:

1. Ensure cultural readiness for the telemedicine service.

   It is about ensuring that the community is ready to receive the telemedicine service and creating measures. This readiness must be assessed regarding convictions and perceptions, attitudes and norms, values, and present requirements.

2. Come to a consensus on the advantages of telemedicine in meeting a compelling need.

   This need must be identified with the help of all the stakeholders involved in the project. The consensus should be not only about identifying the need but also about the recognition and agreement on the benefits of telemedicine to each necessity.

   The People area describes leadership, stakeholder involvement, patient-centeredness and user-friendliness. This domain includes the following factors:

3. Ensure leadership through a champion.

   It is crucial to have a champion or team of champions who believe in the value and feasibility of the telemedicine service and who invest effort and energy in its progress. Someone who has power or influence in the organisation or healthcare system, can establish trust at all stages, has appropriate information, connections, and relationships, has credibility or a track record is a champion.

4. Involve healthcare professionals and decision-makers.

   This involves ensuring that healthcare professionals and decision-makers work together to design, embrace, and support the changes imposed by the new telemedicine service. This may be pretty valuable since acquiring their acceptance and feedback will allow to develop the service and effectively handle adoption hurdles.

5. Put the patient at the centre of the service.

It is essential to have the patient's perspective in mind while developing the new telemedicine service. This will improve their adherence to the medical indications, resulting in better healthcare services.

6. Ensure that the technology is user-friendly.

   For all telemedicine service customers, user-friendliness includes simplicity, responsive design, usability, fit for purpose, cost-effectiveness, ease of understanding, ease of use, and dependability. These characteristics will help people to accept the technology readily.

   The Plan area supports a description of resource collection, primary consumer, business plan, change control, legal and security requirements and potential for scale-up. This domain consists of the following factors:

7. Pull together the resources needed for deployment.

   In this context, resources include funding, people, information, and time, as well as the tools to create, launch, and operate the telemedicine service.

8. Address the needs of the primary client(s).

   It is essential to understand and address the primary client(s) needs to shape the telemedicine service according to it. A primary client could be the leading partner who is actively involved in the service's launch or the creation of the telemedicine tool, a direct or indirect payer of the service, or individuals or groups whose needs should be recognised by the telemedicine doer.

9. Prepare and implement a business plan.

   A business plan is a data analysis and description of the planned telemedicine service, in which the paying customers, the revenue model, the customer value proposition and service levels, existing solutions, competitive advantage, any obstacles that must be overcome, and the resources required are all described.

10. Prepare and implement a change management plan.

    A change management plan should be designed together with the business plan. It enables healthcare professionals to understand and accept the changes in their daily routines. It includes information about an explanation of the reasons for the changes, the addition of extra resources during the transition phase, or the support for the telemedicine service to be located in an appropriate position within an existing care pathway, for example.

11. Assess the conditions under which the service is legal.

    This means understanding if the telemedicine service is regarded by the authorities as an appropriate way to offer healthcare services if the circumstances under which it is regarded as legal by carrying out what is called a legal risk assessment, if it

is covered by law or if it is not inhibited by law or by bodies with competence in the telemedicine field, and if it is in accordance with general requirements for best practice in medicine.

12. Guarantee that the technology has the potential for scale-up.

    Taking into account what actions are needed to transform the telemedicine service from a pilot project to deployment will avoid causing bottlenecks at a later stage. This can be achieved, for example, by using standard technologies or similar technologies.

    The Run area is about managing or operationalising a telemedicine service. It describes legal and security guidelines, legal and security experts, privacy awareness, Information Technology (IT) and eHealth infrastructure, service monitoring and market procurement. This domain comprises the following factors:

13. Identify and apply relevant legal and security guidelines.

    In this sense, guidelines can be seen as non-binding recommendations. They can be non-binding international codes of practice, national operational guidelines related to applying relevant legislation and regulations, or codes of conduct, which can also be developed within professional organisations.

14. Involve legal and security experts.

    This component seeks to stimulate the participation of those who can assist and advise in this field, ensuring that the new telemedicine service is legal and secure.

15. Ensure that telemedicine doers and users are privacy-aware.

    This entails providing privacy awareness training to new users when additional services are implemented or upgraded. Privacy and Personally Identifiable Information (PII), privacy laws, policies, and principles, roles and responsibilities in protecting privacy, potential threats to privacy, consequences of privacy violations, or protection of PII in various contexts and formats are some of the topics covered in this training.

16. Ensure that the appropriate information technology and eHealth infrastructure are available.

    This means ensuring that the appropriate IT infrastructures (typically including hardware, software, networks, and the IT staff responsible for its development and maintenance) and eHealth infrastructures (an IT subset including hardware, software or networks) are available so that the telemedicine system can rely on these infrastructures at all stages.

17. Put in place the technology and processes needed to monitor the service.

Monitoring the service implies ensuring that it operates without undue delay in normal usage or technical interruption, save for maintenance, in order to provide continuity of care and avoid time loss. It covers maintenance plans, security concerns, service continuity, a help desk, and access control.

18. Establish and maintain good procurement processes.

    Good procurement processes have to be evaluated in terms of content and process. Regarding the content, in order to ensure that the service is delivered with quality, it is necessary to specify its aspects in a transparent service level agreement to be signed by the contracting parties. In terms of process, it is essential to have a formal procurement method for the purchase, displaying transparency and competition.

In summary, in Figure 2.6, it is possible to understand better the relation between the 18 factors and their categories [73].

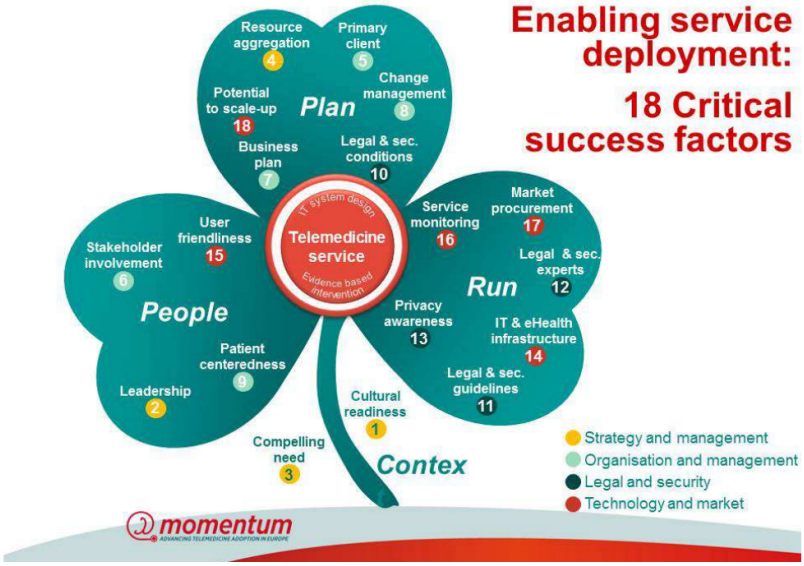

Figure 2.6: The Momentum 18 Critical Success Factors [73].

This way, the Momentum Framework is a guideline that can help any organisation, particularly a healthcare organisation, to adapt to a digital transformation process.

3

State Of The Art

3.1 Healthcare Services

People are living longer, thanks to mainly two reasons: there have been significant improvements in life expectancy and a steadily decrease in fertility. Additionally, people have fewer children and are having children later in life [74]. However, since individuals live longer lives than before, more medical resources must support healthy lifestyles. Because of the growing demand, the cost of healthcare has risen for most consumers [3].

According to the Centers for Medicare and Medicaid Services (CMS), healthcare spending is predicted to increase an annual average of 5.5% from 2017 to 2026. Healthcare spending in the United States is predicted to reach at least 5.7 trillion dollars by 2026 because of rising prescription prices [75].

Prevention will be crucial in addressing the problem of rising healthcare costs. Preventing chronic disease is far more cost-efficient in the long term than treating it. Technology will play a significant role in this, particularly wearable technology: sensors that allow real-time monitoring from activity level to pulse and blood glucose levels. By promoting the mass adoption by physicians of these devices with data analytics, it may one day soon be feasible to monitor chronic patient health remotely and intervene immediately to prevent these costly, chronic diseases from occurring [3].

According to a poll conducted in the United States, 90% of healthcare executives have already begun designing or implementing a telemedicine program in their companies. [76]. According to a recent Cisco global survey, almost 75% of consumers are comfortable with the idea of communicating with physicians using technology instead of seeing them in person [77]. On the other side, currently, the growth of telemedicine in Portuguese health services is still notorious. Applications and websites to manage prescriptions, schedule appointments, check vaccination records, and obtain digital certificates for users with low digital literacy, the SNS24 Desks, were created [78]. The results of a study conducted in Portugal [79] suggest that teleconsultation seems to have the potential to become a common practice in the future of medicine, especially for subsequent consultations, and highlights the benefit attributed by physicians to the implementation of means

that allow the realisation of video calls, which are currently precarious. However, it is also necessary to solve clinical, technical, organisational, legal and ethical questions.

Convenience is vital in today's healthcare industry, which is one of the benefits of telemedicine. Incorporating virtual care provides patients with direct, on-demand care without the usual waste of time and expense associated with most appointments. Patients who reside in rural areas or cannot take time off from work can obtain care electronically. More patients are connected to clinicians than ever before because of video conferencing, smartphone apps, and online management systems [80].

As previously noted, telehealth and virtual appointments are beneficial when there is no need to go to the hospital. Similarly, big data analytics, artificial intelligence, and machine learning may play significant roles in identifying patients who are at higher risk of disease, post-operative infections, or other issues, allowing physicians to prevent these consequences from occurring. Artificial intelligence can analyse enormous amounts of data to decide which treatments work best for a specific condition or patient [3].

3.2 Evolution of Medical Devices

As seen in section 2.6, there are many categories for medical devices. Some medical devices require users to collect data on paper, computer, or USB drive and then present it to their physicians for interpretation. More advanced devices send data electronically, even via wi-fi. These devices collect and send data over a variety of interfaces. Data is sent through an aggregation hub, such as a mobile phone or computer, to a back-end server, which saves and transmits the information to an EHR [81]. This work will be focused on digital medical devices, the ones that collect signals and transmit data.

Following technological advances in healthcare to enhance people's welfare, the medical device industry has evolved rapidly. The Americas Region is a significant market for medical equipment, as seen in Figure 3.2. In fact, this sector has had yearly solid development in some nations. Except for a few outliers, the countries import more than 80% of their medical devices. Nonetheless, patient safety and access to high-quality, safe, and effective medical equipment continue to be governments' primary priorities [82].

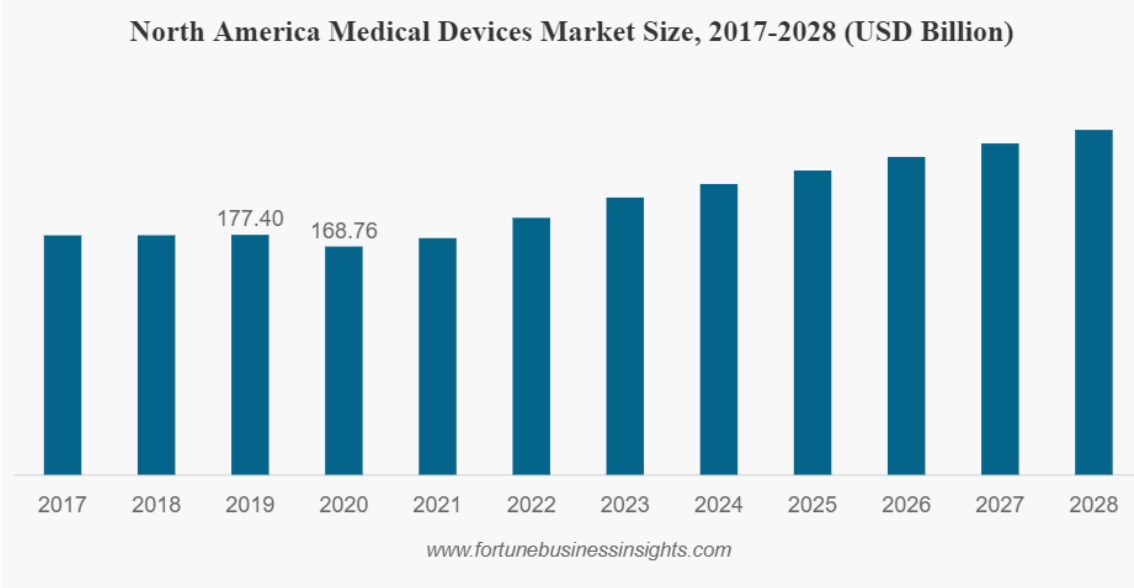

Figure 3.1: North America medical devices size market [32].

In 2021, the European medical technology industry was expected to be worth over €150 billion. Germany, France, the United Kingdom, Italy, and Spain are the top five most important markets. IVD is the largest industry globally, followed by cardiology and diagnostic imaging [83].

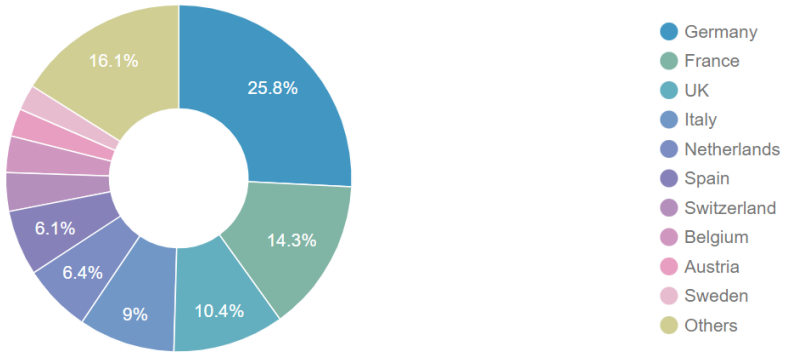

Figure 3.2: European medical device market by country - 2021 [83].

According to manufacturer pricing, the European medical device industry accounts for 27.3% of the global market. It is the world's second-largest medical equipment market behind the United States (43.5%). Over the last ten years, the European medical device industry has grown at an average of 4.8% each year. Due to the economic crisis, demand declined in 2009, resulting in a 1% growth rate (lowest in 13 years). The market recovered impetus in 2010, with annual growth rates ranging from 2.4% (2017) to 9.3% (2015) [83].

Medical devices are also increasingly being used at home, which implies that more

individuals will be required to deal with their medical issues and become more involved in medical equipment. Medical device usage varies from equipment used in other sectors due to the variety of contexts of use, the range of user characteristics, and the very dynamic quality of elements in delivering treatment [84].

The area of health monitoring systems is evolving toward smaller devices that measure even more vital signs and deliver safe and trustworthy data via smartphone technology. [35]. Biosensors have earned a great interest in the health industry, where they aim to extract clinically useful information from physiological signals such as heart rate, blood pressure, skin temperature and respiratory rate [85]. The enormous advancement in electronic, biocompatible materials and nanomaterials over the last decades has resulted in the development of implantable devices that enable diagnosis and prognosis through small sensors and biomedical devices.

As evidence shows [86], mobile applications encourage patients to become engaged with personalising interaction related with their care. The possibility of remote monitoring is one of the crucial means of precision medicine (enabling access to almost real-time data), allowing the medical team to permanently adjust the therapy according to the patient's response as a result of the parameters measured by the applications to which the patient is connected. Precision medicine requires precision measurements by the sensors. The use of genomics, the detection of drug interactions, and the ease of reading the impact of each treatment in real-time will make it possible to adjust or abandon specific treatment plans when the effectiveness is not as desired [87].

3.2.1 Blood Pressure Noninvasive Methods

The traditional measurement of blood pressure is called the auscultatory method and uses a sphygmomanometer composed of an inflatable cuff and a manometer, traditionally filled with mercury combined with a stethoscope to detect sounds made by the flow of blood as it comes under the cuff. It is also called the Riva-Rocci—Korotkoff auscultatory method [88]. The cuff is inflated to the point where the pressure it produces on the underlying arm is sufficient to block blood flow beneath, resulting in no blood flow noises being heard. As the cuff pressure is reduced, the pressure decreases, such blood flow restarts, and noises are heard [89].

The sounds vary in strength and generally end just before the next pulse arrives at the point of lowest pressure inside the arteries. The initial sound corresponds to the systolic pressure, and the last sound corresponds to the diastolic pressure. It can be challenging to listen to and decipher these noises, especially if there is a lot of background noise [88].

This method relies on a mercury manometer, which is now considered a health risk. As a result, several nations in EU and USA are replacing mercury sphygmomanometers with mercury-free automated blood pressure monitors [89].

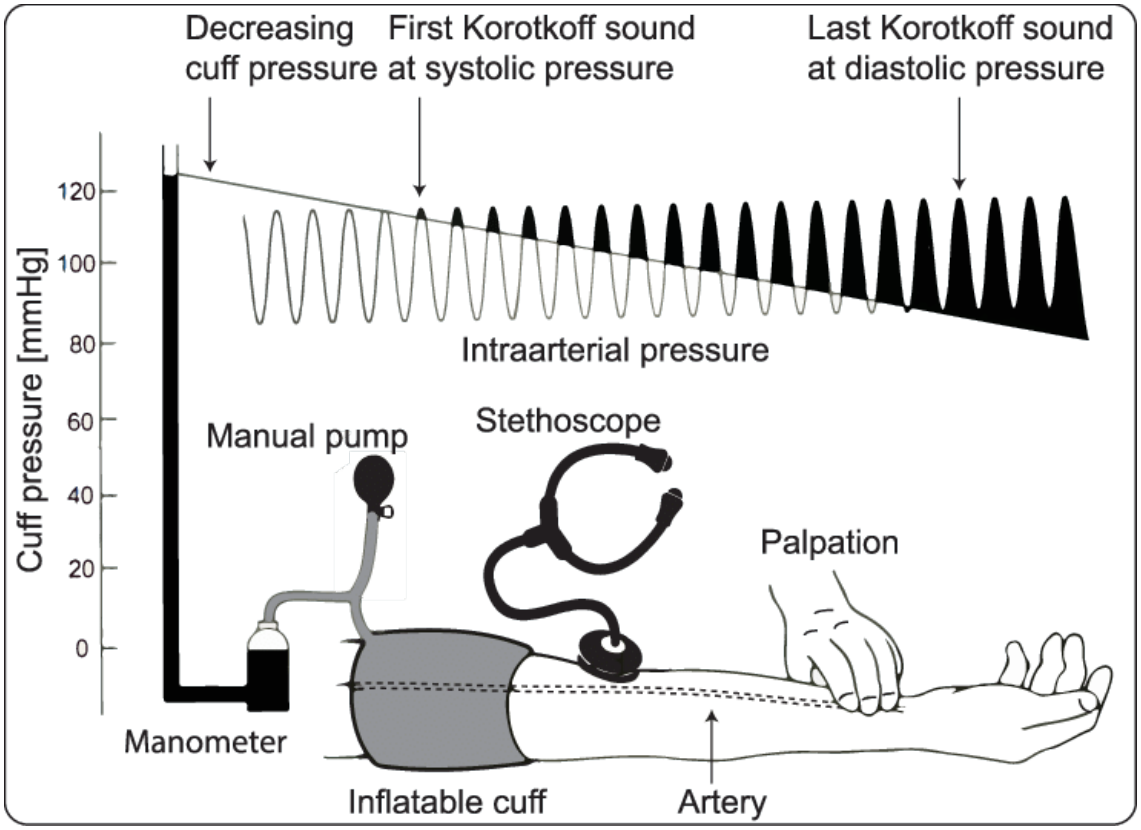

Figure 3.3: Auscultatory method [89].

Like the auscultatory method, the oscillometric approach employs a sphygmomanometer cuff with an electronic pressure sensor (transducer) to automatically detect and interpret pressure oscillations. Oscillometric measurements are the most appropriate for telemonitoring patients.

The cuff pressure is high pass filtered in the oscillometric approach to recover the tiny oscillations at the heart frequency. The envelope of these oscillations can be calculated, for example, by integrating each pulse. As cuff pressure falls between systolic and means arterial pressure, the amplitude of these oscillations increases. As cuff pressure goes below mean arterial pressure, the amplitude of the oscillations decreases. The computer-aided analysis obtains blood pressure estimations from the related oscillation envelope function. The maximum oscillation point is closely related to mean arterial pressure [90].

On the other hand, points on the envelope corresponding to systolic and diastolic pressure are less well established. A variant of the maximum amplitude technique is frequently utilised to estimate systolic and diastolic pressure values. The envelope is divided into rising and descending phases based on the location of maximum oscillations. Then, during the rising phase of the envelope, typical ratios or fractions of the peak amplitude are employed to locate spots corresponding to systolic and diastolic pressure [90].

Most inaccuracies result in overestimations of blood pressure, which might lead to

nearly twice as many individuals being diagnosed with hypertension as having high blood pressure. In other circumstances, hypertension is likely underdiagnosed due to blood pressure underestimation [91]. Most clinical offices, hospitals, and home monitoring devices use automated oscillometric technology to assess patients' blood pressure. However, the accuracy of this approach against auscultatory measurement with a mercury manometer is debatable, even though mercury products are being phased out [92].

According to one research [93], the mercury manometer recorded readings more precisely than oscillometric instruments. These findings have significant therapeutic consequences, including the possibility that patients whose blood pressure seems to be under control using the oscillometric approach may not be at their target because it was undertreated [92]. Another study demonstrated inaccuracy in using automated blood pressure monitors and traditional aneroid manometers compared to the gold standard mercury column manometer for subjects of all ages and blood pressure ranges [93]. Inaccurate sphygmomanometers are common: 30% to 40% of aneroid sphygmomanometers used by physicians are out of calibration by 4 mm Hg or more, and about 10% are out of calibration by 10 mm Hg or more [91].

Recently, more and more wearable blood pressure monitors have been developed. For example, an inflatable wrist strap, similar to the cuff of an automated blood pressure monitor, can stop blood circulation briefly to measure blood pressure accurately. A new generation of smartwatches on the market can also detect and estimate blood pressure with reasonable accuracy by utilising optical sensors [94]. However, the risk of reading error must be acknowledged, and physicians must be aware that some techniques used to estimate blood pressure in inpatients are unsuitable in the ambulatory context. Only readings acquired using the most accurate approaches are suitable when determining long-term cardiovascular risk or therapeutic intervention decisions [91].

3.2.2 Blood Glucose Methods

Glucose sensors are biosensors designed to detect glucose levels, and they can be in the form of a blood glucose meter with test strips or a Continuous Glucose Monitor (CGM). Although the design features appear distinct to the user, both biosensors employ identical detecting mechanisms. A glucose oxidase biosensor, for example, might take the form of a test strip or a wearable CGM sensor [95].

The most common and oldest glucose monitoring device is the blood glucose meter. This device employs enzyme-coated test strips that contain a precise number of certain enzymes that can only respond to a single blood sample. As a result, test strips are meant for single use only and cannot be reused. When put into a blood glucose meter, the test strip connects with the meter, which calculates the blood glucose quantity and shows the result on the meter's screen [95], as observed in figure 3.4.

A study demonstrated [96] that a Blood Glucose Monitor (BGM) does not always meet the analytical accuracy required for regulatory clearance. Six of the 18 systems analysed

met the predetermined accuracy standard in all three studies, five met it in two studies, and three only met it in one study. Four monitors did not meet the accuracy standard in the three studies. Suppose BGMs do not meet accuracy standards. In that case, they pose a risk to the patients that rely on this information for [97]:

- Making treatment decisions about insulin dosing and taking other actions based on the blood glucose level;
- Calibrating continuous glucose monitors, which can inform treatment decisions;
- Controlling closed-loop insulin delivery systems that depend on accurate calibration of continuous glucose monitors.

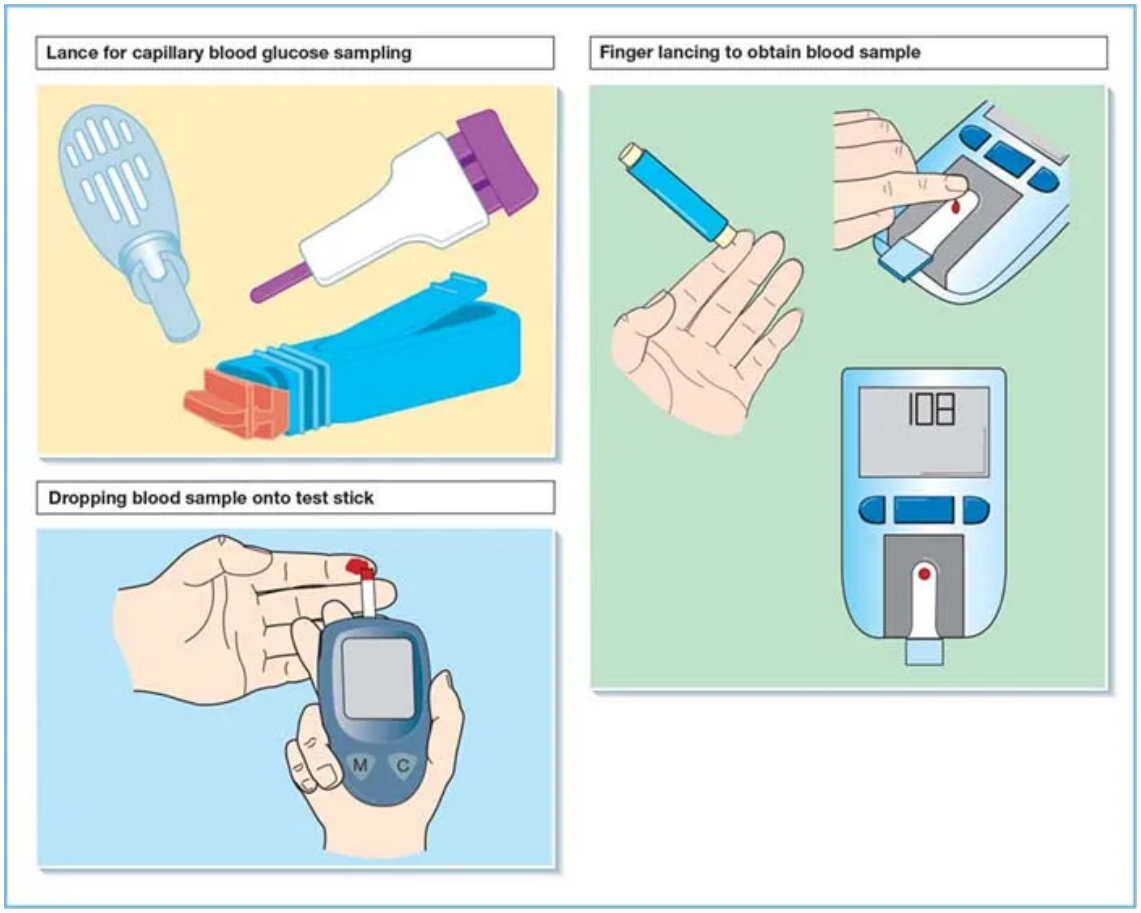

Figure 3.4: Blood Glucose Meter [98].

A CGM detects glucose in the interstitial fluid using a filament coated in glucose detecting enzymes. As a wearable sensor, a CGM monitors and analyses glucose levels automatically 24 hours a day and can be utilised continuously for several days or weeks, depending on the manufacturer. Implantable CGM sensor choices provide months of

wear since they are placed beneath the skin in a giant capsule. The sensor then communicates with an above-the-skin transmitter to relay data to a receiver or smart device. The transmitter enables wireless observation of the current glucose level and trends [95].

The accuracy of BGM and CGM devices has proven difficult to compare for various reasons. Even though the episodic strip and CGM sensor use similar enzyme-based reagents to measure glucose, they are exposed to different glucose concentrations, requiring specific algorithmic compensations or real-time calibrations to improve accuracy. Accuracy metrics have evolved to account for changes in the magnitude of the BGM and CGM datasets (and comparative values collected), making comparisons more difficult. BGM devices are commonly used for insulin dosage choices due to their greater point accuracy [99].

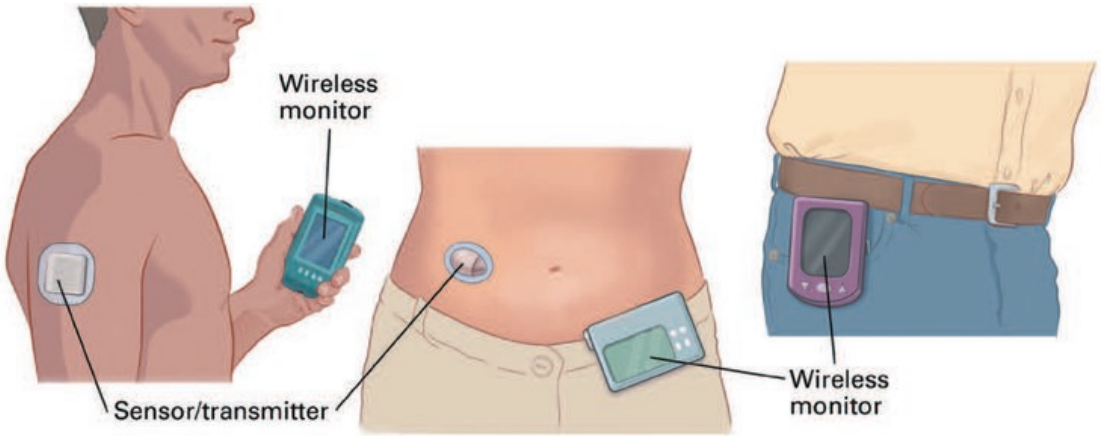

Figure 3.5: Continuous Glucose Monitor [100].

3.3 Medical Devices Data Model and Databases

Currently, there are several means of information on medical devices, namely databases, where it is possible to find several devices available in the market. In Portugal, the most current database is the *Sistema de Informação para Dispositivos Médicos* (SIDM), and at the EU level, there is the European Database for Medical Devices (EUDAMED) which is still under development.

3.3.1 SIDM

Infarmed has developed the SIDM, a new information system to medical devices, in order to facilitate and promote the registration of medical devices by operators and increase the transparency of the process, making public all registration information residing in the regulatory authority. Infarmed developed the system to optimise the management of information related to medical devices, streamlining and simplifying the registration process and the technologies supporting it.

The new SIDM provides information on medical devices sold in Portugal and promotes communication by users of problems with these health products. It is intended for the registration of medical devices and IVD, which are placed on the market by their manufacturers under the applicable legislation. On the website, it is possible to search for the medical device by its manufacturer, distributor, brand or model. Then, the labelling and information leaflet is accessible to the user.

3.3.2 EUDAMED

The EUDAMED is an information system designed by the European Commission and improves transparency and uniformity of medical device information accessible on the EU market. It was the first to address the lack of communication between notified bodies and EU member states [101]. The database's goal is to store regulatory data so that Competent Authorities can carry out their tasks as stated in the Directives in an informed manner. The Directives also mandate that the data be sent to the database in a specified format [102].

EUDAMED began as a European-funded initiative supervised by the German Institute of Medical Documentation and Information in 1997. After that, the European Commission (EC) took over EUDAMED, upgrading it in 2009 and requiring its usage by all responsible bodies in 2010. EUDAMED is now a centralised repository where competent national authorities send information to the EC concerning manufacturers, certifications, clinical trials, and vigilance/monitoring. Today, minimal information concerning medical device CE marks received, rejected, and revoked is publicly available, but similar information is readily available for pharmaceutical items.

4

Design Science Research Methodology

This research was performed using the DSRM, which aims to increase technology and scientific knowledge by developing new artefacts represented by models, methods, or instantiations that solve issues to achieve goals. DSRM in the Information Systems (IS) field, for example, comprises an understanding of how to organise and build a database system, model business processes, integrate IS with organisational strategy, and offer data analytics for optimal decision-making. For generating innovative answers to relevant design difficulties, DSRM is a research topic paradigm in many different subjects, including architecture, engineering, economics, and other technology- disciplines [103]. It is also broadly used in healthcare [104, 105].

DSRM is based on a process with six sequential steps, as shown in Figure 4.1.

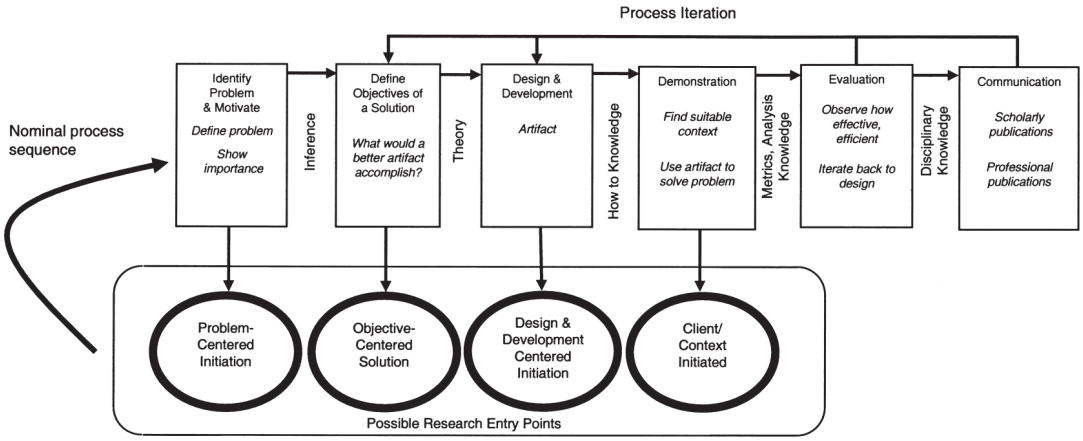

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Figure 4.1: DSRM Process Model [106].

The following list details the various steps of DSRM applied to this dissertation.

- **Problem definition**

  Healthcare data can come from diverse sources and can be of any type. There are profiles of patients, care providers, and pharmaceutical companies and lists of diseases, diagnostic tests, and treatment options that get longer daily. Databases

get filled with diagnostic, treatment, and discharge records. Moreover, the complex data to use must comply with evolving regulatory requirements on top of all the different data types [107].

Various processes exist between a patient's diagnosis and the data being entered in hospital records. Each stage is critical in assuring the quality of the data, from the health care professional gathering information from prior admissions through clinical coders transcribing medical notes and discharge letters into standardised diagnostic and procedure codes. These processes ideally necessitate good information technology systems that give quick access to reliable and complete data, which is not always the case [107].

The better and more standardised the data, regardless of how it is used, the more valuable it is. High-quality data improves patient care and facilitates research and analysis. We also need to understand what information is critical to capture. Without this, the quality of the data and the insights it may give would be restricted [108]. Therefore, managing data in a chronic patient monitoring system is the main problem intended to resolve.

- **Objectives for a solution**

  The principle objectives of this work are:

  - Develop knowledge on using the information in the decision-making process in digital PHC between physicians and chronic patients.
  - Analyse the digital health services network required.
  - Develop the CMDI framework.

- **Design and development**

  In this work, it is developed a proposed data model for medical devices in PHC, which will be included in the METHIS platform, aggregating the patients' and medical devices' information. A data model shows the logical structure of a database, including the relationships and constraints that determine how data can be stored and accessed. Data models define how data is connected and processed, and stored inside the system [109].

- **Demonstration**

  For the demonstration step, we applied the designed data model to an example of 50 chronic patients aged over 60 with multimorbidities: type 2 diabetes and hypertension.

- **Evaluation**

  The evaluation stage will study how good the demonstration was and how it fit considering the purposes defined at the objectives of a solution stage. We will verify

the characteristics of the data model and how the measures can be implemented to improve precision and accuracy.

- **Communication**

  The communication part will include the defence of this dissertation and presentations to be made to the UNIDEMI research community and other seminars. A policy brief is also expected to be published.

5

The METHIS Project

The digital platform, METHIS, based on previous research projects, **ePharmaCare/FCT** and **HAITOOL/EEAGrants**, is a multidisciplinary, goal-oriented, design-science-based intervention to increase physician-patient communication and patient engagement. This platform is expected to enable better coverage of chronic patients at home, so health professionals can safely and accurately consult chronic patients and prescribe the necessary medicines [110].

This project is part of the context of eHealth and digital health, representing an opportunity to manage chronic patients during epidemics, allowing the monitoring of these patients, preventing their diseases from getting out of control and needing to go to the emergency room. This digital platform will contain "smart" components, such as algorithms that allow a set of alerts for physicians and nurses, and health professionals to remotely consult patients at home, managing all health information securely. Therefore, the METHIS project proposes a novel approach to healthcare, as demonstrated in the following chapters [104].

In this context, the METHIS project focuses on multimorbidity and ageing, analysing people with several chronic diseases who are over 65 years old. To accomplish this, the following objectives were established:

1. Clinical management and health goals: definition of essential patient information and history necessary for effective monitoring.

2. Management and organisational objectives:

    - Study of the FHU present circuit.
    - Suggestion of a new circuit (defining for each situation the number of physicians, nurses, patients, interactions, and other indicators).

3. Technology management objectives:

    - Analyse the information flow created and determine the digital health services network required.

- Identify the most relevant medical devices and describe how data is gathered and sent.
- Describe the collected information and its meaning in the context of PHC.

The work of this dissertation focuses on the goals mentioned in item 1, also addressing part of item 3. METHIS has already being tested and validated in real PHC context [104]. Now, the aim is to develop a cluster trial to validate scientifically the value of digital monitoring in PHC. In this stage the use of sensors will be critical. Therefore, we need to have a CMDI system to make sure that data collected and presented by the system is accurate and safe, and complies with the General Data Protection Regulation (GDPR).

6

Results

In this Chapter, we propose the design and development steps of the DSRM. First, we present the system developed for the METHIS, and then we describe the different types of information for the CMDI framework.

6.1 The Telemonitoring Process

This section presents the Information System, i.e., the system designed in the METHIS project in a previous work [111]. This is a centralised system that uses three databases, one for test, other for research (with anonymised data) and a production database. The production database is only accessible by health professionals. This last database is also called a warehouse since it contains all the entered data, regardless of where it is. The cloud is frequently utilised as a centralised store for data that can be securely accessed from any internet-connected device via password in a secure network.

6.1.1 The Data Collection

The system's first essential component is a smartwatch that measures the patient's medical data in real-time and parameters that are impossible to measure in a medical appointment. This way, three main parameters were selected to be measured and collected: blood pressure, blood glucose and the number of steps per day. Each parameter will be measured with different frequencies, as described in subsection 6.3.6.

Three different sensors will measure the blood glucose, blood pressure, and the number of steps: a glucose sensor (Class C IVD), a pressure sensor (Class IIa medical device) and a pedometer, respectively (the last two will be incorporated in the smartwatch). Although a pedometer is not a medical device and does not fit into the classes aforementioned in subsection 2.6.3, the number of steps can be a curious parameter to monitor and motivate patients to lead a more active life.

These devices must be easy to maintain, as we do not want the maintenance to become an obstacle for patients. The smartwatch will function with a chargeable battery and last

for a day or more, depending on its use. The glucose sensor can stay in place for several days, depending on the manufacturer's specifications.

6.1.2 The Data Transmission

A gateway connects the smartwatch, via a telecom operator, to a cloud server. A gateway is a network node that links two networks that employ distinct transmission protocols. There are two sorts of gateways: basic gateways and smart gateways. The basic gateway works as a proxy between low-end IoT devices and data centres by transmitting incoming data. On the other hand, a smart gateway processes data effectively by preprocessing, filtering, and analysing it before transferring the relevant or essential data to the cloud platform. Gateways can connect via various communication technologies such as Wi-Fi, Bluetooth, or Zigbee to gather information and transfer data to the cloud using protocols such as Message Queuing Telemetry Transport or Constraint Application Protocol [112].

The streaming data processor at the cloud server's entry transfers input data from smart medical devices to the data lake and control applications. A data lake is a central repository that enables the storage of large amounts of organised and unstructured data. Data is often stored in its raw form without being processed or formatted first. It may be used to store unusual data such as log and sensor data. Data in data lakes may be utilised for various applications, including machine learning, streaming analytics, and artificial intelligence [113].

Conversely, data warehouses contain clean, pre-processed, polished, highly organised data. This information is saved for specific purposes, such as business intelligence. Data warehouses store far less data, on the order of terabytes [113]. Most companies utilise a mix of the two. They explore and analyse data in the data lake and then migrate the rich data to data warehouses for rapid and advanced reporting.

6.1.3 The Control Application

A physician can modify monitoring parameters of medical devices to tailor them to a specific patient and their medical condition using past data on a patient's health status and medical history and execute device inspections and maintenance remotely. The data may be moved from the warehouse to analysis or machine learning models to recognise specific patterns and create a model for a control application to increase the precision and efficiency of patient care [113].

6.1.4 The Patient Interface

The patient web-based interface lets patients view their health parameters, log their symptoms, receive alerts on a potential medical device failure, or request a video consultation with a physician or nurse. Within METHIS platform, they can also register the hour they took the prescripted medication and submit the quality of life survey.

It can also automatically receive a new medication's prescription, with the physician's approval, when the one in use is ending.

6.1.5 The Medical Staff Interface

The medical staff interface provides physicians and nurses with patient health data and alerts them on abnormalities in patients' vitals or possible medical device issues. An abnormality is when the measurements are out of range.

Although part of the data is obtained with the smartwatch represents a considerable help in monitoring the patient's conditions, regular medical appointments are essential. The physician must introduce new relevant information to the system, like blood analysis, exam results, or even medical device measurements, during consultation.

6.1.6 The Admin Interface

Admin web panel manages user role settings for medical staff and patients, for example, enabling or restricting the view of monitoring data, adding and confirming virtual appointment requests, or updating medical staff schedules.

6.1.7 Quality of Life Survey

In addition to the parameters mentioned in subsection 6.1.1, there is also a qualitative parameter to measure, the quality of life. To assess it, we propose in this project the use of the 12-Item Short Form Survey (SF-12), which is a questionnaire used to assess generic health outcomes from the patient's perspective in the previous four weeks and to evaluate health-related quality of life. The SF-12 is one of the most widely used instruments for assessing self-reported health-related quality of life. The SF-12 employs the exact eight dimensions as the 36-Item Short Form Survey (SF-36) but with many fewer questions, making it a more practical research instrument, particularly among groups with short attention spans or mental health issues [114]:

1. Physical activity restrictions due to health issues.
2. Restrictions on social activities due to health or mental issues.
3. Limitations in normal role activities due to physical health issues.
4. Bodily pain.
5. Mental health in general (psychological distress and well-being).
6. Limitations in normal role activities due to emotional issues.
7. Vitality (energy and fatigue).
8. Perceptions of general health.

The SF-12 responses are used to calculate two separate scores ranging from zero to one hundred: the physic (Physical Component Summary (PCS)) and the mental (Mental Component Summary (MCS)). We can quantify this critical metric since higher scores indicate better physical and mental well-functioning. A PCS or MCS of less than 70% is regarded as concerning [115]. Thus this value should be established as the quality of life threshold. Furthermore, a PCS score of 50 or less has been proposed as a cut-off for determining a physical condition, and an MCS score of 42 may indicate "clinical depression" [116].

This questionnaire should not take too long for the patient to complete (two to three minutes), and it can be accessed through the patient interface. Because we want to analyse the patient's perspective over time, we need to gather this parameter every month.

6.1.8 Electronic Clinical Record

In Portugal, hospitals and health centres have certain computerised clinical records, but their flexibility and usefulness, as with *Sistema Integrado de Informação Hospitalar* (SONHO) or SCLÍNICO, are primitive [117]. Furthermore, access and communication between the public and private networks are impossible. The patient does not carry his clinical information in digital form with him and does not have access to it when he needs it.

The broad use of electronic medical records, which consolidate all information about each patient - demographic, clinical history, medical records, vital preferences, payers or insurers - would improve patient and professional safety while expediting healthcare delivery. This should be one of the first topics tackled in Portugal's future health reform [117]. Due to its importance, this electronic clinical record is represented in the architecture of figure 6.1.

6.1.9 The Alert Service

The Alert Service is a complementary service that allows controlling the patient's medical parameters in real-time by emitting alerts for the patient through the interface in the smartwatch and the physician/nurse through the medical staff interface. These alerts were defined by the clinical team and are explained in the list below [104].

The alerts to be emitted for the patient:

1. Alerts that depend on:

    a) Quality of life [115]:

        i. If PCS < 70% and MCS < 70%: "You seem physically and mentally unhappy. You should make an appointment with your physician. He will help you!"

ii. If PCS < 70% and MCS ≥ 70% : "You seem mentally happy but physically unhappy. You should make an appointment with your physician. He will help you!"

iii. If PCS ≥ 70% : and MCS < 70%: "You seem physically happy, but mentally unhappy. You should make an appointment with your physician. He will help you!"

iv. If PCS ≥ 70% : and MCS ≥ 70% : "You seem physically and mentally happy, that is great!"

b) Blood pressure [118]:

i. If systolic pressure < 120mm/Hg and diastolic pressure < 80mm/Hg: "Your blood pressure is great!"

ii. If $120mm/Hg \leq$ systolic pressure < 130mm/Hg and diastolic pressure < 80mm/Hg: "Your blood pressure is slightly elevated. You should balance your diet and get regular exercise."

iii. If $130mm/Hg \leq$ systolic pressure < 140mm/Hg or $80mm/Hg \leq$ diastolic pressure < 90mm/Hg: "Your blood pressure is high. You should make an appointment to consult your physician when possible."

iv. If 140mm/Hg ≤ systolic pressure < 180mm/Hg or 90mm/Hg ≤ diastolic pressure < 120mm/Hg: "Your blood pressure is very high. You should make an appointment to consult your physician when possible."

v. If systolic pressure ≥ 180mm/Hg and/or diastolic pressure ≥ 120mm/Hg: "Your blood pressure is hypertensive. You should call 991 or consult your physician immediately!"

c) Blood glucose [11]:

i. If the patient does not have diabetes:

A. Fasting/upon waking or before meals/preprandial:

- If blood glucose < 70mg/dl: "Your blood glucose is too low. You should make an appointment to consult your physician when possible."
- If 70mg/dl ≤ blood glucose ≤ 99mg/dl: 'Your blood glucose is great!
- If blood glucose > 99mg/dl: "Your blood glucose is too high. You should make an appointment to consult your physician when possible."

B. After meals/postprandial:

- If blood glucose < 70mg/dl: "Your blood glucose is too low. You should make an appointment to consult your physician when possible."
- If 70mg/dl ≤ blood glucose ≤ 140mg/dl: "Your blood glucose is great!"

- If blood glucose > 140mg/dl: ”Your blood glucose is too high. You should make an appointment to consult your physician when possible.”

ii. If the patient has type I or type II diabetes:

A. Fasting/upon waking or before meals/preprandial:

- If blood glucose < 80mg/dl: ”Your blood glucose is too low. You should make an appointment to consult your physician when possible.”
- If 80mg/dl ≤ blood glucose ≤ 130mg/dl: ”Your blood glucose is great!”
- If blood glucose > 130mg/dl: ”Your blood glucose is too high. You should make an appointment to consult your physician when possible.”

B. After meals/postprandial:

- If blood glucose < 80mg/dl: ”Your blood glucose is too low. You should make an appointment to consult your physician when possible.”
- If 80mg/dl ≤ blood glucose ≤ 180mg/dl: ”Your blood glucose is great!”
- If blood glucose > 180mg/dl: ”Your blood glucose is too high. You should make an appointment to consult your physician when possible.”

d) Number of steps per day, considering x as the number of steps defined by the physician, together with the patient, to achieve daily:

i. If the number of steps < 0.9x: ”It seems like you are not walking a lot today, let’s go for a walk!”

ii. If 0.9x ≤ number of steps < x: ”You’re close to your goal! Why don’t you go for a little walk?”

iii. If the number of steps ≥ x: ”You’ve walked a lot today and achieved your goal, congratulations! Keep up with your determination!”

2. Alerts that do not depend on the collected data:

a) Reminders for medication, exercise and consultations.

b) Short questions.

c) Short motivational and informational quotes highlight the benefits other people have from a healthy life.

d) Warnings referring specific things that patients can do to reduce certain risks.

The alerts to be emitted for the physician/nurse:

1. Alerts that depend on:
   a) Quality of life [115]:
      i. If PCS < 70% and MCS < 70%: "The patient has low PCS and MCS."
      ii. If PCS < 70% and MCS ≥ 70%:"The patient has low PCS"
      iii. If PCS ≥ 70% and MCS < 70%: "The patient has low MCS."
   b) Blood pressure [118]:
      i. If 130mm/Hg ≤ systolic pressure < 140mm/Hg or 80mm/Hg ≤ diastolic pressure < 90mm/Hg: "The patient has hypertension (stage 1) and needs medication prescription."
      ii. If 140mm/Hg ≤ systolic pressure < 180mm/Hg or 90mm/Hg ≤ diastolic pressure < 120mm/Hg: "The patient has hypertension (stage 2) and needs medication prescription."
      iii. If systolic pressure ≥ 180mm/Hg and/or diastolic pressure ≥ 120mm/Hg: "The patient is having a hypertensive crisis and needs medical healthcare immediately."
   c) Blood glucose [11]:
      i. If the patient does not have diabetes:
         A. Fasting/upon waking or before meals/preprandial:
            - If blood glucose < 70mg/dl: "The patient has low blood glucose"
            - If blood glucose > 99mg/dl: "The patient has high blood glucose."
         B. After meals/postprandial:
            - If blood glucose < 80mg/dl: "The patient has low blood glucose."
            - If blood glucose > 140mg/dl: "The patient has high blood glucose."
      ii. If the patient has type I or type II diabetes:
         A. Fasting/upon waking or before meals/preprandial:
            - If blood glucose < 80mg/dl: "The patient has low blood glucose."
            - If blood glucose > 130mg/dl: "The patient has high blood glucose."
         B. After meals/postprandial:
            - If blood glucose < 80mg/dl: "The patient has low blood glucose."
            - If blood glucose > 180mg/dl: "The patient has high blood glucose."
   d) Number of steps per day, considering x as the number of steps defined by the physician, together with the patient, to achieve daily:
      i. If the number of steps < 0.9x: "The Patient is not walking enough."
   e) Patient's medication
      i. If the patient's medication is ending: "The patient's medication is ending. Please check if you want to send him a new prescription."

This way, the Alert Service is crucial to controlling the patient's medical parameters in real time and represents a fundamental part of this system.

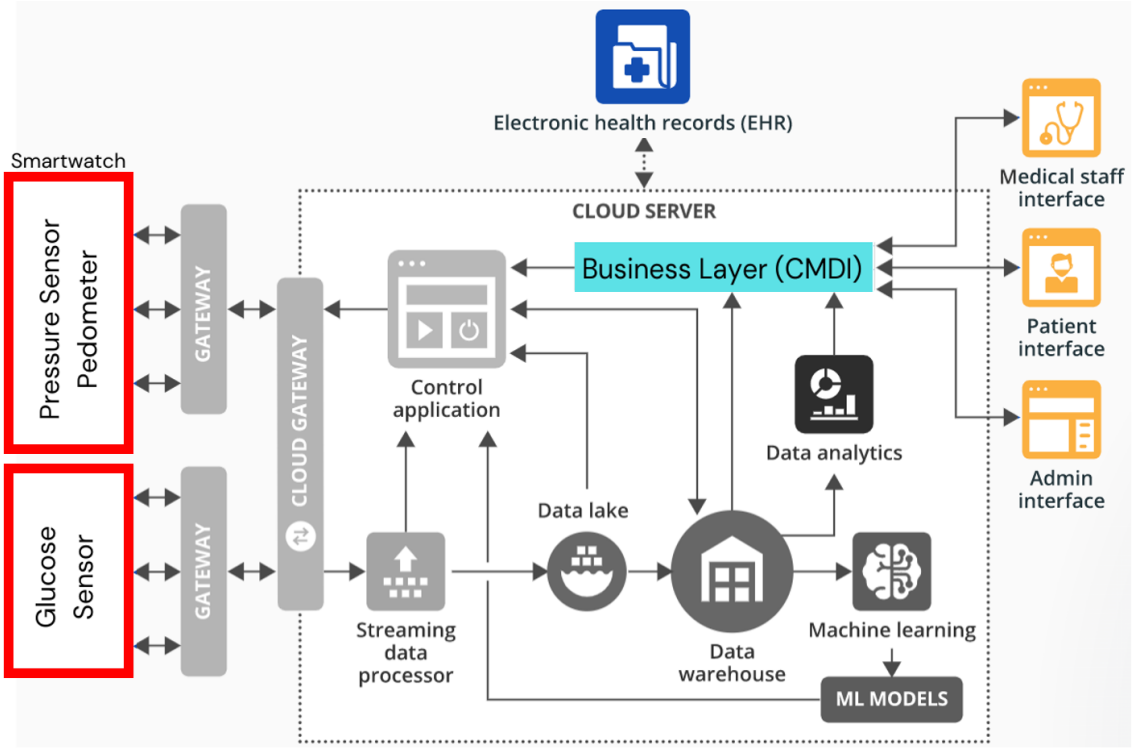

Figure 6.1: METHIS System Architecture. Adapted from [119].

In the following sections, it is presented the proposed CMDI model, which corresponds mainly to the "Business Layer" in the System Architecture. CMDI is mainly a data model for building an information database that includes the patients' and the medical devices' data. According to ISO 13131-2021, CMDI's goal is to send continuing information and trend data to the patient's health professional so that a decrease in health may be noticed and addressed well before it reaches a crisis point. The data is compared to the patient's "normal" readings, and any abnormal reading is reported for further investigation and forwarded to the patient's healthcare provider. The physician can then advise the patient on what steps to take, including medication modifications [120].

6.2 Clinical and Personal Data

One of the main information presented in the CMDI data model is related to patients, namely their personal and clinical data. The GDPR protects this data usage. This Regulation establishes standards for protecting fundamental rights and freedoms, notably the person's right to personal data protection and free movement [121].

6.2.1 Patient Identification

Unfortunately, there is not a worldwide identification number for patients. This would allow different healthcare providers to accurately identify the patients so they could manage all relevant information without mixing it up with someone else's information. However, many countries have already adopted their Unique Patient Identifier (UPI), including England, Wales and the Isle of Man, Denmark, Estonia, and, more recently, Spain and Ireland [122]. In Portugal, one of the significant difficulties in health information systems is the lack of a standard unique identifier for each patient. There is the SNS number or user number, which only applies to the *Serviço Nacional de Saúde*, the public health service of Portugal. Consequently, gathering all patient information through different health care systems is impossible. The Social Security Number is used as a healthcare identifier in some countries [117].

Therefore, we propose for each patient to be identified by 2 of the following data, according to ISO 27269:2021 Health informatics — International patient summary [123, 124]:

- Patient's name:

  A person's name comprises a series of name elements, such as a given name, family name, prefix, or suffix. There is a need for single-string and component-based representations of people's names in various contexts that reflect jurisdiction and cultural traditions.

  Business Rules:

  1. If not specified, it is allowed to provide more 'person's name' elements for the same person.
  2. Person's name should include the given and family components, and at least one of the two shall be present.
  3. In the case of non-alphabetic representations of the names, at least one alphabetic representation shall be provided. Variants such as "preferred name" or "alias" are implicit in the person's name data type.

- Patient's address:

  The patient's address is administrative but can also be used in the clinical process to verify the patient's identification.

- Administrative gender:

  The WHO's European regional office defines sex as biologically specified qualities, whereas gender is based on socially produced attributes. Some countries require the gender as part of their identification of the patient. A person's sex is a clinical term but is not always provided or collected at the source [125].

- Healthcare-related identifiers:

  When it comes to the identity traits used to uniquely identify a patient in the Portuguese national infrastructure, Portugal has defined that the national health system identifier (a 9-digit number printed in the citizen's card) is the one to be used by health professionals during cross-border encounters. It is also possible for a person to have multiple numbers connected to one or more healthcare providers. In an international setting, a national healthcare identity card may be helpful. However, not every country has such a system.

- Birthdate:

  According to ISO 8601 (date and time format), the birth date is represented by six integer numbers, from 0 to 9, in the following format: YYYY-MM-DD [126]:

  - YYYY is the year (four numeric characters);
  - MM is the month (01 to 12);
  - DD is the day (01 to 31);

6.2.2 Clinical History

Since we are dealing with primary health care, it is predictable that the majority of patients have multimorbidities, and it is essential to have access to their clinical history. Therefore, one of the most critical data in the CMDI data model is the data related to the diagnoses, which includes diseases, allergies, surgeries or other medical procedures and vaccines.

The WHO administers the International Classification of Diseases (ICD) coding system, which is used in various formats worldwide. Today, most countries use the International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes to categorise diagnoses in all healthcare settings, whereas International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS) codes are used for hospital inpatient treatments. ICD codes include information on a patient's health, the location and degree of an injury or symptom, and whether the visit relates to an original or later encounter. The ICD-10-CM code set alone has about 70,000 unique IDs [127].

The International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) was used in Portugal from 1989 to 2016. Despite the annual updates, it was found that the ICD-9-CM has become inadequate to adequately portray the spectrum of pathologies and procedures existing in hospitals and the technological innovations that exist every year. Given the limitations of the ICD-9-CM, WHO authorised the USA government to adopt the ICD-10-CM and the ICD-10-PCS to classify diagnoses and procedures. Its adoption in the USA was completed on October 1, 2015, and the ICD-9-CM was discontinued on October 1, 2013. In Portugal, as a structuring project of the SNS, it was created, in 2013, a team responsible for planning the implementation project

of the ICD-10-CM and the ICD-10-PCS, replacing the ICD-9-CM. Later, in 2015, it was stipulated that the new clinical coding system would enter into force in Portugal on January 1, 2017. The ICD-10-CM and the ICD-10-PCS have a more up-to-date medical terminology compatible with current clinical practice, allows for greater exhaustiveness, specificity and precision in the characterisation of morbidity, and provides conditions to establish more equitable and promoters of good practices and clinical innovation [128].

The classification of diagnoses (diseases, symptoms and signs, traumatic injuries) is organised into chapters. Each diagnostics chapter is divided into sections that bring together related diagnostic codes. The ICD-10-CM is divided into [128]:

1. Index of Traumatic Diseases and Injuries, which consists of an alphabetical list of terms and respective codes, where the sub-terms appear below the primary term, namely:

    a) Alphabetical Index of Diseases and Injuries Traumatic;

    b) Alphabetical Index of External Injury Causes;

    c) Table of Neoplasms;

    d) Table of Drugs and Chemicals.

2. Tabular List of Traumatic Diseases and Injuries consists of a chronological list of codes divided into chapters based on the affected anatomical apparatus and conditions.

Structure and format of diagnostic codes:

- Minimum 3 characters.
- Maximum 7 characters.
- 1st character is always a letter (except U).
- Characters 2-7 can be letters or numerals (the second digit is numeric, and the seventh is used only in some chapters).
- Characters have no associated meaning.
- Letters are not case sensitive.
- Full descriptions – up to 250 characters missing.
- Short descriptions – up to 100 characters missing.

Table 6.1: Description of ICD-10-PCS positions.

Position	1	2	3	4	5	6	7
Information	Section	Body System	Procedure Type	Body Region	Approach	Device	Qualifier

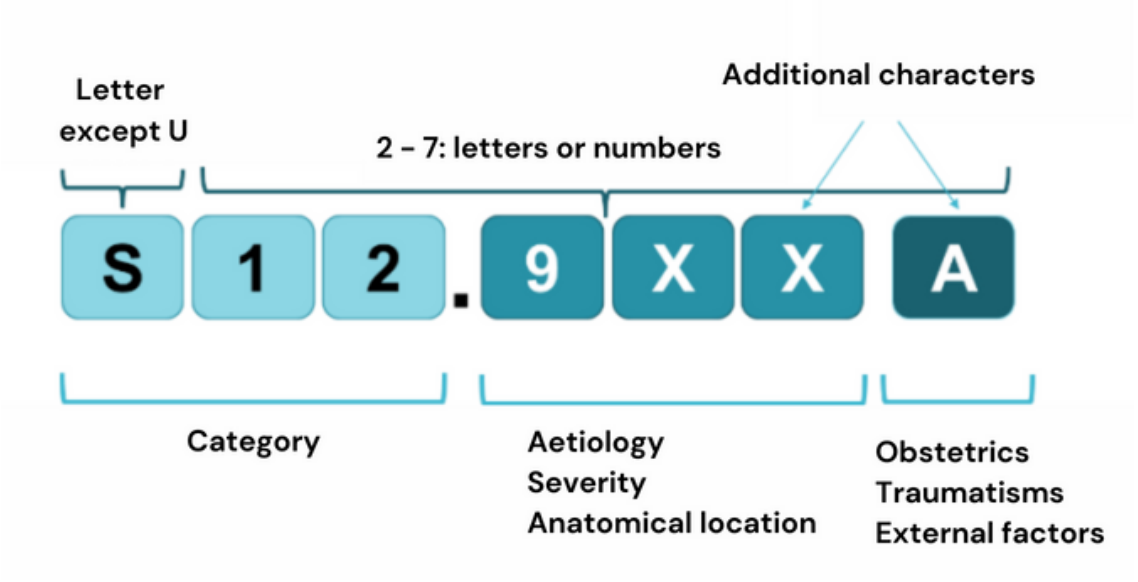

Figure 6.2: ICD-10-CM: Structure and Format. Adapted from [128].

On the other hand, ICD-10-PCS codes are always seven characters long. Each of the positions assigned to each character provides specific information about the procedure performed, according to table 6.1. This structure of procedural codes allows for their eventual extension without the classification structure being compromised [128].

Structure and format of procedure codes:

- Minimum 7 digits.
- Maximum 7 digits.
- Alphanumeric - Digits can be numbers or letters:
  - Numbers 0-9.
  - Letters A-H, J-N, P-Z.
- Letters are not case sensitive.
- Digits have associated meaning.

6.2.3 Medical Team and Protocol

One medical team is allocated for each patient, numbered from 1 to n. This team consists of one physician and two nurses. There is also a clinical protocol for each patient,

which describes the frequency of data collection, the medication and intake, among other recommendations.

6.3 Medical Devices Data

Medical devices are among the essential elements of this system. It is necessary to ensure that they are easily identified, their location, and the most important precautions to be taken in their use. It is essential that this equipment complies with national medical device regulations, which are aligned with the International Standards relating to medical devices (ISO 13485 and ISO 14971). The quality of medical devices is crucial to the quality of the CMDI. The manufacturer is solely responsible for the quality and safety of the device. However, the users, in this case, health professionals and patients, have a responsibility to collaborate in post-market surveillance of the device to ensure any defects are detected which could pose a risk to the safety of the care recipient [120].

6.3.1 Identification

According to ISO 20417:2021, the information shall contain a distinct identification of the medical device by including the following [129]:

- Its use in a clear way. Example: 'Drug Eluting Stent', ' Blood Glucose Meter', ' Pulse Oximeter', or 'Infusion Pump'.
- Commercial product name
  - A medical device may be identified with a commercial product name specific to the medical device or the manufacturer.
  - A commercial product name shall be identified by a text string.
- Unique Device Identifier

  The FDA, the European Commission and other regulators consider patient safety a strategic priority leading to the creation of legislation within the scope of Unique Device Identifier (UDI). The UDI is a unique numeric or alphanumeric code related to a medical device. It allows unambiguous identification of specific devices on the market and facilitates their traceability.

  These identifiers provide access to helpful information about the device. The UDI increases the efficiency of device traceability, simplifies the collection of devices, fights counterfeiting and improves patient safety. The UDI complements but does not replace current medical device labelling requirements. The new system will apply to all medical devices and IVD placed on the EU market, except custom-made devices [130]. This mandates manufacturers to report the UDI for all devices in EUDAMED.

On each medical device, labels and packaging subject to the regulation, a UDI code must be provided in a readable form. It must also be displayed in a machine-readable form that uses Automatic Identification and Data Capture technology [131]. In figures 6.3 and 6.4 are represented examples of codes to capture the UDI.

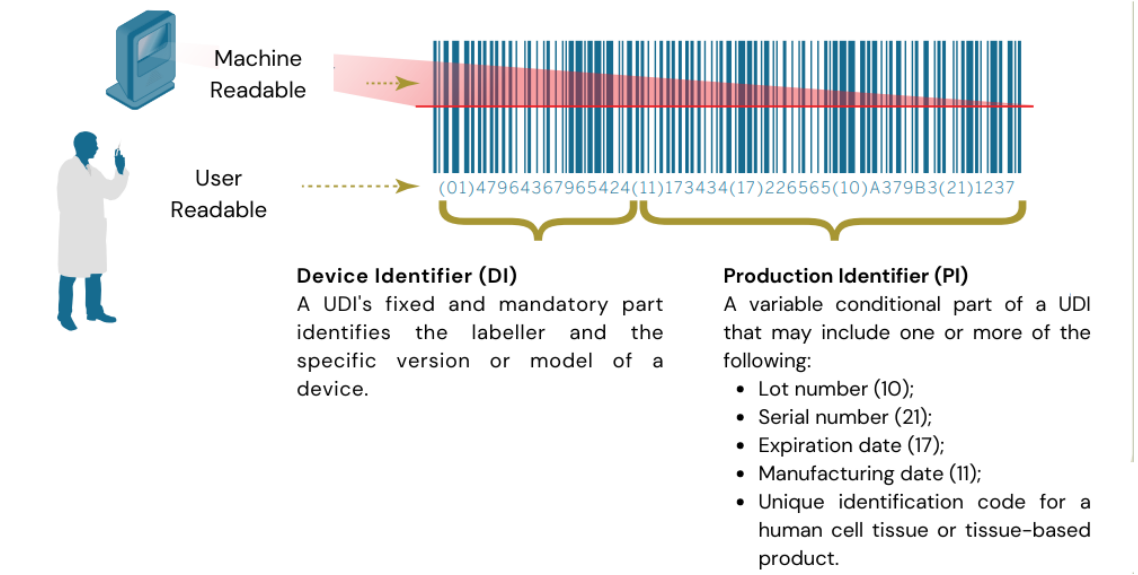

Figure 6.3: GS1-128 linear barcode example. Adapted from [132].

Figure 6.4: GS1 DataMatrix code example. Adapted from [132].

6.3.2 Location

Since patients will be using medical devices in their homes, it will be helpful to access their locations. Regular addresses contain many characters of different types, and it is challenging to standardise them. Example: square, street, neighbourhood, among others. On the other hand, typical coordinates can be very long. Thus, the best current option is using the Plus Codes from Google.

Rather than addresses with street names and numbers, Plus Codes are based on latitude and longitude and are made up of 20 alphanumeric characters. Because they are

substantially shorter than standard global coordinates, they are simple to distribute. They do not contain readily mistyped letters such as '1' or 'I,' are not case-sensitive, and omit vowels. Plus Codes signify a geographical region. The area's resolution can be modified by adding or deleting characters following the '+' symbol [133].

6.3.3 Measurements

As mentioned before, the quantitative data measured by medical devices are blood pressure and blood glucose. Blood pressure is measured in mmHg and blood glucose in mmol/L. These data are recorded in the database, along with the day and time of their measurement. The day and time comply with the ISO 8601, with the following format: YYY-MM-DD HH:MM:SS. Time zones in ISO 8601 are represented as local time (with the location unspecified), as UTC [126].

- YYYY is the year (four numeric characters);
- MM is the month (01 to 12);
- DD is the day (01 to 31);
- HH is the hour (00 to 23)
- MM are the minutes (00 to 59)
- SS are the seconds (00 to 59)

6.3.4 Error and Uncertainty

A measurement has two components: error and measurement uncertainty, both of which influence how the findings are interpreted. Measurement uncertainty is a non-negative metric characterising the dispersion of quantity values given to a measurement depending on the information employed. Uncertainty is a measurement result parameter representing a tolerable dispersion level of measurement findings [134].

Measurement errors might have a substantial impact on the diagnosis. For example, a healthy patient may be diagnosed with hypertension and treated for an illness that does not exist. In accordance with the FDA, reliable glucose meters deliver values 95% of the time within 15% of the lab result. If the blood glucose level at the lab is 170, the glucose meter reading must be between 145 and 195 to be regarded within the accuracy window [135].

For this reason, these two parameters must be included in the data model so that the patient and the physician know how reliable the measurement results are.

6.3.5 Warnings and Precautions

Although these are accessible and easy-to-use medical devices, the following information should cover, where appropriate, the most relevant warnings, precautions or measures to be taken according to ISO 20417-2021 [129]. Some examples are listed below:

1. Any special operating instructions that need to be brought to the immediate attention of the user.

2. Usage times:

    - If intended for single use, a text string indicating 'do not reuse', or a text string indicating 'single-use only'.
    - If intended for single patient multiple uses a text string indicating 'single patient multiple uses'.
    - If reuse is limited, the limitation on reuse. Example: The maximum number of allowable reuses or processing cycles.

3. Information of any necessary maintenance to ensure that the medical device operates appropriately and safely during the expected lifetime;

4. Measures to be taken in regards to the exposure to external influences or environmental conditions, such as temperature, humidity, pressure, or magnetic fields.

6.3.6 Collection Frequency

The American Heart Association and other organisations recommend that people with a high blood pressure often monitor their blood pressure at home [118]. Regularly checking blood pressure at home helps care providers determine if the treatment works. In the beginning, blood pressure should be measured at least twice daily for hypertension patients: first in the morning before eating or taking any medication and in the evening. However, it is essential to mention that the frequency of measurements should be exclusively decided by the healthcare professional, as it depends on several factors, including the patient's illnesses and lifestyle [136].

The frequency of testing blood glucose usually depends on the type of diabetes and the treatment plan. If it is a type 1 diabetes patient, the health care provider may recommend blood sugar testing 4 to 10 times a day:

- Before meals and snacks;
- Before and after exercise;
- Before bed;
- During the night (sometimes);

- More often, if sick;
- More often, if the daily routine was changed;
- More often, if a new medication was started.

On the other side, if the patient is type 2 diabetes and takes insulin, the health care provider may recommend blood glucose testing several times a day, depending on the type and amount of insulin. Testing is usually recommended before meals and bedtime if the patient takes multiple daily injections. If the patient can manage type 2 diabetes without insulin medications or with diet and exercise alone, it may not be necessary to test daily [137].

6.4 Conceptual framework

In order to summarise the data model parameters and the last sections, a conceptual framework was developed, as shown in figure 6.5.

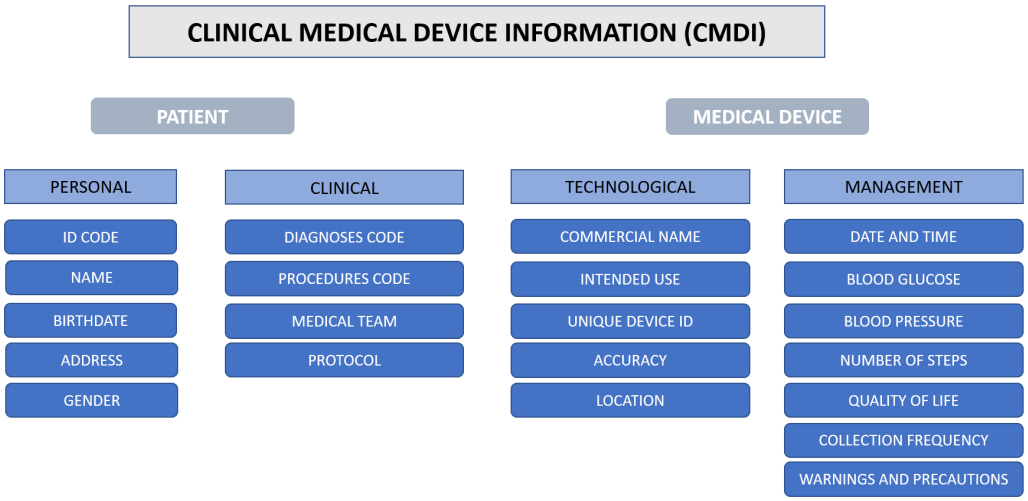

Figure 6.5: CMDI Conceptual Framework.

The CMDI is divided into 2 components: patients and medical devices. Patient data can be divided into personal and clinical data. The personal data chosen was supported by ISO 27269:2021, which aims to deliver a single, standard International Patient Summary comprising core content. Regarding clinical data, the diagnoses and procedures codes use the International Classification of Diseases, administered by WHO.

The medical devices were divided into technological components and data management. ISO 20417:2021 supports medical devices' identification elements, and the location is based on Plus Codes from Google. On the other hand, management comprises all the measured values, the date and time in which they were taken, the quality of life survey results, the collection frequency of each device and their warnings and precautions. These 2

last parameters are supported by the ISO 20417:2021. As aforementioned, the collection frequency and the number of steps are defined by the physician.

6.5 Data Model Demonstration

The CMDI data model was designed and applied to an example of n=50 patients in a FHU, which were numbered from 1 to n, along with their SNS number and birthdate. This form of identification is sufficient for this example and respects patients' privacy. The location serves to more easily identify where the medical devices are in case of an emergency. This location refers to the patients' homes, where the devices will be mainly used.

Regarding the clinical history, for this demonstration, only the diseases relevant to this study, i.e. the chronic ones, were considered. All the patients studied have type 2 diabetes mellitus and some degree of hypertension. Additionally, each patient has been assigned a medical team that monitors him/her remotely and has access to the medical staff interface, and 2 equipments, identified by the medical device's number (Et) and the patient's number (Pn). The frequency of use of each device is also shown, and the database may record a higher number of measurements than the recommended one.

Patient (Pn)	Patient ID (SNS number)	Location (Plus Codes)	Clinical Team (Tn)	Birthdate	Disease Code (ICD-10-DM)	Equipment Et(Pn)	Recommended Frequency of Use
P1	325 616 827	PQ64+M5 Linda-a-Velha	T1	1937-09-03	E11 (Type 2 diabetes mellitus)	E1P1	2
					I10 (Primary hypertension)	E2P1	3
P2	988 319 678	PR44+H6 Lisboa	T2	1954-01-04	E11 (Type 2 diabetes mellitus)	E1P2	2
					I11 (Hypertensive heart disease)	E2P2	4
P3	117 196 597	PR3H+5H Lisboa	T3	1961-07-25	E11 (Type 2 diabetes mellitus)	E3P3	2
					I15 (Secondary hypertension)	E2P3	4
P4	436 217 240	PV95+GF Lisboa	T4	1942-11-17	I10 (Primary hypertension)	E3P4	2
					E11 (Type 2 diabetes mellitus)	E2P4	3
P5	745 513 335	QV43+C6 Lisboa	T5	1947-05-07	I10 (Primary hypertension)	E1P5	4
					E11 (Type 2 diabetes mellitus)	E2P5	3

Figure 6.6: Example of personal and clinical data from 5 patients.

Therefore, each patient has two medical devices: a smartwatch with a blood pressure sensor and a pedometer, and a blood glucose monitor. The smartwatch available for these patients is the *Omron HeartGuide*, which was the first one to get FDA approval to monitor blood pressure. This device uses an inflatable cuff inside the watchband that the patient can activate when they want to take measures. Readings take around 30 seconds and are transmitted via Bluetooth. The watch also helps to track and monitor fitness goals and sleep patterns [138].

Two different blood glucose monitors are available for this type of patient: *One Touch Verio Reflect* and *Freestyle Libre 2*. *Verio Reflect* is the only blood glucose monitoring system from *OneTouch* with *Blood Sugar Mentor*, which provides personalised guidance (tips), information (standard messages) and motivation (rewards) for patients to take action to help avoid highs and lows [139]. The dynamic range helps see when blood glucose results are close to high or low, so the patient can take action before they get out of the target

range. *Blood Sugar Mentor* offers even more information to help manage diabetes when connected with the mobile application via Bluetooth. *Verio Reflect* consists of a meter, the lancing device, lancets and test strips [139]. On the other side, *Freestyle Libre 2* is a CGM that can stay on a patient's arm for up to 14 days. Its system has a glucose alarm, which immediately tells if the glucose value is too low or too high [140].

The devices are identified via their commercial name and UDI, as shown in figure 6.7. The serial and lot numbers are important in quality control. If a defect is found in producing a particular batch of products, the serial number will quickly identify which units will be affected. The accuracy is also an important parameter to consider.

Equipment Et(Pn)	Intended Use	Commercial Product Name	Unique Device Identifier					Accuracy
			Device identifier (01)	Expiration date (17)	Manufacturing date (11)	Lot number (10)	Serial number (21)	
E1(Pn)	Blood glucose	One Touch Verio Reflect	7613427002460	260430	210621	K2106559X	KDPLLG4K	15 mg/dL
E2(Pn)	Blood pressure	Omron HeartGuide	2548963528014	300804	220522	H3245439G	DFEFGT6U	3 mmHg
E3(Pn)	Blood glucose	Freestyle Libre 2	2758962548559	280314	220130	V5467897T	LTYUT7U	20 mg/dL

Figure 6.7: Example of 3 medical devices. Adapted from One Touch Verio Reflect UDI.

In addition to device identification, the data also contains information on precautions and device warnings. Some examples of One Touch Verio Reflect and Freestyle Libre 2 are shown in figure 6.8.

Commercial Product Name	Usage times	Important safety	Maintenance	External Influences
One Touch Verio Reflect	Single patient multiple uses.	Do not put the used test strip back in the tube after you have done the test. Do not reuse a test strip to which you have applied blood, control solution, or other contaminants. Test strips are for single use only.	Do not use rechargeable batteries. Always keep the meter and lancing device clean.	Testing should be done within the operating temperature range (6 to 44°C). Make sure the meter and test strips are at the temperature before testing. Keep the test strips in a cool, dry place at a temperature between 5 °C and 30 °C.
Freestyle Libre 2	Single patient. The Sensor and Sensor Applicator are designed for single use.	Do not use if the Sensor Kit package, Sensor Pack, or Sensor Applicator appear damaged or already opened due to the risk of no results and/or infection.	The Reader has a mean use life of 3 years, which is 156 cleaning and disinfection cycles (1 cycle per week for 3 years).	Store the Sensor Kit between 36°F and 82°F. Storage outside of this range may cause inaccurate Sensor glucose readings. Store the Sensor Kit between 10-90% non-condensing humidity

Figure 6.8: Examples of warnings and precautions for medical devices.

As said before, the smartwatch and the blood glucose monitor measure three quantitative values: the number of steps, blood pressure and blood glucose levels. These values are recorded in the database, as well as the date and time of each measurement. In the example of figure 6.9 only two daily measured values are represented, during eight days, for patient P1.

In the example of Figure 6.9, it can be seen that the measured values of blood glucose and blood pressure are within the recommended range explained in subsection 2.1.2. Regarding the number of daily steps, patient P1 could only reach the objective proposed (walk at least 90% of the recommended) on day 3 (green), and almost reached the goal at day 7 (yellow).

Patient (Pn)	Date	BP Time	Blood pressure value (mmHg)	BG Time	Blood glucose value (mg/dL)	Number of steps (%)
P1	2022-09-01	08:32:56	112/74	19:16:13	107	72
		15:34:41	95/68	15:07:14	88	
	2022-09-02	14:45:42	111/70	19:10:05	96	63
		16:01:47	98/65	12:09:56	83	
	2022-09-03	14:05:13	122/81	15:24:53	119	98
		10:12:58	110/65	12:28:33	92	
	2022-09-04	09:11:34	93/61	12:16:56	106	51
		15:27:01	100/72	14:13:08	108	
	2022-09-05	17:26:53	97/59	13:44:46	96	75
		17:55:36	120/80	09:21:32	111	
	2022-09-06	11:23:12	98/63	19:16:13	81	74
		12:10:06	121/81	10:07:57	83	
	2022-09-07	11:58:08	99/66	11:48:22	114	81
		10:27:26	120/84	17:52:39	124	
	2022-09-08	08:48:02	120/85	13:52:55	89	53
		08:34:52	98/60	14:37:52	94	

Figure 6.9: Example of quantitative measurements for one patient.

As mentioned in subsection 6.1.7, the quality of life is a monthly assessed factor in 2 strands: MCS and PCS. In the example of figure 6.10 we can see the quality of life results of 2 patients in the last 3 months. The physical condition of patient P1 has excellent values, while the mental condition was affected in July. However, he made a good recovery in the following months and is now stable. Patient P2 had a lower PCS score than expected in July and August, but it was insufficient to determine a physical condition since it is only for a score of 50 or lower. However, in September, its PCS score increased to above the recommended value (70%).

Patient (Pn)	Month	PCS (%)	MCS (%)
P1	2022-07	81	69
	2022-08	80	75
	2022-09	82	89
P2	2022-07	67	82
	2022-08	69	83
	2022-09	75	90

Figure 6.10: Example of quality of life results.

7

Discussion

In this chapter, the Momentum Framework and the Österle principles were applied to give a critical discussion of the proposed solution. To recapitulate, the purpose of this dissertation was to propose a model for developing the architecture of a medical device information system and database to improve communication between patients at home and medical staff.

7.1 Momentum framework Application

This section discusses how a Digital Transformation Framework can be used to accomplish the health system and the CMDI database. The Momentum Framework was chosen to address this since it is focused on digital health. This framework enables the context for transition at several levels and helps to understand how barriers can be overcome [141]. In this sense, it offers a short 18 Critical Success Factors list which can help decision makers to scale up healthcare services and to determine if an organisation is ready for telemedicine service deployment [73].

The eighteen Critical Success Factors list is presented in the following paragraphs, explaining the measures that will be adopted to accomplish each of the 18 Critical Success Factors. It is essential to mention that the telemedicine service referred to throughout the Momentum Framework represents our PHC monitoring digital service, designed for monitoring and accompanying chronic patients.

Regarding the Context area, the following measures will be taken into account [73]:

1. **Ensure cultural readiness for the CMDI service.**

   The physicians must be ready to use and leverage the technology involved in this project (smartwatch, glucose sensor and interfaces) and teach patients how to use it to avoid mistakes and improve precision and privacy. They should understand the paradigm of change and the benefits that this Digital Transformation will bring. However, the regulator is still not fully engaged regarding problems like cybersecurity.

2. **Come to a consensus on the advantages of CMDI in meeting a compelling need(s).**

   The need to improve patient monitoring and data standardisation was identified by a set of flaws in PHC systems. They can be overcome with the help of this PHC monitoring digital service designed for this purpose and supported by CMDI. The advantages of teleconsultation and real-time monitoring systems will be known and understood by all physicians.

   Concerning the People area, the following measures were considered [73]:

3. **Ensure CMDI leadership through a champion.**

   CMDI benefits must be presented clearly to stakeholders. Medical teams should function as a team of champions who accept the benefits of the new CMDI system and database. They will lead the way towards incorporating telemedicine in PHC since they can generate trust at all levels and have relevant knowledge, contacts and relationships. CMDI will improve access to rigorous patient data.

4. **Involve healthcare professionals and decision-makers.**

   The successful implementation of this CMDI system and the database will only be possible with the involvement of health professionals, technology experts and decision-makers. They should accept and support the modifications imposed by the new system, which in the future will be a massive help in making further improvements to the service and in addressing barriers to adoption.

5. **Put the patient at the centre of the service.**

   CMDI will enable patient-centeredness by guaranteeing a more precise and secure exchange of clinical information with patients. Implementing a goal-oriented care approach is a long process that needs to be built and achieved based on a good relationship between the patient and the physician. This cooperation will lead to better healthcare services, which is why taking into account patients' perspectives is so important and why goal-oriented care will continue to be used in the future.

6. **Ensure that the CMDI technology is user-friendly.**

   The CMDI technology involved in this system does not require an extended training process before using it and is user-friendly for physicians and patients. It is simple, usable, cost-efficient, easy to understand, has a responsive design, fits for purpose, and is reliable for all PHC monitoring digital service users. In the future, user-friendliness will be continually tested and improved if needed.

   Concerning the Plan area, the following measures were applied [73]:

7. **Pull together the resources needed for deployment.**

   The FHU and the METHIS Project will provide all the resources needed to implement the CMDI system and database. They are financial resources (supported by

the FHU), human resources (patients, physicians, nurses and clinical assistants), information resources (information provided by the METHIS Project's researchers), and time resources (the time needed to implement the new system). These are the resources needed to implement and ensure the system's sustainability. CMDI implementation should include the engagement of health professionals, technology experts and decision-makers, but also biomedical engineers, lawyers and (technology and medicine) regulators.

8. **Address the needs of the primary client(s).**

   In this project, the primary client is a chronic patient. The physicians are also interested in CMDI. Therefore, both can play an essential role in pushing for more security and providing an exchange of clinical information. This system has been shaped according to chronic patients' needs through research.

9. **Prepare and implement a business plan.**

   A business plan should be developed since it helps an organisation when facing complicated situations. It enables it to build alternative solutions in healthcare (including when dealing with chronic diseases). The CMDI business plan should include the benefits of the secure and private exchange of clinical information and the costs of technology investment and maintenance.

10. **Prepare and implement a change management plan.**

    CMDI benefits and use must be properly explained. A pilot project could be an important opportunity to improve the CMDI visibility among the stakeholders.

11. **Assess the conditions under which the service is legal.**

    CMDI can reinforce the legal base for digital health services. The exercise of telemedicine is provided for in Article 46 and follows the Code of Ethics of the Order of Physicians, published as an annexe to Regulation no. 707/2016 of 21 July 2016. Among its provisions, article 46 states the following [142]:

    a) Telemedicine must respect the physician-patient relationship, maintain mutual trust, the independence of the physician's opinion, the patient's autonomy and confidentiality.

    b) When the patient requests or undergoes a telemedicine appointment, it should not replace the physician-patient relationship. It should be carried out under conditions superimposing to a face-to-face consultation and will only be given when the physician has a clear and justifiable idea of the clinic situation.

    c) The physician who uses telemedicine and does not observe the patient in person must carefully evaluate the information received and can only give opinions and recommendations or make medical decisions if the quality of the information received is sufficient and relevant.

d) When using telemedicine in urgent situations, the physician's opinion may be based on incomplete information. However, in this exceptional situation, the attending physician is responsible for taking the decision. Thus, telemedicine is possible as long as it is possible to ensure these four aspects. This way, it is ensured that the new system is legal, according to Portuguese law.

12. **Guarantee that the technology has the potential for scale-up.**

The technology used in the system and implemented in an FHU will have the potential for scale-up and to be later implemented in other FHUs in Portugal or other countries since user-friendliness is ensured.

Regarding the Run area, the following measures were considered [73]:

13. **Identify and apply relevant legal and security guidelines.**

CMDI is fundamentally a techno-legal framework to provide a more secure and precise exchange of clinical information. Legal and security guidelines were identified, based on Portuguese law [142], and applied to the new system. These guidelines are:

a) The physician-patient relationship will be respected: the mutual trust, the independence of the physician's opinion, the patient's autonomy and confidentiality will be maintained.

b) The telemedicine appointment, when requested by the patient, will not replace the physician-patient relationship, will be carried out under conditions superimposing to a face-to-face consultation and will only be given when the physician has a clear and justifiable idea of the clinic situation.

c) The physician who uses telemedicine and does not observe the patient in person will carefully evaluate the information received and will only give opinions and recommendations or make medical decisions if the quality of the information received is sufficient and relevant.

d) When using telemedicine in urgent situations, the physician's opinion may be based on incomplete information. However, in this exceptional situation, the attending physician is responsible for taking the decision. Thus, by complying with these guidelines, it is possible to ensure that telemedicine will be correctly performed.

14. **Involve legal and security experts.**

Just as physicians and technologists, legal and security experts will be involved in guiding and giving advice about this area and ensuring the new digital health service is legal and secure.

15. **Ensure that the CMDI doers and users are privacy-aware.**

    Training in privacy awareness will be offered to physicians, nurses and patients at the time of implementation of the new system. This training can include themes like privacy and PII, privacy laws, policies, and principles, roles and responsibilities in protecting privacy, potential threats to privacy, consequences of privacy violations, or protection of PII in different contexts and formats.

16. **Ensure that the appropriate information technology and eHealth infrastructure are available.**

    CMDI framework will require a precise fulfilment of a solid technological infrastructure to support digital care. It will be ensured that the IT infrastructures will be in place to implement the system and database once the METHIS Project is finished. These infrastructures include the system's network, the glucose sensor, the smartwatch, the database and the METHIS Web application.

17. **Put in place the technology and processes needed to monitor the service.**

    The technology used in the new system will monitor the healthcare services offered by the FHU and guarantee its correct functioning. This monitoring will be complemented with the support of the METHIS Project's team, which is available to solve any situations that may arise. Implementing CMDI will establish a framework for monitoring the complete digital care service.

18. **Establish and maintain good procurement processes.**

    We will ensure we have clear agreements regarding the service level provided by our vendors. CMDI will also require specific demands from providers enabling a more precise procurement process.

7.2 Österle principles

Regarding methodology, the artefact assessment must comply with the four Österle principles for design-oriented IS research: Abstraction, Originality, Justification, and Benefits [143]. The CMDI framework completely fulfils these four Österle principles [144]:

- **Abstraction**: CMDI may be used by the health system to engage health professionals to be ready to tackle chronic disease management and medical device use at public and private health units.

- **Originality**: CMDI was designed to continue the work previously developed in the METHIS project, which is an innovative solution for managing chronic patient data. This contributes to creating a system oriented to chronic patients' needs.

- **Justification**: As mentioned in subsection 2.1.1, chronic diseases are among the primary cause of death worldwide and are a longitudinal process, therefore requiring frequent interactions with patients [8]. CMDI will help to prevent, manage and control chronic diseases with the help of medical devices and guarantee precise and secure exchange of clinical information.

- **Benefits**: This system and framework assist healthcare organisations and society by offering an integrated patient perspective and making healthcare professionals' jobs easier. CMDI will be a guarantee for precise and secure exchange of clinical information, avoiding costly clinical errors. It also improves chronic illness management by allowing clinicians to review patient data in their circumstances preventing patients from getting worse and needing to use costlier resources.

This way, the CMDI is ready to be correctly implemented in the METHIS Project.

7.3 Demonstration Evaluation

The data model application in section 6.5 allows to better understand each parameter of the CMDI and their relevance. However, it is important to mention that the demonstration carried out is theoretical and it is necessary to apply it in a real FHU. In an actual demonstration, the number of patients would be higher, and they would probably have a longer list of diseases and medical procedures and be able to use other medical devices. Since the medical devices used as examples were unavailable, it was impossible to place the error and uncertainty, only the accuracy, through a literature search. Nevertheless, it allowed visualising the various elements of the CMDI in a database context.

8

Conclusion and Future Work

This Chapter concludes the study by providing an overall balance of the developed work and a summary of future research.

8.1 Main Conclusions

With this dissertation, it was possible to go deeper into the design of the METHIS system and accomplish the primarily established goal: the analysis and identification of the data to be in the CMDI framework. First, the system proposed by a previous dissertation was studied, and the various elements were described in more detail. This way, it was easier to understand how data flows inside the system. Several conclusions could be drawn regarding the design:

- EHRs are extremely important for the smooth functioning of the system and the health system in general.
- The control application becomes a beneficial element to set measurement frequencies and other parameters of medical devices automatically.
- Patient and physician interfaces are essential to receive critical information such as patient's symptoms, quality of life survey, alerts about abnormal values or analysis and examination results.

Regarding the CMDI model data, it was possible to group the patients' most relevant personal and clinical data. It is not enough to identify patients only by their name, as there are people with the same name or only by their address, as there may be several people living in the same house and even fewer by their date of birth. Thus, the most suitable is for the patient to be identified by two of these parameters. The Plus Code from Google is a good option for the location code since it keeps people's privacy by not recognising the door or floor number but still allows the identification of the patient's home area. Another advantage of this code is that it can locate houses with no address, such as in some older villages of the country. Ideally, patients should be identified by a

unique health code. In the case of Portugal, this code can be the SNS number; however, this only works for the public health system. Moreover, the way of identification varies between health systems and countries. Therefore, if a person is in a different country and needs medical assistance, it is practically impossible to access their medical history.

The equipment used, i.e. the smartwatch and the blood glucose monitors, are the central point for communication between patients and physicians. It is, therefore, crucial to ensure that they are working correctly and to be able to identify possible faults quickly. Although there are several ways to identify devices, the most standard method is the UDI, which contains helpful information such as the expiry date, lot number and serial number to help identify faulty devices. It is essential to mention that the information in the CMDI does not replace the user manual and the use instructions. The patients should read these to avoid problems when handling the devices, namely the list of precautions and warnings. Another topic of interest is the importance of the devices working as regulated. The FDA cited glucometers as an example of a sensor that may be deregulated if created and promoted for non-medical uses such as nutrition. Other examples of these sensors are smartwatches. While many monitor blood pressure, few of them have FDA or EMA approval.

As mentioned, three quantitative data are measured by the medical devices: blood pressure, blood glucose and the number of steps. When the measurements are outside the recommended range, the METHIS system sends an alert via the user interfaces. The quality of life survey results is registered in the database after submission through the patient interface. Although some devices have their application, bringing all the information together in one place, in this case, the CMDI, will benefit both the patient and the physician.

The correct use of patient data will allow better monitoring of chronic diseases, and patients can be more informed about their health by accessing specific information about their medical devices. The efficiency of the health sector is highly dependent on the data used in the delivery of care and the management of this sector. For this reason, the role of information standards is vital.

8.2 Future Work

For future work, we propose the actual implementation of the CMDI database in the METHIS project based on this dissertation's work after sensor network integration in the platform. Other recommendations are choosing new medical devices (with different classifications) that can be introduced into the system, adapting the database to other contexts, like hospitalised patients and programming the devices in the control application to function correctly, for example. Additionally, ISO standards for interfaces could be used to improve the whole process further.

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I

The 12-Item Short Form Survey

An example of a SF-12 is presented below [145].

SF-12® Patient Questionnaire

Patient Initials _____ _____ _____ Date of Birth: ___/___/___ Patkey: _____

Surgeon Name: _____ Date: _____

Examination Period:
_____ Preop (1)
_____ Immediate Postop (2)
_____ 1 Year (3)
_____ 3 Year (4)
_____ 5 Year (5)
_____ Other (specify) (6): _____

SF-12®:
This information will help your doctors keep track of how you feel and how well you are able to do your usual activities. Answer every question by placing a check mark on the line in front of the appropriate answer. It is not specific for arthritis. If you are unsure about how to answer a question, please give the best answer you can and make a written comment beside your answer.

1. In general, would you say your health is:
   _____ Excellent (1)
   _____ Very Good (2)
   _____ Good (3)
   _____ Fair (4)
   _____ Poor (5)

The following two questions are about activities you might do during a typical day. Does YOUR HEALTH NOW LIMIT YOU in these activities? If so, how much?

2. MODERATE ACTIVITIES, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf:
   _____ Yes, Limited A Lot (1)
   _____ Yes, Limited A Little (2)
   _____ No, Not Limited At All (3)

3. Climbing SEVERAL flights of stairs:
   _____ Yes, Limited A Lot (1)
   _____ Yes, Limited A Little (2)
   _____ No, Not Limited At All (3)

During the PAST 4 WEEKS have you had any of the following problems with your work or other regular activities AS A RESULT OF YOUR PHYSICAL HEALTH?

4. ACCOMPLISHED LESS than you would like:
   _____ Yes (1)
   _____ No (2)

5. Were limited in the KIND of work or other activities:
   _____ Yes (1)
   _____ No (2)

Patient Initials _____ _____ _____ Date of Birth: ___/___/___ Patkey: _____

Surgeon Name: _____ Date: _____

Examination Period:
_____ Preop (1)
_____ Immediate Postop (2)
_____ 1 Year (3)
_____ 3 Year (4)
_____ 5 Year (5)
_____ Other (specify) (6): _____

SF-12® Cont'd:

During the PAST 4 WEEKS, were you limited in the kind of work you do or other regular activities AS A RESULT OF ANY EMOTIONAL PROBLEMS (such as feeling depressed or anxious)?

6. ACCOMPLISHED LESS than you would like:
   _____ Yes (1)
   _____ No (2)

7. Didn't do work or other activities as CAREFULLY as usual:
   _____ Yes (1)
   _____ No (2)

8. During the PAST 4 WEEKS, how much did PAIN interfere with your normal work (including both work outside the home and housework)?
   _____ Not At All (1)
   _____ A Little Bit (2)
   _____ Moderately (3)
   _____ Quite A Bit (4)
   _____ Extremely (5)

The next three questions are about how you feel and how things have been DURING THE PAST 4 WEEKS. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the PAST 4 WEEKS –

9. Have you felt calm and peaceful?
   _____ All of the Time (1)
   _____ Most of the Time (2)
   _____ A Good Bit of the Time (3)
   _____ Some of the Time (4)
   _____ A Little of the Time (5)
   _____ None of the Time (6)

Patient Initials _____ _____ _____ **Date of Birth:** ___/___/___ **Patkey:** _____

Surgeon Name: _____ **Date:** _____

Examination Period:
_____ Preop (1)
_____ Immediate Postop (2)
_____ 1 Year (3)
_____ 3 Year (4)
_____ 5 Year (5)
_____ Other (specify) (6): _____

SF-12® Cont'd:

10. Did you have a lot of energy?
    _____ All of the Time (1)
    _____ Most of the Time (2)
    _____ A Good Bit of the Time (3)
    _____ Some of the Time (4)
    _____ A Little of the Time (5)
    _____ None of the Time (6)

11. Have you felt downhearted and blue?
    _____ All of the Time (1)
    _____ Most of the Time (2)
    _____ A Good Bit of the Time (3)
    _____ Some of the Time (4)
    _____ A Little of the Time (5)
    _____ None of the Time (6)

12. During the PAST 4 WEEKS, how much of the time has your PHYSICAL HEALTH OR EMOTIONAL PROBLEMS interfered with your social activities (like visiting with friends, relatives, etc.)?
    _____ All of the Time (1)
    _____ Most of the Time (2)
    _____ A Good Bit of the Time (3)
    _____ Some of the Time (4)
    _____ A Little of the Time (5)
    _____ None of the Time (6)

Surgeon Signature_____ **Date**_____