FACULDADE DE ENGENHARIA DA UNIVERSIDADE DO PORTO

Adoption of the "My Health Diary" platform: a health technology assessment study

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Mestrado em Engenharia de Software

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Abstract

My Health Diary is a platform that was designed by the neurologists from Unidade Local de Saúde de Matosinhos (ULSM), with the objective to expand the adherence of migraine patients to filling out a headache diary, in order to increase the accuracy of the diagnosis and monitor the evolution of symptoms. This platform was developed in partnership between FEUP and ULSM, during the 2020 GPIE course.

In order to evaluate the impact of My Health Diary platform adoption by the Unidade Local de Saúde de Matosinhos, a Health Technology Assessment is going to be performed. Health Technology Assessment is a systematic appraisal of health technology to analyze its impact, enhance efficiency, and inform and support the decision-making process.

Usually, to evaluate a health technology, nine domains must be addressed in order to assure the full assessment. However, some differences arise when the intention is to assess digital health technology. The domains defined may not be enough to assess this kind of technology, as they present specific characteristics, different from other health technologies. Therefore new methodologies are necessary to appraise both nine domains and the specific characteristics of software as health technology.

This dissertation arises with the purpose of developing an HTA process that would be able to assess a software system used as health technology, taking into account the specific characteristics of software as well as maintaining the usual nine core domains assessed in a full HTA.

A pilot study was implemented to validate the HTA process developed, and also fulfill the purpose of evaluating the impact of My Health Diary. This pilot study is being carried out in ULSM, with the collaboration of the neurologists from this local unit, as well as the participation of 60 patients suffering from migraines. It is a randomized controlled trial with a crossover design, which aims to evaluate the My Health Diary platform in comparison with the current tool used, the paper diary.

The general evaluation of My Health Diary, considering all analyzed domains, is very positive, as the system performed well in each of the considered domains. In addition, the health technology proved to be more efficient, more practical, and more enjoyable to use than the paper diary tool, as one would expect.

Keywords: Health Technology Assessment, HTA, Impact Analysis, Digital Health Technologies, Headache, Migraine

Resumo

My Health Diary é uma plataforma idealizada pelos neurologistas da Unidade Local de Saúde de Matosinhos (ULSM). Esta plataforma tem como objetivo aumentar a adesão dos doentes com enxaqueca ao preenchimento de um diário de cefaleias, de modo a aumentar a precisão do diagnóstico e monitorizar a evolução dos sintomas. A plataforma foi desenvolvida numa parceria entre a FEUP e a ULSM, durante o ano de 2020, na disciplina de GPIE.

De forma a avaliar o impacto que a adoção da plataforma My Health Diary terá na Unidade Local de Saúde de Matosinhos, realizar-se-á uma Avaliação de Tecnologia da Saúde. Ums Avaliação de Tecnologia da Saúde é uma avaliação sistemática da tecnologia para analisar o seu impacto, aumentar a eficiência e informar e apoiar no processo de tomada de decisão.

Normalmente, para avaliar uma tecnologia da saúde, nove domínios devem ser abordados de forma a garantir uma avaliação completa. No entanto, quando a intenção é avaliar uma tecnologia da saúde digital, algumas diferenças surgem, e os domínios definidos podem não ser suficientes para avaliar este tipo de tecnologia, já que esta apresenta características específicas e diferentes de outras tecnologias da saúde. Desta forma, novas metodologias são necessárias para avaliar os nove domínios e, adicionalmente, as características específicas do software como tecnologia da saúde.

Esta dissertação surge com o objetivo de desenvolver um processo de ATS que seja capaz de avaliar um sistema de software utilizado como tecnologia da saúde, levando em consideração as características específicas do software, bem como mantendo os nove domínios centrais avaliados numa ATS completa.

Foi implementado, então, um estudo piloto para validar o processo de ATS desenvolvido, e também cumprir o objetivo de avaliar o impacto da plataforma My Health Diary. Este estudo piloto está a ser realizado na ULSM, com a colaboração dos neurologistas desta unidade local, e contando com a participação de 60 pacientes que sofrem de enxaqueca. Trata-se de um Ensaio clínico randomizado com desenho crossover, que pretende avaliar a plataforma My Health Diary em comparação com a ferramenta usada atualmente, o diário em papel.

A avaliação geral da plataforma My Health Diary, considerando todos os domínios analisados, foi bastante positiva, pois o sistema teve um bom desempenho em cada um dos domínios considerados. Além disso, esta tecnologia provou ser mais eficiente, mais prática e mais agradável de usar do que a ferramenta de diário de papel, como era de se esperar.

Palavras-chave: Avaliação de Tecnologias da Saúde, ATS, Análise de Impacto, Cefaleias, Enxaqueca

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Carolina Rosa

"Science can amuse and fascinate us all,
but it is engineering that changes the world"

Isaac Asimov

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Abbreviations

API	Application Programming Interface
APK	Android Package
DTO	Data Transfer Objects
EUnetHTA	European network for Health Technology Assessment
FEUP	Faculdade de Engenharia da Universidade do Porto
GDPR	General Data Protection Regulation
GPIE	Gestão de Projetos, Inovação e Empreendedorismo
HIT	Headache Impact Test
HTA	Health Technology Assessment
ICHD	International Classification of Headache Disorders
INAHTA	International Network of Agencies for Health Technology Assessment
ISPOR	International Society for Pharmacoeconomics and Outcomes Research
JSON	JavaScript Object Notation
JWT	JSON Web Tokens
MCDA	Multiple Criteria Decision Analysis
MDs	Medical Devices
mHealth	Mobile Health
MiDAS	Migraine Disability Assessment Test
MSQ	Migraine Specific Quality of Life
RCT	Randomized Controlled Trial
SaMD	Software as a Medical Device
ULSM	Unidade Local de Saúde de Matosinhos
WHO	World Health Organization
WHOQOL-BREF	World Health Organization Quality of Life Instruments - Bref

Chapter 1

Introduction

1.1 Context

In a world where migraines are the second main neurological cause of incapacity, and where headaches are a frequent complaint, being one of the main reasons for seeking health care, as well as for decreased quality of life, there is a need to deal with this condition. However, the treatment for patients' condition may vary according to the diagnosis of primary headaches or with the frequency of episodes, and therefore a correct diagnosis is crucial for the improvement of the condition.

The diagnosis of the headaches is based almost exclusively on the clinical history of the patients. Thus, in the Unidade Local de Saúde de Matosinhos - ULSM, to monitor the episodes of headaches, and the response to treatment in a more reliable way, the patients use a paper calendar to register their episodes. However, with the paper calendar, there are some unavoidable limitations, like the loss of the paper, or forgetting to bring the calendar to the medical appointment, or even the fulfillment of multiple registries in a biased way right before the appointments.

For this reason, the doctors from ULSM proposed the development of "My Health Diary", a Headache Diary system for the patients, so they can be more easily monitored by the doctors, and so their treatment can be adjusted to their specific needs. This platform was fully designed by the health professionals and developed in GPIE class.

My Health Diary is a system developed in order to help doctors to monitor the headaches of their patients so they can make clinical decisions regarding the treatment of the patients, in a more knowingly way. It is a combination of two platforms, a health professionals' web app accessible to doctors and nurses, a patients' mobile app available for Android devices, and accessible only to patients who are being followed up at the neurology service at Hospital Pedro Hispano.

The mobile application is a diary of headaches where the patients should register, on a daily basis, their headaches, and migraines, answering a questionnaire designed by the doctors. The recorded information will help the doctors to make decisions with respect to the treatment. The

web application is only accessible by doctors and nurses and allows them to have remote access to the data filled by the patients on the mobile app.

The My Health Diary platform was conceived to overcome the limitations existing on the paper calendar and provide accurate and reliable information about the patients' headaches. Moreover, the platform would allow the health professional to remotely access the patients' information at any time.

1.2 Motivation

It goes without saying that no industry is currently lagging behind in terms of technological development. Also in the healthcare field, the use of digital technology is growing significantly. From improving personnel management to improved services and better quality of patient care, the healthcare sector is employing software in many of its functions, keeping up with the times.

Thereby, this dissertation intends to design and implement a Health Technology Assessment methodology to systematically assess the "My Health Diary" platform, addressing the direct and intended effects of this technology, as well as its indirect and unintended consequences.

Health Technology Assessment is defined by the World Health Organization as the systematic evaluation of properties, effects, and/or impacts of a health technology [18]. It comprises a transparent and multidisciplinary process that uses explicit state-of-the-art methods to assess a health technology at different points of its life-cycle, considering the best evidence available. It aims to evaluate the ethical, organizational, and social-economic issues of a health technology [18, 19].

The main intention of this study is to understand how to perform a Health Technology Assessment on the My Health Diary platform, in order to clarify whether the platform is more effective than the use of paper diaries, which is the current tool used in ULSM but also to understand whether its use brings benefits to both patients and doctors.

The study also intends to help in the decision regarding the adoption of the "My Health Diary" platform as the go-to tool for monitoring headaches in this local unit.

1.3 Existing Gap

Software that is used in healthcare is a kind of health technology, being Health Technologies *"the application of organized knowledge and skills in the form of medicines, medical devices, vaccines, procedures, and systems developed to solve a health problem and improve the quality of life"*, according to the World Health Organization.

As health technologies are constantly being created and inserted in the market with the goal of improving the lives of the patients, there appears a need to appraise these technologies to understand if they bring value to patients and have a positive impact on their lives. For that purpose, the concept of Health Technology Assessment start being used to express the systematic evaluation made to the health technologies in order to understand their properties, the effects they bring, and the impact, with the goal of helping on the decision-making process.

Health Technology Assessment (HTA) is an evaluation performed in health technologies in order to understand the impact they bring to the health care system. Health technologies are the medicines, procedures, medical devices, and systems that are meant to solve or improve, a health condition. These assessments are being used to evaluate all kinds of health technologies so they can provide information to decision-makers that will decide regarding the introduction of the technologies in healthcare. *"HTAs are a bridge between science and policy and require a balance between the ideals of scientific rigor and the realities of policy making"* [55].

Although these methods have been used to evaluate the efficacy of drugs and therapeutic interventions as part of the regulatory process [54], this is still not the case for digital health technologies. Additionally, with the use of digital health technologies constantly growing, the need to understand how to evaluate these new technologies also arises.

The HTA traditionally used, is not sufficient to cover all the relevant aspects of the digital technologies, like usability, accessibility, and data protection, and, therefore, an improved assessment framework is required [34].

Thus, this dissertation appears with the intention to develop a Health Technology Assessment process, that would maintain the usual nine core domains, but appending some other domains, capable of evaluating the characteristics of software health technologies.

1.4 Document Structure

The structure of the document is now presented and goes as follows:

The current chapter corresponds to the introduction of the dissertation. Here it is presented the context of the work as well as its motivations and challenges, which prompted the topic and dissertation.

Chapter 2 presents the State of the Art focusing on the existing methodologies that are being used in Health Technology Assessment, and specifically on health technologies that are software products discussing them in order to provide a clear position on how this dissertation is relevant to the topic of HTA.

In chapter 3 it is intended to present a process of Health Technology Assessment that is based on processes currently used and that aims to bridge the existing gaps for the assessment of software as health technology, by adding new domains targeting the software evaluation.

The next chapter, chapter 4, aims to make known the validation scenario used to validate the process presented in the previous chapter. In this chapter, it is explained the partnership with Unidade Local de Saúde de Matosinhos - ULSM, followed by the presentation of the platform My Health Diary, as well as the necessary preparation for the platform to be available and the description of the Pilot Study implemented in collaboration with ULSM.

Regarding chapter 5, it corresponds to a description of the application of the process presented in chapter 3, to the My Health Diary platform that is shown in chapter 4. The chapter presents the data collected and subsequently organized in order to provide relevant information for each of the domains of the HTA process that was developed.

The last chapter is dedicated to presenting the main conclusions that can be taken from this work, enhancing the improvement aspects for the technology being assessed. Here, the issues and obstacles that arose along the way will also be discussed. At last, the perspectives for future work that may be developed are presented.

The document is complemented with 5 appendices, in order to provide additional information on the topics covered. The first appendix, A, presents the questionnaires that were used on this assessment. Appendix B contains the acceptance tests performed on the My Health Diary application. Appendix C corresponds to the paper diary that is being used as the different diary approach to be compared with the My Health Diary system during the clinical trial. The fourth appendix, D, contains the results obtained in the questionnaires, answered by the patients during the trial, but also for the usability questionnaire of health professionals. Appendix E presents the Utilization Manual that was developed to ease the learning process of health professionals on how to use the two applications.

Chapter 2

State of the Art

2.1 Introduction

As stated in the introduction section, My Health Diary is a platform that was designed by the neurologists of Hospital Pedro Hispano to help them monitor the headaches of their patients so they can better diagnose and adjust treatments for migraines, and also to overcome the limitations of the current tool used - the paper diary.

The system is composed of two applications: a mobile application for patients to register their headaches and a web application for the professionals so they can have access to the registries of the patients.

Therefore, the purpose of this dissertation is to develop a health technology assessment process for the new platform My Health Diary, that is, to evaluate the platform having as a foundation the health technology assessment process.

This chapter arises as a motivation and a justification for the dissertation as it intends to analyze the current use of HTA, as well as the HTA processes that are being used to assess technologies, in particular digital technologies.

This State of the Art aims to:

- Understand what is a Health Technology Assessment;
- What are the methodologies being used on HTA, and how are they implemented;
- What are the differences when performing a Health Technology Assessment on digital health technology.

The chapter is structured in the following way: Section II explores the concepts of Health Technology, Medical Devices, e-health, and m-health, followed by Section III where the Health Technology Assessment is defined and explored. Section IV presents some of the methodologies that are being used to assess Health Technologies. Section V explores Health Technology Assessment when applied to m-health technologies. Finally, in Section VI the conclusions will be presented with a reflection about the subject.

2.2 Health Technology

Health Technology, according to the **World Health Organization** [18], is:

> *"the application of organized knowledge and skills in the form of medicines, medical devices, vaccines, procedures, and systems developed to solve a health problem and improve the quality of life."*

Thus, it is seen as any kind of intervention that is developed for prevention, diagnosis, or treatment of medical conditions, but also to promote health, to provide rehabilitation, or to organize healthcare delivery [20].

Therefore, the term health technology can be applied to a large number of different kinds of services and products that are available in the healthcare system. It is everything that can be utilized in medical processes within which healthcare is delivered [5].

There are three ways of describing health technology: it can be described according to its material nature, for instance, if it corresponds to drugs, devices, surgical procedures, support systems, etc. It can also be described according to its purpose if it is meant for prevention, diagnosis, treatment, or rehabilitation. It can, as well, be described by its stage of the life cycle, in case it is in the earliest stages of development, experimental, established, or abandoned [31].

Garrido et al., (2010) [64] divide health technology into three groups. One group contains the health care products that are available "within the healthcare system", like drugs, devices, and procedures. The second group aggregates the "technologies applied to the healthcare system" corresponding to the interventions with the purpose of organizing the access, the service delivery, etc. The last group described, corresponds to the "technologies outside the healthcare system", meaning the interventions that protect and promote health, like educational services, for example.

2.2.1 Is My Health Diary a Medical Device?

Health technologies are essential for a health system to function. In particular, medical devices (MDs) are crucial to prevent, diagnose, and treat illnesses and diseases, as well as helping in the rehabilitation phase. Usually, pharmacologic, immunologic, or metabolic means are not able to achieve the purpose of medical devices. MDs can also be used to detect, measure, restore, correct or modify the structure or function of the body for some health purposes [2].

World Health Organization define a medical device as [49]

> *" 'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:*
>
> - *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
> - *diagnosis, monitoring, treatment, alleviation of or compensation for an injury,*

- *investigation, replacement, modification, or support of the anatomy or of a physiological process,*
- *supporting or sustaining life,*
- *control of conception,*
- *disinfection of medical devices,*
- *providing information by means of in vitro examination of specimens derived from the human body;*

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means. Note: Products which may be considered to be medical devices in some jurisdictions but not in others include:

- *disinfection substances,*
- *aids for persons with disabilities,*
- *devices incorporating animal and/or human tissues,*
- *devices for.in-vitro fertilization or assisted reproduction technologies."*

Medical devices can fall into three main categories: Assistive technology, artificial body parts, and assistance for medical professionals. In case they are directly used by patients, MDs are considered assistive technology devices, for instance, a wheelchair. A stent, for example, is considered an artificial body part, that may be implanted by a medical procedure. Also, the assistance for medical professionals can be provided by a medical device, like a PET/CT scanner, for instance [29].

On its own, the software can be a medical device, and the term used to describe it is Software as a Medical Device or SaMD. It "is defined as software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device", according to the International Medical Device Regulators Forum (IMDRF) [35, 28]. It can also be referred to as standalone software.

Besides SaMD, the software can be related to medical devices in two more ways, being Software in a Medical Device, which corresponds to software integrated into a medical device, and software that is used in the production and/or maintenance of a medical device [28].

It should be noted that software is not a medical device if its intention is to "drive a hardware medical device" [35]. A mobile application can be a medical device if it meets this definition.

According to Medicines & Healthcare products Regulatory Agency (MHRA) from the United Kingdom - "Guidance: Medical device stand-alone software including apps", if the software used for healthcare purposes only has one of the following functions, it is not considered to be a medical device.

- *Patient medical education;*

- *Monitors fitness/health/well-being;*
- *Professional medical education;*
- *Stores or transmits medical data without change;*
- *Software that is used to book an appointment, request a prescription or have a virtual consultation is also unlikely to be considered a medical device if it only has an administrative function;*
- *Software that provides reference information to help a Healthcare Professional to use their knowledge to make a clinical decision;*
- *Data or database for storing data;*

Being My Health Diary an application, where patients register, on a daily basis, information regarding their headaches and migraines, and the doctors have access to that information so they can make clinical decisions about the patient, having the information as a basis. Therefore, My Health Diary is not considered a medical device.

2.2.2 Mobile Medical Applications

Nowadays, information and communication technologies (ICT) are being used in the most diverse areas and with very different purposes. Thus, also in the health area, ICT is being implemented in order to support and improve healthcare delivery.

Digital health or e-health is defined by Vukovic et al., (2018) [65] as *"the application of information and communication technologies (ICT) across the wide range of activities that are carried out in the health care, from diagnosis to follow-up"*. Thus, the term is applied to the digital solutions and tools that help to improve the lives of the patients through the "prevention, diagnosis, treatment, and monitoring" of the illness, as well as the monitoring of the patient's health, lifestyle, and activities [65]. It is, thus, the application of digital technologies to reach "health objectives" [68].

The use of digital health apps has been expanding very quickly and allows to overtake some obstacles that exist in the usual methods, like economic and capacity restrictions, distance and time problems, for example [70]. This can, also, be applied to mobile health.

Mobile Health, also known as m-health, is a subcategory of e-health, and both are subcategories of health technologies. Mobile health is defined by the **World Health Organization** as the *"medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices"* [69]. The devices should be used and accessed by the user on a daily basis [38].

The use of m-Health applications has increased as a result of smartphones spreading across the world. Therefore, mobile health is expected to occupy an important position in the future of healthcare delivery [37]. It could change completely the way healthcare is delivered in low-

and middle-income countries, as well as all around the world, since it provides medical practices through mobility, fast access, and easy transmission of health data [42].

Since most people, currently possess and use mobile phones, it is easier for the patients to engage in their individual health care management and to deliver health information [58]. These technologies are accessible at any time and anywhere and they are being used to [42, 38]:

- Educate, communicate, and monitor the patients.
- Decrease the need to visit healthcare facilities.
- Manage chronic diseases.
- Promote healthier behaviors in order to avoid health problems.
- Support access to health services, clinical diagnosis, and treatment adherence.
- Reduce poverty-related illnesses.
- Provide health care in a way that was not possible in previous times, and in a "personalized, localized and on-demand" manner.

Also for clinicians, m-healths are an asset as they allow to monitor the patients in real-time, analyze the prescribed process, and define possible modifications that might be more appropriate [67].

As these apps are meant to be used by patients and health professionals, and as they may rely on the information provided by the app to decide on important issues, the reliability and accuracy of those applications is crucial and must be assessed [41]. The assessment should take place in order to understand the effectiveness of the m-health apps or if adverse outcomes are brought to the patients' life, both in quality and cost, with its use [38]. Thus, *" rigorous research is needed to examine the potential, as well as the challenges, of utilizing mobile technologies to improve health outcomes"* [38].

Although m-health brings many advantages to the way healthcare is delivered, there are still areas for which there is no evidence of effectiveness [42]. Additionally, there is also some evidence of applications that are not safe, not effective, do not respect users' privacy, or have bad documentation [70].

Thus, the evidence found is dispersed regarding the effectiveness of m-health. And, although m-health seems harmless and attractive, there is still a lot of research to be done in order to understand "when, where and for whom" m-health technologies are efficient [38]. Moreover, the early adoption of untested m-health technologies can harm, rather than contribute to an overall health improvement, in a healthcare system with above-than-ideal costs and lower-than-ideal results [38].

2.3 Health Technology Assessment

New health technologies are available every day, to enhance the efficiency of the health system and improve the lives of patients.

In order to review these technologies and specify the value they bring to patients and families, and society in general, Health Technology Assessment (HTA) is, often, the tool used [21].

Health Technology Assessment started in the 1970s, with the high demand for computer-assisted tomography (CT-scans), because of the high cost per unit - many times exceeding $300.000 - thus becoming a public policy issue. It began in order to help in the decision-making process for the "uncontrolled diffusion of costly medical equipment" [2].

Health Technology Assessment is defined by the World Health Organization as the systematic evaluation of properties, effects, and/or impacts of a health technology [18].

It comprises a transparent and multidisciplinary process that uses an explicit framework based on state-of-the-art methods to assess a health technology at different points of its life-cycle, considering the best evidence available. It aims to evaluate the ethical, organizational, and social-economic issues of a health technology [18, 19]. When the purpose of a study is solely to increase scientific knowledge, as in clinical trials or researches, then the study is not considered a technology assessment [5].

As previously mentioned, health technologies are the "medicines, medical devices, vaccines, procedures, and systems developed to solve a health problem and improve the quality of life" [18]. They are developed in order to prevent, diagnose, or treat the medical conditions, but also to promote health, to provide rehabilitation, or to organize healthcare delivery [20].

HTA intends to assess how science and technology are implemented in healthcare [22]. It documents the direct and intended consequences, as well as the indirect and unintended consequences [2], of using a health technology, comparing them to existing alternatives, and do this in a systematic way. It, also, examines the short and long-term consequences regarding the use of the technology.

The main purpose of this kind of assessment is to provide objective information to a technology-related policy decision-making about the safety and effectiveness of health technologies in order to promote an equitable, efficient, and high-quality health system. Also, it intends to create effective, safe, health policies that are patient-focused and seek to accomplish the best value. HTA is carried out in order to support the decision regarding the acquisition or adoption of the technology being assessed [4, 19, 3]. It can also be performed to inform about the reimbursement decision-making of health technologies [47].

A Health Technology Assessment is a process that does not have a methodology defined. The assessment is defined by its intent. An ethical analysis for gene therapy or a technical assessment of a pharmaceutical or medical device are examples of Health Technology Assessments. The most common use of HTA is to provide systematic reviews, especially on efficacy and cost-effectiveness, to determine the benefits and financial costs of a particular technology, and therefore to help in the decision-making [5].

Although there is no defined methodology, most HTA follows these ten steps, which are not necessarily performed linearly [31]:

1. Identification of the assessment object;

2. Specification of the problem;
3. Determine the focus of the assessment;
4. Retrieval of evidence;
5. Collection of new data;
6. Appraisal and interpretation of evidence;
7. Integration of evidence;
8. Formulation of findings and recommendations;
9. Dissemination of the findings and recommendations;
10. and Monitorization of the impact.

To perform a full Health Technology Assessment, it is necessary to address the nine domains firstly identified by the EUR-ASSES. The domains are [1]:

- Current use of the technology;
- Description and technical characteristics;
- Safety;
- Effectiveness;
- Cost and cost-effectiveness;
- Ethical aspects;
- Organizational aspects;
- Social aspects;
- Legal aspects.

These domains will be explained later in the text.

The European Network for HTA (EUnetHTA), which works to create an effective and sustainable network for health technology assessment across Europe in partnership with organizations and institutions in the European countries, developed an HTA Core Model that enables effective, reliable, and transferable information to contribute to HTAs in European countries. This model intends to enhance efficiency and to share knowledge, contributing to the European HTA knowledge base [36, 6]. The HTA Core Model defines the focus of HTA using the nine domains defined by EUR-ASSESS and demonstrates how to appraise those domains.

Therefore, in order to conduct an HTA, it is necessary to define the object of the assessment through policy questions regarding the domains of an HTA. These questions are crucial, as they

present the decision-making problem so that they can be answered by appraising scientific evidence. It is based on these questions that the HTA process will be defined, as well as the aspects to be evaluated [2]. For instance, some of the questions that the evidence may answer are: *"Does the technology work? What benefit does it provide and for whom? What is the cost (to the healthcare service, to the patient, etc.)? (...) How does it compare in terms of efficiency with the available alternatives? Does it work in this healthcare setting?"* [4].

HTA can be conducted at any time in the life cycle of the technology [32]. The moment it is conducted is defined by the needs of the decision-making. If a technology is assessed in its early stages, it is more likely to prevent it to spread in case it is unsafe or ineffective. However, accepting the findings of an early evaluation as definitive can be deceptive [31].

A Health Technology Assessment study can be conducted by several types of experts, as it may analyze a wide variety of impacts and use different methods. Therefore, as these experts have different levels of knowledge and interests, they will need different levels of reports, and findings to be brought out from the assessment [31]. Nevertheless, it is important that the perspective of patients and caregivers is taken into consideration when conducting these studies, as they are the most affected group by the decisions being made.

Thus, each Health Technology Assessment will be designed according to its goals, and to the questions, it intends to answer.

This kind of assessment must be rooted in science and scientific methods, the process must be executed with integrity and the results must be delivered in a systematic, unbiased, transparent, robust way [5]. It contributes in many ways to the knowledge base for improving the quality of healthcare, mainly to help developing and updating policies, guidelines, and standards related to healthcare [31].

2.4 HTA Methodologies

2.4.1 Systematic Reviews

As previously referred, Health Technology Assessment is a kind of study that is completely rooted in science and scientific methods, in order to help in the decision-making process by providing "effective, efficient and safe" information. Therefore, Systematic Reviews are often used for this purpose [57].

Systematic Reviews in the medical field are reviews of medical literature on a specifically stated issue that uses comprehensive and reproducible methods to search, identify, select, produce a critical appraisal, and summarize and analyze all the relevant studies for a specific research question, that went through a screening process in order to check if they met the inclusion and exclusion criteria, in order to produce an unbiased review based on those studies [10, 30].

Thus, the main intention of systematic reviews is to compile the material referring to a specific health procedure or intervention that was raised in the research, perform a critical evaluation, and then present the data in a transparent and impartial way, so that the reader can extract the "state of

research" on the topic in an understanding and succinct way, without having to read all the studies, and so that he can have this information as a basis for policies and decisions [57].

The systematic review can be carried out to assess the quantitative aspects, which are based on studies that report "numerical data", or the qualitative aspects, in case the review uses information taken from "observation, interviews or verbal interactions", but also on the understanding of the participants [10].

A Systematic Review *"do not generate new data but can produce new knowledge from existing evidence"* [57]. It combines the results of existing studies to create one single study that presents all results in a clear and meaningful way so that "any inconsistency or ambiguity" across studies can be answered [57]. In addition, it can be used to understand where there is a lack of knowledge on the topic of interest and so to lead further research [30].

According to Saulle and Torre (2016) [57], the systematic review process should be performed in the following way: First, it is necessary to define the goal of the literature review. The second step is the definition of a "structured protocol review", where the inclusion and exclusion criteria are defined, and also the databases to use, the keywords for research, the methods to implement. After that, the search of the literature is conducted, by establishing the relevant studies in the databases defined. The next step is to apply the inclusion and exclusion criteria to the studies in order to determine the studies that are pertinent to answer to the goal previously established. The fifth step is the analysis of the search results in relation to the exclusion and inclusion criteria. Then, one has to extract important information from all the studies, separately, followed by the quality assessment of those studies as well as the identification of conflicts between studies. The next step is to perform the meta-analysis study, in case the protocol defines it and the data collected allows for a statistical summary. After that, is important to perform a quality appraisal in regards to the information of each study about the "scientific evidence". Then, the conclusions, recommendations, and results must be reported, which is followed by a summary of the data and evidence. Next, it is necessary to carry out a "sensitivity analysis" about the results obtained. The next step is the description of the limits regarding "conflicts of interest and the process biases". At last, the results gathered should be published in order for them to be used in clinical practice.

This type of study has many advantages, some of which are as follows [30]:

- Reduces bias in the studies.
- Allows to "Draw reliable and accurate conclusions".
- Facilitates the transmission of information that people with an interest in the topic need.
- Decreases the delay in investigation findings for implementation.
- Helps the results to be more comprehensive and consistent.
- Formulation of new assumptions about specific groups of the population being considered.
- Enhances the accuracy of results.

They also present some limitations like the following [57, 30]:

- Some important information might be lost in the review process.
- There might be the need to choose between high-quality information and "useful results".
- In the case of a small number of evidence of quality, it might be inevitable to include potentially biased evidence.
- Reviews that were made from carefully selected studies and that respect the inclusion criteria may still suffer from bias.
- The outcome of the review is conditioned by what already exists, by what was gathered in the search, and also by the report.
- The quality of the report influences the assessment of "strengths and weaknesses" of the studies.

Many systematic reviews applied to m-health can be found in the literature. An example of that is suggested by Wang et al., (2018) [66], which presents a systematic review to appraise the "effectiveness of mobile apps for monitoring and management of mental health symptoms or disorders".

In the study, the authors performed literature research from May 2013 to December 2017 in five different databases, searching them by using terms related to mobile apps and mental disorders, gathering 1501 records. The studies were primarily screened through their abstract and title, and duplicates were removed dismissing 1381 records. Then, the remaining 120 full-articles were assessed and screened, being removed if they didn't meet the inclusion criteria, 103 articles were removed.

The authors, present, then, a table that presents all the selected studies which are, then, thoroughly analyzed and summarized, grouping them according to the disorder they concern [66].

After that, the conclusions are presented suggesting that the mobile apps can be an effective tool to improve and monitor the symptoms of some mental disorders, and can also improve "mental health care delivery". However, there is a great discrepancy between existing apps and clinically validated apps, "only 14 out of approximately 100 studies that reportedly utilized an app had a clinically validated evidence of the effectiveness". These results were very concerning because the non-validated apps may be harmful to the users, as they give instructions to improve on the symptoms. The reason for the lack of validation falls on the low budget and the low expertise on mental health, which may result in a lack of testing [66].

2.4.2 Randomized Controlled Trial

A Randomized Controlled Trial has been seen as the research gold standard for determining the efficacy of health interventions [33]. It is an experimental study designed to evaluate the impact of an intervention on human beings[7]. In the study, it is intended to compare the results obtained

from at least two groups, being one the control group, which will not receive the intervention, and the other the intervention group which will receive the intervention [68].

The groups are composed of people from an eligible population, that are divided and allocated randomly to each group. The random assignment to intervention or control group is the distinguishing feature of RCT, and it is done to improve the comparability between groups, also to avoid selection bias, and yet to remove the risks of unobserved and unmeasured exposures to influence the results [68]. The randomization can be made at the level of individual participants but also based on clusters of participants by villages, schools, etc. [7].

This kind of study provides a very powerful response on the evidence of a causal relationship between intervention and health outcomes, assuring that the achievements are a result of the intervention. For this reason, Randomized Controlled Trial is often considered the most robust study design in demonstrating that an intervention allowed to achieve changes in the process and/or in the health outcome [68].

Regarding the limitations of RCT, they are both costly and time-consuming, with an average duration of 5.5 years, from the initiation of the study until the publication of the outcome. Also, they pose additional challenges with regard to the randomization process to the treatment assignment [38]. Moreover, the ethical considerations may appear as a limitation to this study design, as to whether is fair for one group to receive an intervention, that possibly makes the lives of the participants better, rather than the other group. In addition, a large sample size is needed to run an RCT study, since a small sample size may increase the risk of reaching the wrong conclusions [68].

An example of an RCT used in a mHealth assessment is presented in Liu et al., (2011) [40] where an investigation on a mobile telephone-based interactive program for asthma self-care control was performed. The program intends for patients to be aware of their current status and receive advice instantly, leading to better control of asthma. The indicators of the assessment were pulmonary function, quality of life, and use of medication for asthma control.

For the assessment, one-hundred-twenty patients with moderate-to-severe persistent asthma participated in the study, with a duration of 6 months, and were divided into two groups: mobile telephone group, with 60 people, and control group, with 60 people, also. During the study 31 patients dropped out of the study for several reasons, ending with 43 patients in the mobile telephone group, and 46 in the control group. Both groups receive the same preparation for the study. The software program in study corresponded to a diary for patients to record on a daily basis, information regarding their condition, like asthma symptom score, the use of relievers, and peak expiratory flow rate. The data recorded on the software was used by the physicians in order to assess the condition of patients and make adjustments to the treatment plan, during the study. Moreover, patients were controlled regularly and advised to adjust their medication. The control group used a written diary booklet to record the peak expiratory flow rate, daily. Also, instructions and guidelines were given to patients, for handling emergencies and exacerbations.

From this study, the results demonstrate that patients on the mobile telephone group increased significantly their pulmonary function, their quality of life, assessed with Short form (SF)-12,

and also their daily dosage of medication, while people from the control group did not present significant changes. Therefore, the authors were able to conclude that the tool was promising for the self-management of asthma, as it could be used as a real-time telemedicine tool that provides immediate responses for asthma control.

2.4.3 EUnetHTA Core Model ®

EUnetHTA was established in 2004 in order to create an effective and sustainable network for the Health Technology Assessment in Europe. The network aimed to develop and implement tools that were able to present information to contribute to HTAs in the European Countries, in a timely, reliable, transparent, and transferable way [23].

"The strategic objectives of the EUnetHTA project were to:

- *reduce duplication of effort in order to promote more effective use of resources*
- *increase HTA input to decision making in Member States and the EU in order to increase the impact of HTA*
- *strengthen the link between HTA and health care policymaking in the EU and its member states*
- *support countries with limited experience of HTA."*

As HTA may be implemented differently at an international level, the sharing of information becomes difficult and the applicability of foreign HTA results is harder, even if the results of the assessment have a low context-dependency [23]. Also, the structure of the reports is non-standardized which makes it complicated to extract the information needed [23].

"The need for clear structure, transparency, and rigorous handling of information in any HTA leads to a need for standardization" [23]. Therefore, the HTA Core Model®is a framework developed by EUnetHTA as an attempt to promote standardized elements of an HTA, as well as standardized results, that can be used across Europe, to share evidence between the member states [53]. The fact that information is presented in a standardized way makes it more clear, "enhances the quality and thoroughness of information", and makes it easier to share information and to get specific information from the assessment. Also, it diminishes the duplication of assessments for the same technologies [53].

The HTA Core Model®is a framework intended for international collaborative production and sharing of HTA information. It tackles both the variation of content and the lack of a standardized structure. The main components are HTA ontology, meaning the questions that should be answered, methodological guidance, which refers to how to answer the questions, and common reporting structure, which provides a standard format [1]. It aims to evaluate the description of the technology as well as the outcomes resulting from its use, to provide enough information in order to make decisions regarding the adoption or revocation of the technology [53].

EUnetHTA builds the HTA Core Model based on the previous work of EUR-ASSESS, HTA Europe, and ECHTA/ECAHI projects, and also other theoretical guidance. This model follows the definition of multidisciplinarity of the HTA and employs the nine domains firstly identified by the EUR-ASSES project. Those are:

- Health problem and current use of technology
- Description and technical characteristics of technology
- Safety
- Clinical effectiveness
- Costs and economic evaluation
- Ethical analysis
- Organizational aspects
- Patients and social aspects
- Legal aspects

The information is, thus, divided into domains, which are split into topics. Each topic is branched in questions referred to as issues. If a core HTA is being constructed, all domains must be addressed, and even if some of the questions are not relevant for the study, a reason for that must be presented in the assessment [1].

The first domain assessed by the model is "Health problem and current use of technology" which explains the conditions, availability, and patterns for the technology usage, the people who intend to use the technology, and the "epidemiology", meaning, the study of *"all the factors that determine the presence or absence of diseases and disorders"* [48]. There is also detailed the difficulty that the health problem brings, as well as the "alternatives to the technology in question". This domain proves its importance by presenting the "baseline knowledge" needed for the appraisal of the other domains [1].

The second domain is "Description and technical characteristics of technology". In here, there is a description of the technology and its technical characteristics, like *"when it was developed and introduced, for what purpose(s); who will use the technology, in what manner, for what condition(s), and at what level of health care"*[1]. This domain also refers the requirements regarding the equipment, the material for the installation, the staff, and the training required. The questions must be answered in detail to highlight the differences between the alternatives. The text must be written in a way that can be understood by people for whom the technology is unknown, and the use of diagrams, pictures, and other visual materials is recommended so that they can understand how the technology works [1].

The third domain is "Safety" that is *"an umbrella term for any unwanted or harmful effects caused by using a health technology"* [1], it corresponds to the appraisal of safety issues regarding

the patients or expected to be critical to informing policy-makers and healthcare providers to their decisions. Due to the diverse range of health technologies, also the issues vary greatly. As a consequence, there may be differences in the way a safety assessment is carried out. The assessment elements of this domain might fall into the following classifications of harm:

- Possibility of causing "direct harm" in terms of mortality, morbidity, or disability; or indirect harm regarding lack of experience, unsuitable patient, or missing maintenance for the intervention.
- Harm may be categorized in mild, moderate, and serious, conforming to its intensity or fatality.
- Harm might affect the environment and other individuals that are not using the technology.
- Harm might be defined as expected or as unexpected.
- The harm caused by the intervention might be related to the "amount of exposure", in time or dose.
- The probability of harm happening might be estimated - risk.

A "consistent and precise terminology" is crucial in the assessment of this domain, for the prevention of ambiguous or deceptive conclusions. The information gathered in the Safety domain allows to "form a balanced view" in regards to the meaning of using the technology, and so it is fundamental. Additionally, it is of most importance the sharing, on a "Europen level", the information gathered regarding the harms, as it is particularly difficult to collect [1].

"Clinical effectiveness" is the fourth domain and examines two main questions: *"Can this technology work?"* and *"does this technology work in practice?"*. It usually looks at the two following definitions [1]:

- *"Efficacy is the extent to which a technology does more good than harm under ideal circumstances (e.g. within the protocol of a randomised controlled trial [RCT]).*
- *Effectiveness assesses whether a technology does more good than harm when provided under usual circumstances of health care practice (e.g. by a physician in a community hospital treating outpatients) (adapted from the International Network of Agencies for Health Technology Assessment [INAHTA] glossary)"*

Thus, the main difference between the two definitions is the circumstances in which the technology is being performed. If the circumstances are ideal, controlled, efficacy is being assessed. On the other hand, if the technology is being applied in a current and usual situation, the effectiveness is being evaluated.

The issues regarding this topic intend to answer these questions, giving more focus to the second one. This assessment aims to define the impact of using the technology in regards to the benefits and harms for health. In general, a randomized controlled trial (RCT) is the standard to

deliver *"evidence of a causal relationship between intervention and health outcomes"* [1]. Moreover, it should address *patient-relevant outcomes such as mortality, morbidity, and quality of life* [1].

The fifth domain is "Cost and economic effectiveness" which intends to *"inform value-for-money judgments about health technologies with information about costs, health-related outcomes and economic efficiency"* [1]. The purpose is to give focus to the reports in order for the people using the study to be able to extract the intended data from the reports, rather than the *"global harmonization of requirements or methods for economic evaluation"* [1]. The manner in which the information used by this domain is produced, analyzed, and then presented, influences the importance of this domain. Also, the "nature of the evidence" is of extreme relevance to appraise the pertinence to the decision-makers regarding the results of the assessment.

The sixth domain is "Ethical analysis" and it takes into consideration *"prevalent social and moral norms and values relevant to the technology"* [1], in terms of the consequences brought by the implementation of the technology regarding the *"prevailing societal values and with regard to the norms and values that the technology itself constructs when it is put into use"* [1]. Some of the ethical values are the same across countries, however, the cultural, legal, and socio-political differences of a society influence the way that the moral values are used in the assessment. The assessment on this domain intends to explain the values that should be addressed during the assessment and decision-making.

When assessing the ethical domain in a health technology assessment, two steps must be addressed, the first is to establish the "moral issues" that are important to take conclusions, or to make decisions regarding the adoption of the technology. The second one is to do a relevant analysis in regards to ethics, which will show the moral values that are relevant to the assessment [1].

"Organizational aspects" is the seventh domain and it is in regards to the many resources that must be taken into consideration and are necessary when putting a health technology in action, as well as the implications that might appear in the organization and in the healthcare. The main challenge about this domain is the "complexity of the health care system and process". The organizational aspects might be organized into three levels:

1. intra-organizational - transmission of information regarding the technology to the patients
2. inter-organizational - communication across organizations
3. healthcare system - objectives definition at the national level

The way that the organization is coordinated establishes the "assignment of tasks, reporting systems, and the mechanisms of interaction and coordination". However, the organization is also affected by culture and society [1].

The eighth domain is "Patient and social aspects" which assesses the aspects regarding the patients or individuals to whom the technology is used as a reference point in the Health Technology Assessment. The *"Patients Aspects relate to issues relevant to patients, individuals and*

caregivers." [1]. The Social Aspects refer to specific groups of "patients or individuals" which might be interesting to the assessment, for example, immigrants, or people with disabilities. The perspective of the patients and caregivers regarding a health condition is extremely relevant to the Health Technology Assessment due to the life experiences, preferences, expectations that are brought to the picture by the people who are most affected by the technology. The assessment tries to collect "as much evidence as possible to understand" so that different perspective from different people is taken into consideration. The evidence that should be collected must address the following topics:

- *The burden of living with the condition being studied;*
- *Experiences of current health technologies;*
- *Experiences with and expectations of the health technology being studied;*

The perspective of the patients is crucial to the HTA process and it should be assessed in a "systematic and methodologically robust process". It provides a different understanding regarding the impact of the technology on the health condition, being the patients and caregivers, the ones with the most "personal experience and knowledge" about their illness. For this reason, they can appraise the quality and utility of the health technology, and how it influences their day-to-day. Moreover, they might feel hopeful, afraid, or uncertain about the health technology. The entire life of the patient might be conditioned by the use of the technology and that information should be considered while assessing the technology.

The ninth domain is "Legal aspects". This domain intends to identify the "rules and regulations" that should be considered by the evaluators when analyzing the "implications and consequences" that are brought with the health technology. The rules to consider might be related to the patients' rights, data protection, or "rights and duties". Currently, it is important for the decision-makers to be familiar with the "legal implications of implementing" the health technology, taking into consideration legal information from the country but also at an international level. Additionally, they should understand the different roles and actors for the technology [1].

In like manner, the EUnetHTA Core Model is a crucial tool for the standardization of the HTA process. It aids in the decision-making process by producing "reliable, transparent, and transferable" assessments with the most relevant information highlighted. Many studies were performed in order to understand if the EUnetHTA Core Model is a suitable method for the Health Technology Assessment. These studies were able to confirm the suitability of the tool, for the creation of reports that help decision-makers, and the sharing of the results and data from the assessments across Europe [53].

2.4.4 HTA Core Model for Rapid Relative Effectiveness Assessment

HTA Core Model for Rapid Relative Effectiveness Assessment "is a methodological framework for the collaborative production and sharing of HTA information" [27]. It was developed by EUnetHTA.

The main purpose of this method is similar to the purpose of the HTA Core Model. It intends to improve the way in which information about HTA is applied to different Health Technology Assessments. It also intends to facilitate the collaborative work between agencies with a standardized framework to assess Health Technologies through Rapid Relative Effectiveness Assessment. More, it aims to diminish the "duplication of work" [27].

This framework, also called 'Model for Rapid REA' provides the assessment of one technology, comparing it with "one or more relevant alternative interventions". It runs within a limited period of time, and also analyses a limited "subset of domains". Model for Rapid REA is only considered to be used for the assessment of pharmaceuticals, diagnostic technologies, medical and surgical interventions, and screening technologies [27].

The Model for Rapid REA intends to guide the users of this framework regarding the stages to follow and the issues that are important to take into account during the Assessment [27].

The core of performing relative effectiveness assessment is to understand the benefits and harms of the technology and existing alternatives in order to analyze them from a comparative perspective [27].

The main components of an HTA are, as well, the main components of the Model for Rapid REA, which are the following [27]:

- Ontology;
- Methodological guidance;
- Common reporting structure;

This method might be used to appraise both technologies that were brought into the market in the recent past, and technologies that started to be used in different circumstances or new information regarding the technology was found [27].

In Model for Rapid REA, only four of the domains of the HTA Core Model are addressed, as a consequence of the model running within a "limited time frame". The domains approached are:

- Health problem and current use of technology
- Description and technical characteristics of technology
- Safety
- Clinical effectiveness

Which are the domains that assess the clinical aspects. During the assessment of these four domains, not all of the questions/issues addressed in the HTA Core Model are discussed. The five domains remaining are not assessed in this model due to the dependency of context that they require, which makes them have low transferability [27].

To put in action a Model for Rapid REA study firstly is necessary to define the scope of the assessment. This should be done using PICO structure, which means **P**opulation, **I**ntervention,

Comparison, and **O**utcome. Therefore, Population refers to the patients who suffer from the health condition of reference. Intervention is the technology in study. In the Comparison part, the alternatives to the technology are used for reference. The Outcomes are the endpoints used in the evaluation of both safety and effectiveness. The decisions taken during the definition of the scope must be presented in the report[27].

The second step of the assessment is in regard to the issues from the domains. Here, all issues of each domain are taken into account and are, then, selected for the assessment as they are of interest to the study or not. After the issues are selected, it is necessary to turn them into "actual research questions". Each answer to the questions is important to the study and is registered in the report [27].

The next step is the collection and analysis of the data in order to produce a systematic review of the technology. It starts with the gathering of potential information sources like databases, surveys, etc. Then, it is made a literature search where studies that are relevant to the topic are selected using search strategies and analyzed to execute a systematic review, that is "thorough, transparent, reproducible" and reduces biased results [27].

Next, it is necessary to define the appropriate study type for each domain. The first two domains are usually analyzed through descriptive and observational study designs and researches, although there is no specified method to be used. Efficacy and effectiveness are frequently assessed with the use of randomized controlled trials which "provide the most robust evidence", however, it might be necessary to implement different studies in order to get relevant information. To assess the safety domain the strategy, commonly, is to analyze "regulatory sources" in order to identify common risks. RCTs are, also, a viable method to assess safety [27]. After the study, a quality assessment of the data gathered is necessary. The quality assessment on the first two domains does not have a standard way to be performed, and it must be decided depending on the "level of detail" and on the accuracy to present the information collected. The intention is to validate this information taking into account its sources and types. About the effectiveness domain, the main concern in assessing the quality is the "risk of bias", which is applied to the internal validity evaluation. It intends to assess if the data resulting from the trial is accurate and it expresses the real response of the population to the technology, using for this purpose "methodological quality criteria". In the safety domain the quality is, also, assessed by the risk of bias, but in this case, in relation to the sources of the information and how it was gathered [27].

Then one needs to analyze the "Effect measures and confidence intervals", which means that the relative and absolute measures, like risk ratio, need to be calculated in order to ease the understanding and when comparing the studies. It is also crucial for the comprehension to provide a "measure of the precision of the effect estimate (standard error or confidence interval (CI))" in the report [27]. Next the "Extrapolation of efficacy to give relative effectiveness data" is performed. Here, one will understand if the results obtained from a trial with specific conditions can be applied to the real-world setting. This is done through the examination of "effect modifiers and critical factors". Also, it might be useful to report about "indirect comparisons" if three or more treatments are taken into account at the same time, or if the evidence is not sufficient [27].

Then it is required to interpret the evidence by verifying the relevance of the data gathered in regards to the research questions created on the second step. It is important to clarify in the report how adequately the evidence responds to the questions. Often this information is reported in plain text, however, sometimes evidence tables are convenient [27]. Evidence tables are, therefore, the last phase should be present in a Model for Rapid REA study. They, not only make the assessment more reliable and transparent, but also, facilitate the comparison between selected studies, and, yet, are used as a basis for drawing conclusions. In order to be more shareable in Europe, these assessments must be transparent and explicitly differentiate what data is evidence and what data is judgment, like preferences [27].

The last step is reporting. In this step, the data gathered during the entire process is recorded and presented in a report which must contain the scope, the results, a "summary table of relative effectiveness", the discussion, and conclusions. The effectiveness and safety are discussed in comparison with alternative technologies [27].

2.4.5 Multiple Criteria Decision Analysis

Decisions have to be made regarding healthcare, and it is difficult for the decision-makers to systematically evaluate relevant information. Despite this, the credibility of the decision-makers may be questioned if there is a lack of transparency regarding the decision-making process. The use of informal processes for decision-making may lead to inconsistent and sub-optimal decisions. However, the quality of the decision-making can be improved with structured and clear approaches that involve multiple criteria [62].

Multiple Criteria Decision Analysis or MCDA is a subdiscipline of operations research and consists of a method that defines clearly which criteria are the most relevant, the weight associated with the criteria, and how to use the provided information in a framework to rank the available alternatives based on the value of the criteria, and thus, allowing to make consistent, legitimate, and transparent decisions [61, 62].

According to *Thokala et al*,(2012) [63], the 4 main aspects to take into consideration regarding "any MCDA method are 1) the alternatives to be appraised, 2) the criteria (or attributes) against which the alternatives are appraised, 3) scores that reflect the value of an alternative's expected performance on the criteria, and 4) criteria weights that measure the relative importance of each criterion as compared with others." The authors also claim that the approaches of MCDA can be divided into "value measurement models", "outranking models", and "goal, aspiration, or reference-level models".

The first one, "value measurement models", refers to approaches that use numerical scores in order to construct and compare the options, is usually the approach chosen to analyze HTA. An example of this approach is the Analytic Hierarchy Process - AHP [63].

The second approach, "outranking models", consists of a "direct comparison of the key characteristics" of the different options, in order to establish the degree of preference for one option over the other for each criterion. Then, the preferences data is aggregated to define how the alternatives are strengthened in relation to the others [63].

"Goal, aspiration, or reference-level models", the third approach, regards the derivation of the alternative that is closest to reach the predefined and preferable levels of success for each criterion [63].

Marsh et al., (2016) [43] present on Report 2, from ISPOR MCDA Task Force, a Good Practice Guidelines Checklist to aid on the process of conducting MCDA studies, providing a list of considerations for the design and report of MCDA. The checklist combines eight steps to follow, with recommendations for each step. Every step of the guideline should have a validation part. This validation is composed of five steps that should be included in a report. The steps from validation consist of presenting the decision problem, the final criteria list and definitions, the performance matrix, test the consistency of scores and weights and finally present the results of the MCDA highlighting the "trade-offs" that were made to achieve the results.

The steps of the checklist are the following:

1. Define the decision problem
    - Clear description of the decision problem
    - Validate and report the decision problem
2. Select and structure the criteria
    - Report and justify the methods used to identify criteria
    - Report and justify the criteria definitions
    - Validate and report the criteria and the value tree
3. Measure performance
    - Report and justify the sources used to measure performance
    - Validate and report the performance matrix
4. Score alternatives
    - Report and justify the methods used for scoring
    - Validate and report scores
5. Weight criteria
    - Report and justify the methods used for weighting
    - Validate and report weights
6. Calculate aggregate scores
    - Report and justify the aggregation function used
    - Validate and report results of the aggregation
7. Deal with uncertainty

- Report sources of uncertainty
- Report and justify the uncertainty analysis

8. Report and examine the findings
    - Report the MCDA method and findings
    - Examine the MCDA finding

This checklist represents a guideline of good practices and recommendations when an MCDA study is being carried on.

2.4.5.1 doHTA

Ritrovato et al (2015) [53] present a method for hospital-based HTA that combines the Analytic Hierarchy Process, which is an MCDA approach, and the EUnetHTA Core Model. This methodology is called Decision-Oriented Health Technology Assessment or doHTA. This method was designed with the intention to "guide and support the introduction of innovative health technologies in hospitals" [53]. It repositions the "domains", "topics" and "issues" from the core model into a new "goal-oriented framework".

It is composed of six main steps, described as follows:

1. Problem definition: Identify the specific "assessment element".

2. Literature review: Perform a research study using "major databases" and HTA agencies using specific keywords, in order to gather scientific evidence about the technology in the study and its alternatives. It intends "identify all the components of the decisional hierarchy structure" or Key Performance Indicators (KPI).

3. Hierarchy construction: Broke down the decision intention into its elements, from high level to specific objectives. Specifically, the first level represents the domains of the core model, followed by the guidelines provided by the core model, like topics and issues.

4. Priority Analysis: Each professional who is participating in the evaluation has to give a rating to the elements on a pairwise comparison of indicators on the same level, for example, "How important is the element A relative to the element B?". The answer is based on professional experience. Some inconsistencies may appear due to the rating being made based on experience and knowledge. Thus, it is important to check the degree of consistency. After the consistency checking, the "derived weights' systems are then averaged using the geometric mean to yield a unified weights' system".

5. Alternative technologies evaluation: The alternatives are evaluated with the use of a decision tree, by analyzing a single technology with the attribution to the lower indicator, the value of the performance of the technology for that indicator. The type of the value depends

on the nature of the indicator, and it can be "metrically estimated", "means of an estimate of coverage of needs", "true/false statement", or "qualitative judgment scale of performance". Is, then, possible to compute the numerical values that represent the "performance of each technology with respect to the overall decision goal", and compare the alternatives' performances regarding the lower-level nodes.

6. Results presentation: The results are, then, presented in graphical format or in a numerical report.

The domains of the EUnetHTA Core Model are crucial and need to be analyzed when a health technology is being assessed. With this methodology of doHTAit is possible to understand the "most characteristic features of the technology" being assessed and gather the importance of the indicators in a final element [53].

This is a tool that helps the decision-making process to be more effective and efficient. It gives a more structured and precise result, with contextualized evidence, providing relevant and easy to interpret data, that is more useful for the decision-making [53].

The evidence obtained with doHTA is more detailed and precise than the evidence from the EUnetHTA Core Model, due to the summary of the results into a standardized and structured outcome, able to be shared across health care facilities [53].

The doHTA method has been tested for many health technologies, and it proves to be a method that allows the decision-makers to choose more consciously between the different alternatives that are being considered. And although there is space for improvement, the implementation is an advance to build the "solid bridge between the available scientific evidence and the final decision maker's choice" [53].

2.5 Health Technology Assessment on m-health

As previously stated in the text, an HTA needs to take into consideration all nine domains of an HTA in order to be a full-HTA. Therefore, these domains can be used to evaluate all types of health technologies, such as drugs, procedures, medical devices, and so on. In order to fully assess a mobile health intervention, the nine domains should also be addressed.

However, *Moshi et al.,* (2018) [46] present a systematic review to understand how mobile medical applications are currently being assessed, and if the frameworks that are being used are suitable to use in health technology assessment. The authors analyzed forty-five frameworks, to determine if they included the nine domains of a full-HTA. They concluded, after a thorough analysis, that none of the forty-five frameworks assessed the nine domains, and for that reason could not "be used, unaltered, to assess" in a full-HTA the m-health technologies. They also realize that a framework with this purpose should have a detailed analysis of ethical issues, it should discuss the impact on safety and on effectiveness that software updates may bring, also, the presence of an assessment of safety and the harms that may arise from misinformation should be addressed, and a comparator should be considered.

When implementing a Health Technology Assessment in digital health technologies, there may be some considerations that must be analyzed in order to assess all aspects of the technology, such as usability, data protection and security, and accessibility, but that does not make sense when evaluating different types of health technologies. These technologies carry harms and risks that are not present in other health technologies, they usually have a "fast life-cycle", and may be used even without the recommendation of the healthcare professionals, can be used across operating systems, and in different mobile devices, also, they may suffer updates in the software, connect to databases and systems using the internet, and more [47]. Another risk brought by the m-health is cybersecurity, due to the network connectivity which makes the device vulnerable and could put the patient in danger[45].

The evidence brought by the assessment of the digital technology will allow the decision-makers to base their decisions regarding the technology [34]. Also, clinicians need this kind of information in order to understand which technologies they should use, and what are the benefits of using those technologies.

Current assessments of m-health have their main attention on usability assessment, user experience, user engagement, evaluation of the interface of the app, changes in the behavior, and clinical application of the technology [56].

Thus, according to *Bradway et al.,* (2017) [24] *"There is a clear need for defining a standard assessment framework for m-health technologies that will help separate the wheat from the chaff and identify those solutions that may provide added value to patients and the health care system"*. The framework should combine both the traditional HTA process and the domains that prove to be relevant for evaluating m-health [34]. However, the HTA agencies and networks have not yet addressed this issue of trying to find a solution [24].

Bradway et al., (2017) [24] stated that an HTA framework for an m-health solution should analyze the following categories:

- Designation of m-health solutions by intended use
- Level of development
- Security and privacy
- Interoperability standards
- Usability
- Functionalities and content

A different approach is brought by NHSX, the National Health System unit responsible for technology, digital and data, from the United Kingdom, which presents a "Digital Technology Assessment Criteria" (DTAC) that intends to validate the "suitability and function" of the digital solutions that respect the principles of privacy, interoperability, accessibility, security, clinical safety, and inclusion [9]. The assessment criteria focus on 5 main domains:

- Clinical safety
- Data protection
- Technical assurance
- Interoperability
- Usability and accessibility

As can be seen, some of the domains presented by these two solutions are similar, like usability, and interoperability. Although, they do not address the nine core domains of HTA.

Haverinen et al., (2019) [34] developed a framework called Digi-HTA which intends to assess digital health solutions: m-health, robotics, and Artificial Intelligence, and that has as a foundation the Mini-HTA approach and the approach of NHS Digital from the United Kingdom, that on October 1st, 2020 is no longer responsible for the assessment process, passing the responsibility to NHSX [8]. The Mini-HTA approach only covers the domains of patient, technology, economy, and organization. The approach of NHS Digital is composed of a pre-assessment followed by the assessment of effectiveness, data protection, security, interoperability, clinical safety, technical stability, and usability and accessibility.

The Digi-HTA framework assesses all the traditional domains, "except ethical, social, and legal issues" [34] due to their difficulty and time-consuming, contrasting with the intention of the framework to develop assessments rapidly, but fully based on HTA principles. The process of the framework is composed of three documents, the "Digi-HTA" document, which gathers information regarding the company, the product, the technical stability, the cost, the effectiveness, the clinical safety, the usability and accessibility, the interoperability, and in AI and Robotics products, also collects data specifically about that; the "Data Security and Protection Preliminary Task" document; and the "Information Security and Data Protection Requirements" document. These last two collect data security and protection issues. These documents are filled out by the company developing the product, and are, then, appraised by HTA experts, that will provide recommendations. Although, there is still no information regarding the results of the pilot study [34].

Moshi et al., (2020) [47], also, present an HTA methodology to evaluate Mobile Medical Applications (MMA), with the intention of easing the assessment for "regulatory and reimbursement purposes". Mobile Medical Applications are a type of m-Health, but they meet the requirements for being a medical device.

The module proposed by the authors is based on their previous work [46] and [45], and also in evidence from interviews performed during the study. It comprises all nine domains and an additional domain "Post-market monitoring". "All of the domains are mandatory, with the exception of the social domain". Within each domain, they specify what are the challenges brought by MMA that they intend to respond to. The domains and respective challenges are presented as follow:

- "Description and technical characteristics"

  - "Operating system(s) for MMA"
  - "Operating platform(s) for MMA"
- "Current use of the technology"
  - "Rationale or use"
  - "Potential software changes"
- "Effectiveness"
  - "Accuracy"
  - "Configuration"
  - "Communication and display"
  - "Cybersecurity and connectivity"
  - "Potential software changes"
  - "Precision"
  - "Analytical validity"
- "Safety"
  - "The risk of misinformation"
- "Cost-Effectiveness"
  - "Technological evolution"
- "Organizational aspects"
  - "Digital health literacy"
  - "Responsibility"
  - "Connectivity"
  - "Technological evolution"
- "Ethical aspects"
  - "Patient privacy and confidentiality"
  - "Equity concerns"
  - "Access concerns"
  - "Technological evolution"
- "Legal aspects"
  - "Responsibility"

- "Post-market monitoring"
  - "Reappraisal"
- "Social aspects"

This module is an attempt to analyze relevant aspects of MMA and increase confidence in MMA through a detailed assessment of specific issues of this type of technology [47].

The authors reinforce the idea of the need to address in the assessment, the specific characteristics of MMA, like reliability, cybersecurity, as examples. They, also, believe that the module will ease the decision-making process regarding the reimbursement of the health technology. Moreover, they highlight the fact of the need to adjust policies in order to also give focus to "the rapid life cycle of MMA as well as cybersecurity concerns" and the protection of patients' data [47].

It is important for the development of m-health, that the developers have access to "guidance and educational resources" with the clarification of concepts, also they should be involved in the assessment process, in order for them to create solutions that assure reliability, safety, and quality [24].

M-health has proven to be an asset for many health conditions, for example, to manage chronic diseases, or to improve the symptoms of asthma and chronic pulmonary diseases, but the appraisal is necessary to integrate these technologies into the healthcare system [42, 65]. It is important to improve the quality of the assessments and the "consensus on the appropriate evaluation methodology", and patients' point of view should be taken into consideration [65].

2.6 Conclusions

Health Technology Assessment is the *"bridge between the world of research and the world of decision making"* [53]. In other words, it is the systematic assessment of health technologies that clarifies the value they bring to the patients, and provides relevant information to decision-makers, so they can decide knowingly regarding the adoption of technologies, or even choose between alternatives.

Nine domains, firstly identified by the EUR-ASSES, were defined for a full assessment with the intention to cover all relevant aspects of a health technology.

Although HTA doesn't have a specific, standard methodology that fits all assessments, there are some methods often used in order to assess the health technologies. It is the case of systematic reviews, which are reviews of literature regarding a specific issue, that make a critical evaluation and compile and analyze the relevant information present in the studies that were selected for the review. This methodology doesn't create new data, but instead, knowledge may arise from the review. Even though it is a process that directly compares different alternative solutions for an existing issue, it is very time-consuming, some information might be lost, and in case the evidence has poor quality, it may induce biased results.

Another methodology frequently used is Randomized Controlled Trials. This method is seen as the "gold standard" to study the efficacy of health technologies. It is a study where a population

randomly defined is, also randomly, divided into two or more groups, being one of the groups a control group, which means they will not have access to the intervention, and the other group will have the intervention, being the intervention group. It is crucial that the groups are assigned randomly in order to assure comparability. Although this kind of study is great in order to assess the efficacy, the other aspects of the HTA may not be considered. Moreover, it is a very expensive and time-consuming study.

EUnetHTA Core Model®is another methodology presented. It was developed in order to create a standard format that assesses standard elements, and so that they can be shared across Europe, and it is easier to understand the results and to find the information needed. The Core Model embraces the multidisciplinarity of the HTA and is based on the nine core domains. The domains are branched into topics, which are split into issues - questions. When implementing this methodology, all issues must be addressed, and in case they don't apply to the technology, a justification must be provided.

A variation of the EUnetHTA Core Model ®was then explored, HTA Core Model for Rapid Relative Effectiveness Assessment. Also developed by EUnetHTA, it has the same purpose as the Core Model, however, it assesses a health technology in comparison with alternatives, it has a time limitation, and only addresses the first four domains, due to the context-dependency of the remaining five domains.

In addition, another methodology often used is MCDA, Multiple Criteria Decision Analysis. The criteria relevant for the assessment are defined with the respective weight, in order to assess the different alternatives with the criteria as a basis and rank them accordingly.

The use of digital technology, and specifically mobile health, brings some concerns and aspects that differ from the rest of health technologies. Examples of that are, usability, accessibility, data protection, cybersecurity, and others. For that reason, also the assessment process of these health technologies requires the analysis of those aspects. The methods described above are not fully prepared to assess m-health technologies, as they do not cover all the aspects brought by the m-health, combined with the nine domains of a full assessment.

Trying to answer the problem of the lack of methodologies able to evaluate all the relevant aspects of an m-health technology, two new models emerge specifically to assess m-health.

The first one, developed by Haverinen et al., (2019) [34], Digi-HTA, in order to support the adoption of m-health technologies into the healthcare of Finland. It is fully based on HTA principles, and it combines two methods, Mini-HTA and NHS Digital evaluation for m-health. It intends to be a rapid framework that can assess digital technologies fast so that it can keep up with the rapid development of applications.

The other, developed by Moshi et al., (2020) [47], with the intention to ease the policy-making process regarding regulation and reimbursements of mobile medical applications. It adapts the content analyzed in each domain of a traditional HTA in order to include the relevant aspects brought by the MMA.

As can be seen, both methodologies were very recently developed due to trying to answer a very current problem, and that although there is still no standard solution presented by HTA

agencies and networks, attempts at solutions are already appearing.

Chapter 3

HTA Process

In a world where software is becoming a necessary part of so many areas and in people's lives, the use of software is also growing in the medical field. Software can be a valuable asset in the health area, although, it can also bring risks and concerns that are not present in other health technologies. Therefore, they need to be properly evaluated, analyzing all aspects of the technology.

As previously seen, the current processes used to assess Health Technologies are not the most adequate to assess software. Even though the 9 domains assessed in a full HTA bring valuable information for the assessment, the information might not be enough when assessing this type of health technology, as some aspects about the evaluation of the software are not taken into consideration.

There is a need to improve the Health Technology Assessment process when evaluating software.

This dissertation makes a proposal for a Health Technology Assessment process to assess specifically digital health technologies. The proposal tries to merge the assessment of Health Technologies, considering the 9 domains [1], and the assessment of software, focusing on functional requirements and quality attributes. Therefore, the process is divided into domains that can fall into two different categories, category 1 - General HTA, and category 2 - Software Assessment.

In terms of the General Health Technology Assessment, it is expected to keep evaluating the 9 domains of HTA as they are relevant to understand the impact that the technology has on patients, professionals, and the health system.

The domains that will be assessed in this category are the following:

- Health problem and current use of technology
- Description and technical characteristics of technology
- Safety
- Clinical effectiveness

- Costs and economic evaluation
- Ethical analysis
- Organizational aspects
- Patients and social aspects
- Legal aspects

The evaluation process for these domains is based on the EUNetHTA Core Model[1], maintaining the objectives outlined by the model but without being tied to the questions presented there.

To these domains, two more will be added, that fall on the second category of the process - Software Assessment, being both related to the assessment of software. The appended domains are Functional Requirements and Quality Attributes. These two domains correspond to the novelty presented in this new Health Technology Assessment process.

In the following sections, the objectives, motivation, and suggestions for the process to assess each domain will be described.

It is important to keep in mind that this process was designed to evaluate the impact of the My Health Diary platform, and therefore, generalizations and adaptations are necessary in order to apply it to another health technology.

3.1 Health problem and current use of technology

The first domain is "Health problem and current use of technology". There is a need to assess this domain, as the information gathered here will help to clarify and provide knowledge to help in the assessment of the domains that follow. It also helps to understand the existing need and the consequences for the implementation of the health technology [1].

The purpose of analyzing the domain is to provide context for the assessment, by specifying the health problem, the people being targeted, and the technology that is being assessed, as well as its alternative technologies. The idea is to clarify who are the people who intend to use the technology, the conditions, and availability for the technology usage and also explain matters regarding the health problem, for example, what is the disease in the scope, what are the symptoms, what is the treatment, and more. There is also detailed the difficulty that the health problem brings, as well as the alternative technologies that are usually used [1].

Therefore, three main subjects must be addressed within this domain, that are: the Health Problem, the Target Population, and the Health Technology [1]. When addressing this domain, one should take into consideration the following suggestions (presented by subject) [1]:

- Health Problem
  - Describe the disease and its "natural course";

  - Enumerate the disease risk factors;
  - Describe the symptoms;
  - Specify how the disease impacts the society;
  - Describe the diagnostic process;
  - Explain the treatment/management process;
  - Explain which aspects of the disease are approached with the technology.

- Target Population
  - Define the target population;
  - Present an overview on the target population;
  - Specify the number of people belonging to that population;
  - Explain how people are considered to be eligible to use the technology.

- Health Technology
  - Present the technology;
  - Briefly describe commonly used alternatives;
  - Explain the motivation for the use of the technology;
  - Specify if the technology is a new way of care, a modification or a replacement of a standard way of care.

The information necessary to analyze this domain will be gathered through reading and understanding of medical documents, and also informal conversations with the health professionals. As these documents might be difficult to interpret for non-medical people due to the medical terms, it is recommended to keep a close relation with the health professionals in this domain.

3.2 Description and technical characteristics of technology

The second domain being addressed is “Description and technical characteristics of technology”. This domain brings clarification about the technology in study, and it should be analyzed in an early phase of the process because it provides relevant knowledge to ease in the assessment of the following domains [1].

The goal with the assessment of this domain is to give information about the health technology being targeted in order to understand relevant aspects about it, like its purposes, the people who will use it, the way they will use it, but also when and by whom the technology was developed. The requirements of the equipment, the material for the installation, the staff, and the training required are also addressed in this domain. Another relevant aspect to be addressed here is to enhance the differences between this health technology and its alternatives [1].

Thus, this domain should be assessed by keeping the focus on four main subjects: Health Technology, Development, Implementation, and Use of the technology [1]. One should address these subjects by taking into account the following considerations [1]:

- Health Technology
  - Present the technology;
  - Describe the main features;
  - Enumerate the alternatives for the technology;
  - Specify the advantages and disadvantages of the technology in relation to the alternatives;
  - State what stage of development the technology is in.
- Development
  - Present the context of development of the technology;
  - Refer when it was developed.
- Implementation
  - Describe the requirements to adopt the technology;
    - Materials
    - Supplies
    - Premises
- Use of the technology
  - State who will provide the technology to the patients;
  - Describe the context in which it will be used;
  - Explain the process of training for health professionals to use the technology;
  - Explain the process of training for patients to use the technology.

In order to gather information to fulfill the needs for the analysis of this domain, one should read and understand the documents regarding the technology or other reliable sources. Informal conversations with the health professionals is also a good strategy to obtain the information needed.

3.3 Safety

The next domain being analyzed is “Safety”. This domain is seen as *“an umbrella term for any unwanted or harmful effects caused by using a health technology”* [1].

It intends to evaluate the safety issues for the patients in terms of the harms that the technology may cause.

The information gathered from the analysis of this domain is fundamental to understand what might be at stake from using the health technology [1].

The harms that the technology may cause are usually analyzed regarding the dosage or frequency of the technology, the risk of harm happening, the intensity or fatality that it presents, and the possibility of causing direct harms - mortality, morbidity, or disability- or indirect harms - from lack of experience, unsuitable patient, or missing maintenance for the intervention [1].

For this reason, this domain should be assessed by keeping the focus on *How can this technology jeopardize safety?* looking at four levels, Safety in general, Safety for the Patients, Safety for the Professionals, and Safety for the Environment. When addressing this domain, one should take into consideration the following suggestions [1]:

- Safety in general
  - Present the main safety concerns regarding the technology;
  - Describe the safety of the technology in comparison with the alternatives;
- Safety for the Patient
  - Describe how can the technology harm a patient;
  - State if the harms are related with frequency of use;
  - Specify if there are a group of people that is more susceptible to be harmed by the technology;
  - Explain how this safety risk can be minimized.
- Safety for the Professionals
  - Describe how can the technology harm a health professional;
  - Explain how this safety risk can be minimized.
- Safety for the Environment
  - Describe how can the technology harm the environment;
  - Explain how this safety risk can be minimized.

The information necessary to analyze this domain should also be gathered through reading and understanding of documentation, and also informal conversations with the health professionals.

3.4 Clinical effectiveness

“Clinical effectiveness” is the fourth domain.

This domain is one of the most important in the assessment, as the information gathered here will be crucial to understand whether or not the health technology brings advantages to the users. It intends to clarify how the technology will impact both patients and health professionals [1].

The main intention of this domain is to understand the impacts that will be brought by the use of the technology in terms of benefits and harms for health and especially for the patients. To assess the clinical effectiveness, a randomized controlled trial should be the go-to study to implement. Therefore, from the study one should try to extract information in regards to the following aspects [1]:

- Describe the expected benefits of the technology;
- Specify how the technology will affect the symptoms of the health condition;
- Describe how the technology affects body function;
- Describe how the technology affects work ability;
- Explain how the technology affects the daily living activities;
- Explain how the technology impacts patients' quality of life;
- Present the benefits and harms on the health of the patients;
- State the level of satisfaction from patients and health professionals with the use of the technology;
- Explain how the technology changes the need for hospitalization;
- Explain how it will impact the frequency of morbidity;
- Explain how the technology will affect mortality;

As previously stated, a randomized controlled trial should be the study implemented to understand the impact of the technology and its effectiveness. During the study, it might be relevant to implement questionnaires, to comprehend the effectiveness of the technology, and to compare results.

The information obtained from the study will be of much value to draw conclusions about the advantages and disadvantages of implementing the technology. This information should be treated and interpreted to get conclusions from the study. Informal conversations with the health professionals is also a good strategy to obtain good information as well as to help with the clarification of results and conclusions.

3.5 Cost and economic effectiveness

The fifth domain to be assessed is "Cost-effectiveness". This domain intends to clarify the costs, economic efficiency, and health-related outcomes regarding the technology in terms of "value-for-money". The purpose is to analyze the impact of the technology but in terms of costs [1].

It is of major importance to assess this domain, in order to obtain information about the financial expenses of the technology, to understand the relation of cost-effectiveness, but also to analyze the financial impacts brought by the technology [1].

To assess the cost-effectiveness, to gather information one should take into consideration the following aspects [1]:

- Specify the necessary resources to deliver the technology;
- Present the estimations for the costs;
- Present the uncertainties about the costs of the technology;
- Present the budget impacts for the implementation of the technology;
- Describe the differences between the technology and the alternatives in terms of costs;
- Describe how the costs of the technology can create differences in the access to the technology;

To analyze this domain it is pertinent to make sure that the evidence gathered is reliable, and pay special attention to the way that the data is produced, analyzed, and presented, as it will be used as the basis for the evaluation and for the decision-making in general.

3.6 Ethical analysis

"Ethical Analysis" is the sixth domain.

It addresses the social and moral values that concern the technology, focusing on the consequences that the implementation of the technology will bring [1].

This domain is important to analyze as it provides information regarding crucial ethical aspects that must be considered when implementing the technology. It takes into consideration moral and social values that might influence the way that the technology is perceived [1].

It is important to address two topics when assessing the ethical domain: the first is to establish the "moral issues" that are important to draw conclusions or to make decisions regarding the adoption of the technology. The second one is to do a relevant analysis in regards to ethics, which will show the moral values that are relevant to the assessment [1].

In order to assess this domain in a complete way one should attend to the following suggestions [1]:

- Understand and explain how the disease impacts the life of the patient;

- Specify the benefits and harms the technology brings for the patients;
- Specify the benefits and harms the technology brings for the society, organization, and relatives, etc.;
- Present hidden or unintended consequences of the technology;
- State if the use of the technology impacts human dignity;
- State if the use of the technology impacts cultural, moral, or religious integrity of the patient;
- State if the use of the technology invade the patient's privacy sphere;
- State if the use of the technology affects the autonomy or capabilities of the patient;
- State if the implementation or cancellation of the technology could jeopardize professional, ethical, or moral values;
- Describe how the implementation of technology will affect health care delivery;
- Understand if the current legislation and regulation covers the technology at an ethical level;
- Specify if the implementation of the technology violates the human rights;
- Enumerate the factors that might deprive a person of access to technology;

3.7 Organizational aspects

The seventh domain is "Organizational aspects". This domain intends to analyze the resources that are necessary to implement a health technology, and also the implications that might be brought to the organization or healthcare [1].

The organizational domain brings to the table crucial information regarding the impact that the technology being assessed will have on the organization adopting/implementing it, but also on the health system. This can be seen as a challenge to the evaluation of the domain due to the complexity of the system and processes. Therefore, the intention of addressing this domain is to understand the relevant aspects brought by it, but its analysis should be focused on the purpose of the assessment [1].

This domain, is usually assessed by keeping the focus on three levels of organizational aspects, that are [1]:

- intra-organizational - process inside the organization;
- inter-organizational - communication across organizations;
- healthcare system - objectives definition at the national level;

In this process, the Organizational aspects domain will have its focus on the first level, the intra-organizational level, thus, how the organization is dealing with the technology [1].

When addressing this domain, one should take into consideration the following suggestions [1]:

- Describe how the work process of the professionals will be modified by the technology;
- Present the involvement needed for patients and health professionals;
- Describe the process to provide training to use the technology for the health professionals;
- Explain how the patients can get access to the technology;
- Specify the costs associated with the acquisition and implementation of the technology;
- Describe how people are being considered eligible to use the technology;
- Describe the acceptance of the technology by the patients and health professionals;
- Explain how the organization is assuring quality and monitoring the new technology;

In order to gather data to evaluate all aspects of this domain, one should analyze the technology as well as additional assets provided with it, but also through direct communication with the organization or users. The communication can be made through more formal channels, like interviews, Focus groups, etc., or through more informal methods, like simple meetings or exchange of e-mails.

3.8 Patient and social aspects

"Patient and Social aspects" is the eighth domain. This domain is of most interest to the assessment as it presents the condition and the technology from the point of view of the patients. It also looks at the social aspects regarding the condition and the technology. It intends to understand and gather aspects about patients, individuals and caregivers' experience of living with the condition in scope [1].

The perspective that the patients and caregivers have about the health condition and the implementation of the health technology is crucial to the assessment, as the people that will be most affected by the introduction of the technology can provide their point of view in terms of experiences, expectations, and preferences [1].

This evaluation provides a different and relevant point of view on the impact that the technology might have on the lives of patients and caregivers, who will have a crucial opinion about the quality and utility of the technology to their condition [1].

The evaluation of social aspects should also analyze the way the technology will condition the life of the patient, how it will influence their daily routine, and the way they might feel about the implementation of the technology [1].

This domain should address two subjects: Patients Aspects and Social Aspects. The information gathered for this domain should take into consideration the following considerations [1]:

- Patients aspects
  - Present the point of view of the patient on living with the condition;
  - Describe the burden of living with the condition for them;
  - Specify the opinions of patients regarding the use of this technology;
  - Describe the experiences of the alternative to the technology;
  - Describe how different treatments are presented to patients;
  - Explain how adherence to the technology can be improved;
- Social Aspects
  - Present if there are specific groups that do not have access to therapies;
  - Specify factors that prevent patients to have access to the technology;

3.9 Legal aspects

The domain about the "Legal aspects" is the ninth.

This domain is also important when assessing health technologies, as it intends to identify the rules and regulations that should be taken into consideration when evaluating the health technology in terms of implications and consequences [1].

These rules and regulations reflect the patients' rights and duties, but also can be related to data protection. The evaluation of this domain should concern legal information from the country and also at an international level concerning the legal implications for the technology implementation [1].

The main objective of the domain is to understand the rules and regulations that the health technology in study needs to satisfy. By doing so, one can verify if the technology is compliant with the regulations [1].

One should take into consideration the following suggestions when assessing this domain [1]:

- Be aware of existing regulations;
- Verify if the technology uses/creates information about the patient that is not related to health care or that might violate their privacy;
- Be aware of regulations concerning the security of patients data;
- State if the technology somehow affects basic human rights;
- Specify the existing regulations regarding the safety of the technology;
- Specify the existing regulations regarding the adoption of the technology;

- Understand if the current legislation and regulation covers the technology;
- Understand if the current legislation and regulation covers the technology at an ethical level;

3.10 Functional Requirements

The tenth domain is "Functional Requirements Evaluation".

This domain is the first presented that intends to specifically evaluate the software product.

Functional requirements evaluation is important to assure that the requirements of the system correspond to the actual functionalities presented by the technology.

However, this domain may not make sense for some software health technologies as the requirements may not be available, may not even have been defined. As previously stated, this process is being designed to evaluate the impact of the My Health Diary platform, and therefore, as the system was idealized by doctors who presented the desired specifications, for this technology, it makes sense to evaluate this domain.

The idea is to understand if the technology being implemented meet the requirements presented in an initial phase, which means that the purpose is to understand if the technology that is being added with the intention to fulfill a need in healthcare was developed taking into consideration the needs, expectations, and constraints presented.

At a second phase, it is important to check if the technology is fulfilling the need for which it was created, even though it meets the requirements presented. Also, it is relevant to understand with the "client" what should be different so that the technology would be a better version of itself.

To assess this domain, and to gather information one should take into consideration the following aspects:

- Description of the requirements;
- Present the requirements as use cases or user stories;
- Present the acceptance test created, at least one per use case/user story;
- Present the results for the tests;
- Explain if the requirements were met;
- Explain if the initial need that motivated the technology was fulfilled with its implementation.

As this domain intends to understand if the requirements presented for the software development are being met, thus the implementation will be validated according to the requirements. In order to validate the system and its functionalities, the requirements should be tested using acceptance tests to ensure they are being fulfilled.

3.11 Quality Attributes

The eleventh domain of the process is the analysis of some Quality Attributes of the software that were selected according to the relevancy they have to this study.

The intention of this domain is to assess the health technology, which is a software product, to understand it and validate it in terms of the quality of the product to be used.

Three quality attributes were selected, which are as follows:

- Usability;
- Security;
- Functional suitability;

Even though these were the attributes selected to evaluate health technology for this specific study, one can decide to use different quality attributes, whichever are most relevant and suitable for their study.

Each of the quality attributes that were selected will be evaluated in regards to the technology being studied. The process to analyze the quality attributes is described in the following subsections.

3.11.1 Usability

Usability is one of the quality attributes that will be assessed in the domain "Quality Attributes Evaluation".

Usability is the attribute that evaluates the degree of ease to use a product, like a software system, in order to achieve defined goals or actions in an effective and efficient way. Therefore, this subdomain intends to understand how usable is the health technology, for patients but also for health professionals.

The purpose is to analyze the system and evaluate its capability to be used in an easy way assessing the following characteristics:

- Learnability;
- Operability;
- User error protection;
- User interface aesthetics;
- Appropriateness recognizability;

Presenting the purpose of analyzing each of these characteristics: **Learnability** refers to how easy the app is for users to learn to use it and understand how it works. **Operability** corresponds to how easy is to use the app and perform the available actions. **User interface aesthetics** intends to

understand how pleasant do the users consider the UI of the software. **User error protection** refers to the way the app is protected to avoid errors from the users. **Appropriateness recognizability** corresponds to the acknowledgment by users that the system is suitable for their needs. [60]

To assess the usability of the health technology and gather information one should consider the users of the software (patients and/or health professionals) consulting them regarding their opinions about the health technology, and gathering feedback from them to address the characteristics mentioned above.

This contact with the users is very important in the process of obtaining information to analyze the usability as they are the main source of feedback regarding the system. As the patients and health professionals will be the ones interacting with the system in case it is adopted, it is crucial to know how easy they feel the system is in terms of learning and using it. It is also important to understand if they think the interface is pleasant in terms of its aspect, and more.

Contact with the users to obtain the necessary information should be made through questionnaires, focus groups, and interviews, or other strategies one finds relevant to the study.

3.11.2 Security

Security is another of the quality attributes that is being assessed in the domain "Quality Attributes Evaluation"

The attribute "Security" intends to evaluate to which degree the software can reduce the prospect of suffering an accidental or malicious attack, as well as the theft or loss of data. The purpose of considering this subdomain is to analyze the security of the health technology and perceive which are the security measures that were implemented in the system.

The security topic may address many relevant attributes that should be taken into consideration when analyzing the security aspects of the system. These attributes are as follows:

- Confidentiality;
- Integrity;
- Non-repudiation;
- Accountability;
- Authenticity;

Presenting the purpose of analyzing each of these characteristics: **Confidentiality** intends to understand if the data is only accessible to users that are authorized. **Integrity** aims to perceive how the application is preventing illegitimate accesses or modifications of software and data. **Non-repudiation** checks if the application collects information in regards to the occurrence of specific actions or events. **Accountability** verifies if it is possible to trace back to an entity the actions performed by that entity. **Authenticity** intends that the identity of a user or asset to be proven.[60]

This Quality attribute will analyze two main aspects regarding the health technology. The first is **What kind of security measures were implemented in the system?**, and the second one is **Which are the critical assets of the system?**.

To assess the security of the health technology and gather information one should consider the source code of the system as well as the documents regarding the development and security of the software, consulting them whenever necessary.

It is intended to understand which are the security measures being implemented on the system, verify if all the attributes mentioned above are being addressed by the security measures, exposing the vulnerabilities of the system, and assessing the risk they may bring to users.

3.11.3 Functional Suitability

Functional suitability is the next quality attribute that will be assessed in the eleventh domain of the HTA - "Quality Attributes Evaluation".

This is the attribute that evaluates the degree to which a software product provides useful functions that meet the needs for which it was developed. This means that this attribute intends to understand if the product is fulfilling the intention that motivated its implementation and if it eases the process of performing particular tasks, that is, to understand if the software is suitable for its purpose.

The purpose of analyzing the functional suitability is to analyze the system and evaluate its capability to fulfill the needs that prompted the product assessing the following characteristics:

- Functional completeness;
- Functional correctness;
- Functional appropriateness;

The analysis of each of these characteristics has a specific purpose. **Functional completeness** refers to the measure of how the functionalities implemented in the application cover the objectives and tasks presented by the users. **Functional correctness** corresponds to the measure of how the product presents accurate and correct results with the required level of precision. **Functional appropriateness** intends to understand the level of how the functionalities implemented in the application help the users to accomplish the objectives and tasks presented. [60]

To assess the functional suitability of health technology and gather information, users of the software (patients and/or health professionals) must once again be consulted about their opinions on health technology and also to obtain feedback from them, trying to address the characteristics mentioned above.

Like in usability, contact with users to obtain the necessary information must be done through questionnaires, focus groups and interviews, or any other strategy that one deems relevant for the study.

3.12 Overview

This new HTA Process was developed with the purpose of filling in the gaps detected in the existing processes of HTA when applied to digital Health Technologies, and also to meet the needs and intentions in the evaluation of the My Health Diary system. One can say that the process was designed by merging the nine core domains of a Health Technology Assessment with the two notions taken into account when evaluating software quality - Functional Requirements and Quality Attributes.

Therefore, the first category of the process, General Domains, that analyzes the nine core domains, was created based on the EUNetHTA Core Model[1]. The objectives and aspects to take into consideration presented in the process here exposed were established using the Core Model as the foundation.

The second category of domains looks at the health technology as a software product, and for this reason, it evaluates the quality of the software taking into account some quality attributes and the functional requirements, assessing the software based on these two aspects.

Regarding the differences from this process to the other processes presented in the State of the Art, one of the differences is the division of domains into two categories, where the first contains the usual domains required when assessing a health technology, and the second comprising the domains that will evaluate the quality of the software. Another difference is the domains that were added to the process and that belong to the second category. These domains added intend to assess the quality of the software.

In summary, the new process of Health Technology Assessment that is being proposed in this chapter intends to evaluate digital health technologies and it is composed of eleven domains: nine for General HTA, and two new domains for Software Assessment, as can be seen by the figure below - fig 3.1.

The nine domains regarding the category General HTA, correspond to the usual nine domains that should be assessed in an HTA, which are the following:

- Health problem and current use of technology
- Description and technical characteristics of technology
- Safety
- Clinical effectiveness
- Costs and economic evaluation
- Ethical analysis
- Organizational aspects
- Patients and social aspects
- Legal aspects

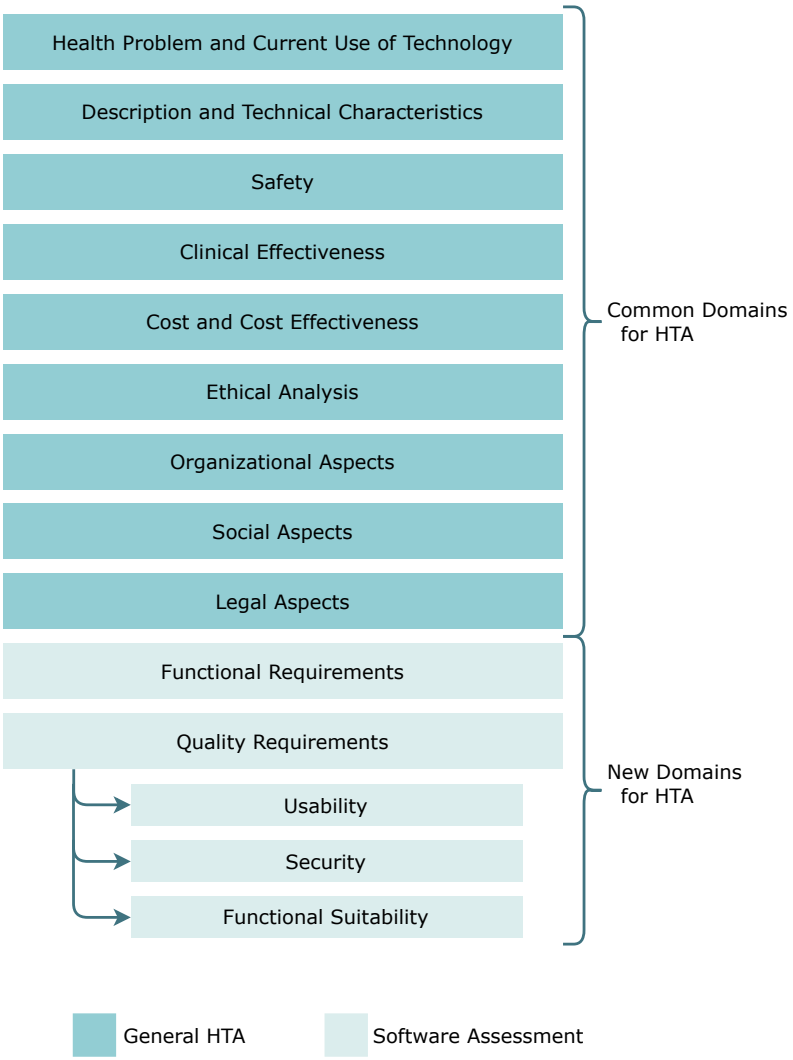


Figure 3.1: HTA Process - presentation of domains

These domains must be analyzed and evaluated having as basis the EUNetHTA Core Model[1]. The objectives for each domain proposed in the Core Model are maintained for this assessment, but without the obligation to answer all questions presented there.

The Software Assessment category will bring to the process two domains, which are Functional Requirements and Quality Attributes. The domains from this category intend to evaluate the quality of the software that is being used as a Health Technology.

As the name indicates, the domain of Functional Requirements intends to analyze the functional requirements that were initially presented and developed, validating that the functionalities were implemented accordingly.

In the Quality Attributes domain, three quality attributes were selected, which are usability, security, and functional suitability. These attributes were selected because they were the ones that could provide the more relevant information to the evaluation being performed. However, depending on the Health Technology to be assessed and the intentions of the assessment, different quality attributes can be selected, according to what information is more relevant for the decision-making process.

Table 3.1 will present a summary of all the domains in this process.

One must take into account that the process here presented was designed specifically to evaluate the My Health Diary technology, and therefore, to be applied to the assessment of different software systems, there might be the need to adapt the process to the specific technology and to the main purpose of the assessment.

Domain	**Description of Domain**
Health Problem and Current Use of Technology	The domain will focus its analysis on three main aspects: the Health Problem, defining the condition in the scope, the symptoms, the treatments and the diagnose process; the Target Population, by presenting an overview on the people that suffer from the condition and how will they be considered eligible to use the health technology; and, at last, it will explore the health technology targeted in the assessment, by presenting the technology, the reasons that motivated its use, and the possible alternative technologies that could be used.
Description and Technical Characteristics	This domain will provide information regarding the technology being targeted as it intends to enhance its purpose, features, and advantages and disadvantages. In addition, it will explore in more detail the alternatives to the health technology. Moreover, some other aspects should also be considered like the people who will use the technology, the way they will use it, and also the context of its development and the requirements for the adoption in terms of supplies or premises, as well as the necessary training to use this health technology.

Safety	The domain of safety intends to identify risks and possible harms that the technology may cause to patients, health professionals, or the environment in general, analyzing the risk of harm happening, and the possibility of direct and indirect harms from technology use.
Clinical Effectiveness	This domain is one of the most important in the evaluation, as the information gathered here will be essential to understand whether the health technology brings benefits to users or not. It will try to understand the impact that the technology is having, which is usually evaluated through a Randomized Controlled Trial. Therefore it will present the expected benefits, comparing them with the actual benefits, as well as assessing the impacts on the health and quality of life of the patients.
Cost and Economic Effectiveness	The fifth domain intends to assess the impact of the technology but in terms of costs and economic efficiency. It should consider the resources required to deliver the technology, as well as the estimations of costs, and describing the differences of costs between the technology and its alternatives. Additionally, it should establish how the cost of the application might create differences in access to the technology.
Ethical Analysis	The Ethical Analysis will address the social and moral values that concern the technology, focusing on the consequences that the implementation of the technology will bring. It should focus the analysis understanding aspects like the impact the disease has in the life of patients, benefits, and harms that the technology has on the patients and on society, but also clarifying if the technology will impact human dignity, and the cultural, moral, and religious integrity of the patients, as well as to what extent it invades the privacy sphere. Moreover, this assessment should take into account the impact on healthcare delivery, and the factors that may deprive someone of using the technology.
Organizational Aspects	This domain analyzes the implications that the implementation/adoption of the technology will bring to the organization and healthcare. It will take into consideration the modification to the work process of health professionals, the involvement that the technology requires, the training process, and the acceptance of the technology from patients and professionals.

Patient and Social Aspects	The domain of Patient and Social Aspects presents the points of view of the patients in regards to the technology and the condition. This perspective from patients is quite relevant as they will be the people that are most affected by the implementation of the technology. The assessment of social aspects must also analyze how the technology will affect the patient's life, how it will influence their daily routine, and how they will feel with the implementation of the technology.
Legal Aspects	This domain intends to identify rules and regulations that should be considered when analyzing the technology. The assessment should concern legal information from the country and at an international level. The purpose is to understand if the health technology is compliant with the regulations that concern it.
Functional Requirements	This domain is intended to evaluate the health technology as a software product. The purpose of assessing the Functional Requirements is to assure that the requirements of the system correspond to the functionalities that it presents, understanding if the technology that is being added with the intention to fulfill a need in healthcare, considering the needs, expectations, and constraints presented.
Quality Attributes	This domain is also intended to evaluate the health technology as a software product, with the intention to understand it in terms of the quality of the product to be used. Three quality attributes were selected, according to the intention of the study: Usability - to assess the ease of use of the product, assessed through questionnaires; Security - to assess the degree to which the software can reduce the prospect of suffering an accidental or malicious attack, as well as the theft or loss of data, by analyzing the security measures that were implemented.; and Functional Suitability - to assess the degree to which a software product provides useful functions that meet the needs for which it was developed.

Table 3.1: HTA process - process summary

Chapter 4

Validation Scenario

In order to validate the process presented in the previous section, it was implemented a pilot study to assess the technology My Health Diary.

The pilot study was developed with the collaboration of Hospital Pedro Hispano, more specifically the neurology department.

This study is being conducted since March 27th involving 60 patients of Hospital Pedro Hispano, as well as health professionals, all using the applications. Even though the study started on that date, it involved a lot of preparation regarding necessary modifications on the applications and deployment, as well as preparation in terms of the hospital organization.

The intent of the pilot study is, not only the validation of the process but also the assessment of the impact that the use of the My Health Diary platform has on the patients and on health care.

This chapter is divided into 5 sections: The first describes the collaboration/partnership with the department of neurology of the Hospital Pedro Hispano; the second section describes the application My Health Diary, in terms of requirements and functionalities. The third section will describe the modifications that were necessary on the applications as well as the deployment process. The fourth section presents the pilot study being implemented in terms of protocol. The last section intends to make a presentation regarding the focus group and questionnaires developed.

4.1 Partnership with Unidade Local de Saúde de Matosinhos

As previously stated, the department of neurology of the Unidade Local de Saúde de Matosinhos, idealized a software system - My Health Diary - so that the patients that suffer from migraines could register on a calendar application relevant information about their headaches, on a daily basis, to allow the health professionals to monitor, in a reliable way, the efficacy of the treatment and the need for adjustments.

This system came up from the need to replace a paper diary created for the same effect, as this diary proved to have some limitations, for example, the patients register multiple headaches before

the medical appointments, or did not bring the diary to the appointments, and so the doctors did not have access to reliable information about the headaches of the patients. For this reason, the neurologists idealized and defined the My Health Diary system.

My Health Diary was developed in a partnership between the department of neurology of the Unidade Local de Saúde de Matosinhos and the Faculdade de Engenharia da Universidade do Porto. So this partnership was formed and continued throughout the current school year, providing the possibility of this dissertation to happen.

The neurology service of the ULSM is physically located on the 3rd floor of Hospital Pedro Hispano and takes on several functions within the Hospital. It takes on patients with Neurological pathology under shared responsibility with Internal Medicine and works as an internal consultancy with the other hospital services.

Additionally, the Service has its own office in the Emergency Service and also handles the following Neurology and subspecialty consultations: Cognition, Headache, Toxin, Brain-Vascular Diseases, Demyelinating Diseases, Movement Diseases, and finally Epilepsy.

In terms of the number of patients with migraines, there are 2 to 6 requests for headache consultations per week in ULSM, and it is estimated that 60-80% of these patients must have migraines.

The close contact with the health professionals was kept during the year, with the realization of remote meetings via Zoom, and exchange of e-mails, which enabled the implementation of the study as well as the communication regarding the changes that were necessary to implement on the applications, and the current situation of the study.

The neurologists were very accessible and provided a lot of documents and information in order to get results for this study.

As the present dissertation intended to implement a Health Technology Assessment on My Health Diary and, also, the health professionals intended to develop a study to evaluate the effectiveness of the system My Health Diary on the patients, one pilot study was implemented where both parties would be able to obtain results of their interest.

As the study was to be implemented within the hospital, involving real patients, it was necessary to submit the study to be approved by the ethical commission and the local commission for the security of information. The study was approved by the two entities.

To implement the pilot study in the hospital, it was necessary to create a protocol for it. This protocol was designed by the neurologists and contained the context of the clinical trial, the objectives, the concerns, timeline, and questionnaires as well as the consent agreements.

Direct contact with the patients was only established by the health professionals, in order to obtain information on the patients, answers to questionnaires, and evaluations for the platform.

4.2 My Health Diary

The dissertation intends to evaluate the impact that the use of the system My Health Diary will have on the patients and health professionals through a health technology assessment.

The system was requested by the doctors of Hospital Pedro Hispano to fulfill the need for a strategy for the patients who suffer from headaches to register information regarding their condition on a daily basis so that the professionals have access to that information to better diagnose and treat the condition.

My Health Diary consists of a platform that has as an intention to manage a headache diary for people that belong to the ULSM and suffer from headaches, more specifically migraines. The diary is created and filled by the patients and then the doctors can access the registries. It is a system of applications composed of a mobile application intended for patients, a web application for health professionals, and a Business Logic application with a REST API that allows the data to flow from one application to the other.

The whole system was develped during the course of "Gestão de Projetos, Inovação e Empreendedorismo (GPIE)".

The doctors required that My Health Diary should be composed of two applications, a mobile application for patients, and one application that could be accessed on a computer for the health professionals (web application). The two applications should communicate through the network.

Both patients and health professionals should have a profile. The patient's profile would be created by the doctor and would have an identification code. It should also keep track of the following information about the patient:

- Name initials;
- Birth date;
- Gender;
- Whether the patient has migraines with or without aura;
- If the patient has migraines exclusively unilateral;
- If the patient is doing a symptomatic treatment, and which one;
- If the patient is doing a prophylactic treatment, which one, and when it started;
- If the patient suffers from depression, anxiety, insomnia;
- If the patient suffers from other diseases.

The mobile application would mainly be used to record daily on a calendar headaches of the patients. The information required to register a headache would be the following:

- Type of headache (tension or migraine);
- Intensity on a scale from 1 to 10;
- Took a painkiller;
- Took a triptan;

- In case of the patient is woman, menstruation;
- Went to the emergency room due to headache;
- Work incapacity due to headache;
- Registry of future medical appointments;

Also, the patients would receive alerts for three kinds of situation:

- In case the patient forgot to fill the diary for 3 days straight;
- In case the patient have a medical appointment in a week;
- In case the patient is taking too much medication:
  - Took painkillers more than 15 times on the past 30 days;
  - Took triptans more than 10 times on the past 30 days;

Another requirement presented by the doctors was the need for an instruction manual for the patients on how to fill in the diary.

Regarding the health professionals' application, it would have a list of patients that are associated with the professional so that they can access the information of those patients. The health professional should be able to add and remove patients from the list.

For each patient the health professional would be able to see a summary of the registries where the following information would be presented:

- Number of days with headaches per month;
- Number of days with migraines per month;
- Percentage of reduction on the number of days with headaches for the past three months;
- Number of days the patient took painkillers per month;
- Number of days the patient took triptan per month;
- Number of days the patient went to the emergency room per month;
- Number of days with work incapacity due to headaches per month;
- Maximum intensity of headache (from 1 to 10);

The health professional should also receive alerts regarding patients on their list:

- In case the number of days with headaches for a patient increases more than 20% on a month;
- In case the number of days that the patient needed to go to the emergency room increases in comparison with the previous month;

- In case the number of days with work incapacity due to headaches increases in comparison with the previous month;

In summary, the main functionalities for the patients' application and for the health professionals' application are the following:

- Patient:
  - Edit profile;
  - Register on headache's diary;
  - Register medical appointments;
  - Receive alerts;
  - Access to the instruction manual;
- Health professional.
  - Create professional profile;
  - Create patient profile;
  - Edit patient profile;
  - Add patient to "my list" of patients;
  - Remove patient from "my list" of patients;
  - Access to the registries of patients on "my list";
    - Access summary about patient;
    - Access calendar with registries;
  - Receive alerts regarding patients on "my list";

The next image 4.1 shows the Use Case Diagram for the entire system. This Diagram was based on the Use Case Diagram presented in the Project Handover, but some fixes were made.

In practice, My Health Diary system is composed of three applications:

- A mobile application for Patients, developed using the technology Flutter - 1.18.0-6.0.pre.80.;
- A web application for the Health Professionals using the React Framework - 16.13.1;
- A business logic application - Backend, using Java 8 with Spring Boot and Maven 3.6.1.

Additionally, the system database is implemented in MySQL, and managed through Spring Boot and Hibernate.

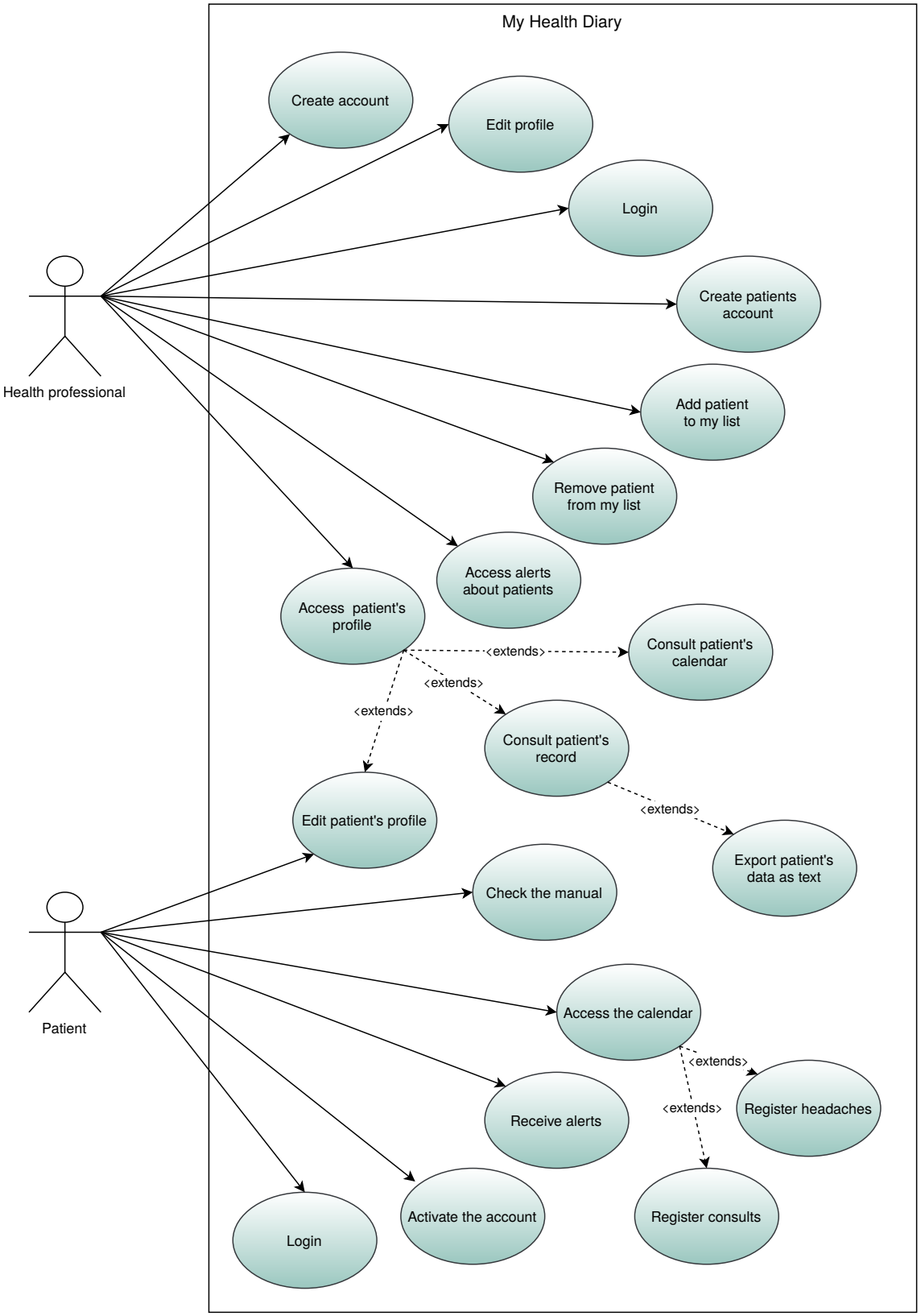


Figure 4.1: Use case Diagram

4.2.1 For the patients

In the My Health Diary system, an application was designed for the patients. This application was required to be a mobile application that should run on Android smartphones. For this reason, the technology selected to develop the app was Flutter, a mobile UI framework, that allows building applications for Android and iOS from a single codebase. Thus, in case it becomes necessary to enable the application to iOS smartphones, it would only take a few modifications in the codebase. Two of the screens from the mobile application are shown below, in figures 4.2 and 4.3.

The application consists of a calendar where the user can mark episodes of headaches or migraines for the current day or past days. In the calendar, the patient can also schedule the appointments that they will have at the hospital or health center.

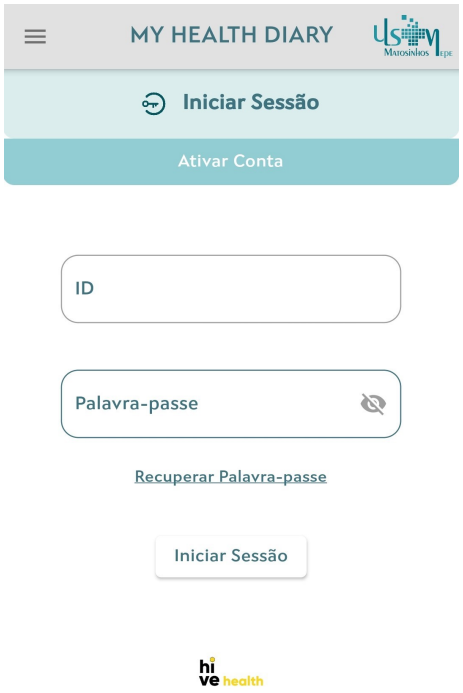


Figure 4.2: UI - Login Page

Figure 4.3: UI - Calendar Page

4.2.1.1 Functionalities

Regarding the functionalities for a patient, user of the application, the first functionality that the user will need is to activate the account. The account activation intends to assure that the user accepts the terms and conditions as well as the privacy policy. With this operation, the user will also need to redefine their password, preferably to something they can easily remember. The activity requires the user to go to the "Activate account" page where they should enter the credentials that were previously sent by e-mail when the account was created by the doctor. The patient should

then check the boxes regarding the privacy policy and the terms and conditions. They will be redirected to a different page where the password must be redefined and submitted, being internally sent to the server which will save it and return a successful message.

The patient may then log in to the account using the user name that was received by email and the password that was defined in the account activation. The user is required to enter their credentials on the respective boxes and submit clicking on the sign-in button, which will send to the server the credentials to confirm they are correct, as well as fetch all the data about the user from the database and redirect it to the app. This data includes the account information, user data, notifications sent, and the calendar.

The app has as main functionality a calendar where the patient can register their headache on a daily basis. The days in which the patient registered the headache are marked so that the patient can distinguish them from the days with no registry. To register a headache in the calendar, the patient needs to sign in on the app, which will communicate with the server to confirm the user account and to fetch the filled calendar for the patient. The patient should then select the day they want to create a registry, fill in the information required regarding the headache, including medication data, and then submit the information. The information will be sent to the server where the entry will be created and the calendar updated, returning to the app a successful message. The patient may consult the diary entries that they entered in the application.

Also, the patient can add medical appointments to the calendar so that they are aware of when the next appointments are. To create a medical appointment in the calendar, the patient needs to be signed in on the app. They should then select a day in the future when the appointment is taking place, and fill in the information required, like the type of appointment, the doctor, the place, the time, and more, and then submit the appointment. These data will be sent to the server, the appointment will be created and the calendar updated. Also, a success message will be returned. A day with a consultation is also marked in the calendar.

They may also check the user manual. For this, the user should go to the user manual page, where they will find a set of tutorial videos on how to proceed on the app, for example, how to create a diary entry, or how to edit the patient's account. This functionality was implemented with a Flutter plugin that fetches videos from YouTube through the URL and displays them inside the application. Although this activity requires access to the network it does not communicate with the server.

4.2.2 For the health professionals

The system My Health Diary required an application designed for the health professionals, that should be accessible on the hospital computers. Therefore a web application was developed for the doctors using React, a JavaScript framework. This application is thus accessible from the browser. The following figures 4.4 and 4.5 show two of the pages of the web application.

The application consists of a platform where a health professional has a list of patients that are associated with them calendar where the user can mark episodes of headaches or migraines for the current day or past days. In the calendar, the patient can also schedule the appointments that they will have at the hospital or health center.

Figure 4.4: UI - Login Page

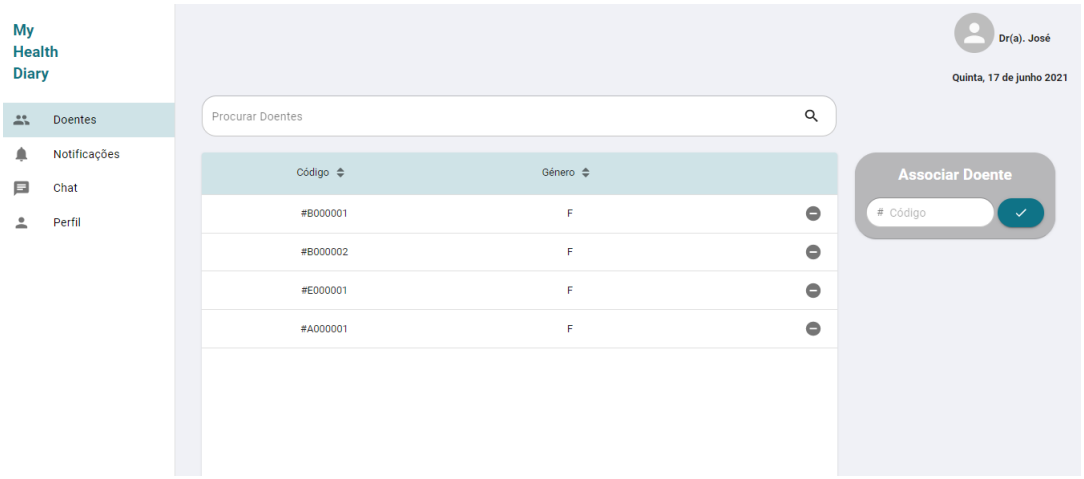


Figure 4.5: UI - Page with the list of patients associated with a health professional

4.2.2.1 Functionalities

In regards to the functionalities for health professionals, who use the application, the first functionality the professional will use is to create a health professionals account. The purpose of this functionality is that each health professional has their own account, to be able to sign in using their institutional e-mail and a password of their choice. This functionality expects the user to go to the sign-up page and insert information about them like name, e-mail, medical specialty, place

of work, and password and submit, being redirected to the login page. The e-mail inserted must have as domain **ulsm.min-saude.pt**.

After creating the account the professional can log in to their account using the institutional e-mail and password defined on the creation. The health professional should insert the credentials on the respective boxes and sign in. this action will send to the server the credentials to confirm they are correct, and also fetch all the data about the professional as well as the patients associated with them from the database and redirect it to the app.

The health professional is able to edit their profile, by going to the profile page and selecting the edit profile button. In here the professional is able to change the name and e-mail. The password can also be changed. The professional is also able to add a profile picture to their account. However, they cannot edit the information about the medical specialty, being able to change the place where they work, if their specialty is "Médico de Medicina Geral e Familiar" or "Enfermeiro de família". When the professional finishes altering their profile, they must save the changes, so that the information is sent to the server and the database updated.

The health professionals are the only users of the system that can create the accounts for the patients that will use the platform. Therefore, in order to create an account, the professional should click on add a patient being redirected to the account creation page. Here, they will fill in the information about the patient. The information is divided into 3 categories: Persona Information - e-mail, genre, birth date, initials, process number, Health service number, and health center to which the patient belongs; Treatment - migraine with aura, exclusively unilateral, symptomatic, and/or prophylactic treatment the patient is currently doing; and comorbidities - depression, anxiety, insomnia or other diseases. After filling in the information about the patient, the professional should submit it, being internally sent to the server and saved in the database. Also, an e-mail will be sent internally to the patient, with the credentials- username and password - they should use to activate the account and then to log in to the system. When the health professional creates an account for a patient, that patient will be automatically associated with the professional.

A professional can still add patients to their list, even if they were not created by them. For this, the professional must insert the patient's identification or code in the box created for the purpose. The patient will be added to the list and, thus, the professional will have access to the information that the patient records about their migraine.

If a professional does not want to follow the information about one of the patients on their list, they can remove a patient from the list. Therefore, the health professional should find the patient on the list and remove them. From that moment, the professional no longer has access to the patient's account.

The main functionality of the web application is to access the patients' profiles. To do so, the health professional should select the user he intends to analyze, from their list of patients. After

selecting the patient, the health professional can choose from three “tabs” to consult patients’ records, consult patients’ calendars, or edit patients’ profiles.

In the option of displaying the patient’s records, the health professional has the possibility to consult a summary about the patient’s migraines in the current month and compare it with the summaries of previous months. Here, the professional can consult the information about the evolution of the number of days with headaches, but also the information about the number of days with headache and specifically migraine, number of days with medication, number of days the patient miss work, number of days the patient went to the emergency room, and the maximum intensity of pain on the current month.

The professional also has the possibility to export the data of the summary by clicking on the export button. This action will copy the summary data in a table format into the clipboard, and the user can then paste the information.

Another option is to consult the patient’s calendar. When a patient has a headache, they should register the information about it in the calendar of the patient’s application. The health professional can then consult the patient’s calendar in the web application, being able to check when did the patient had a headache, and the information about it like the intensity and type, the medication, and more.

The health professional can also edit the patient’s profile. In this option, the professional is redirected to a page with the information about the patient that was inserted in the process of the creation of the patient’s account.

The health professional can have access to alerts about the patients. The notifications refer to the data completed by the patients regarding their headaches. They intend to alert doctors to an increase in headache days, an increase in the number of days the patient missed work or went to the emergency room, in comparison with the previous month. The Notification page also has a search bar, thus the doctor can search for notifications by patient code or by the subject of the notification, using words from the notification, such as “disability ” or “urgency ”.

4.3 Preparation of the app for the study

The system was requested by the doctors of Hospital Pedro Hispano to fulfill the need for a strategy for the patients who suffer from headaches to register information regarding their condition on a daily basis. Therefore, the applications were designed and implemented as it seemed necessary to the health professionals.

However, some of the information about the patients that were initially required and that was being entered in the software was considered to be sensitive and non-essential to the good functioning of the system. So, for the study, it was necessary to make a few alterations to the system to assure that only required data was being collected.

Information such as health service number, process number, date of birth, and initials, which was initially considered necessary for patients to be more easily identified by professionals, was requested to be withdrawn before the pilot study started, as it was sensitive information that could appear as a problem for the local commission of security of information.

Moreover, as the health professionals could easily access that information through the hospital system, the information was unnecessary to be in the application.

Another modification that was necessary, according to the doctors was that, as the patients would have to log in every time they entered the app, in order to facilitate the process and therefore ensure more participation by patients, the password should have its minimum character number reduced from 9 to 4.

To make the patients' application more personal and so that the users could have a name associated with their accounts, a name field was created in the application. However, this field was never sent to the server and therefore never saved on the database of the system. The only place where the name is saved is in the users' smartphone.

Additionally, the professionals realized that some of the information that was being asked about the characterization of the patients' migraines was not relevant to the study, but there were other characteristics that would bring more appropriate information. Thus, the fields: "Enxaqueca com aura" and "Exclusivamente Unilateral" were replaced by "Associado a náusea e/ou vómitos" and "Associado a fotofobia e/ou fonofobia".

Regarding the deployment of the My Health Diary platform, there was a green light to deploy the system outside of the hospital network. For this reason, the system was deployed on the FEUP servers.

In order to put the system running, one needs to have installed the following technologies: GIT, Apache, Java, Maven, and NPM, in order to run the backend and web applications.

It was decided that would not be necessary that the mobile application was published on the Play Store, and for this reason, on the web app, it was created a route where the APK of the mobile app could be downloaded, and then installed on users' smartphones.

The web application is accessible from `https://myhealthdiary.fe.up.pt/` and the mobile app can be downloaded from `https://myhealthdiary.fe.up.pt/download_user_app`.

The deployment diagram is presented in the figure below - Fig. 4.6.

4.4 Pilot Study

As previously stated, in order to evaluate the technology My Health Diary, a pilot study was implemented, in collaboration with the neurology department from ULSM.

The technology being assessed in this study, My Health Diary, is intended to be used by the patients from ULSM that suffer from migraines. This health technology is going to be used to help the health professionals and the patients to monitor and understand the condition of these last, by keeping a diary with information regarding the headaches they have.

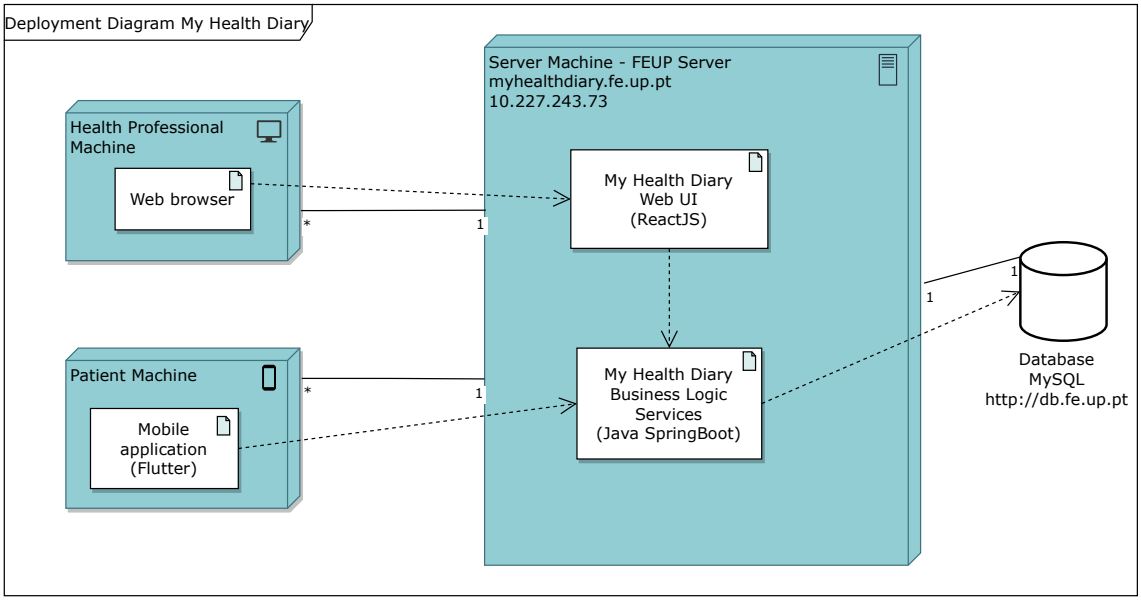


Figure 4.6: Deployment Diagram

This study is a Crossover Randomized Controlled Trial, where the patients will be subject to two different diary approaches, the paper diary and the application My Health Diary, which means that each patient will use the two diaries in two distinct and successive phases, in which the type of diary they will use in each phase is selected randomly. The paper diary used can be seen in Appendix C

Each phase is going to last 13 weeks, and therefore the total duration of the trial is 26 weeks, approximately 6 months.

The study will recruit 60 patients that are consecutive patients on medical appointments of Neurology at Hospital Pedro Hispano and that are willing to participate in the study. The patients should meet all of the following inclusion criteria:

- Patient that is being followed on the neurology department for episodic or chronic migraine, with diagnostic of more than 6 months.
- Patient with at least 4 days of migraines per month.
- Patient with prophylactic medication.
- Patient with ages between 18 and 50, at the time of recruitment.
- User of Android smartphone.
- With informed consent.

They must also not meet any of the exclusion criteria, which are as follows:

- Patients with major psychiatric illness.

- Patients currently participating in another clinical trial.
- Patients who do not meet diagnostic criteria for episodic migraine according to ICHD-3.
- Illiterate patients or that are incapable to fulfill the records independently.
- Patients with a previous history of filling in the headache calendar, in the 3 months prior to the beginning of the trial.
- Patients who do not use an android smartphone.
- Patients who cannot read or write in the Portuguese language.

The purpose of this study, as stated before, is not only to validate the process but also to assess the impact that the use of the My Health Diary platform has on the patients and on health care. It is intended to understand if the application will have more adherence by patients than the paper diary, as the method to keep track of the headaches. This goal will be assessed through two values, which are: the percentage of days of register per month, and the percentage of patients that withdraw from the registry of headaches.

The study also intends to evaluate the quality of life, and the level of incapacity, measured by questionnaires. Moreover, it intends to understand the existing relation between the use of each diary and the number of days with medication use, the number of days with emergency service visits, and the number of days with incapacity to go to work.

The study will take into consideration the assessment of the technology My Health Diary information about the patients in five categories. The first is the demographic characteristics, like gender, age, profession, and educational level. The second is the clinical data, like medications, or other diseases. It will also consider the impact that the headaches have on the patients, which will be defined through questionnaires. Another category is the quality of life, which also be assessed through the use of questionnaires. And, at last, the study will take into consideration the information inserted on both diaries, paper and My Health Diary.

Therefore, to obtain data from the study, it will be used the data that was entered on both diaries, the clinical data about the patients, and also the data from the questionnaires that the patients will need to fill in in three specific moments of the study: at the beginning of the study - week 0; in the middle of the study - week 13 - when the user will change the type of calendar being used; and at the end of the study - week 26.

The patients will answer seven questionnaires, that are as follows:

1. **Questionário 1** - Intends to register the current condition of the patients;
2. **Questionário 2** - intends to understand the preference of the patients between the two types of diary;
3. **MiDAS** - Migraine Disability Assessment Test;
4. **HIT-6** - Headache Impact Test;

5. **MSQ V2.1** - Quality of life questionnaire specific for migraines;
6. **WHOQOL- BREF** - World Health Organization Quality of Life Instruments - Bref;
7. **Questionário My Health Diary** - Usability questionnaire.

All questionnaires are available in the appendix section A.

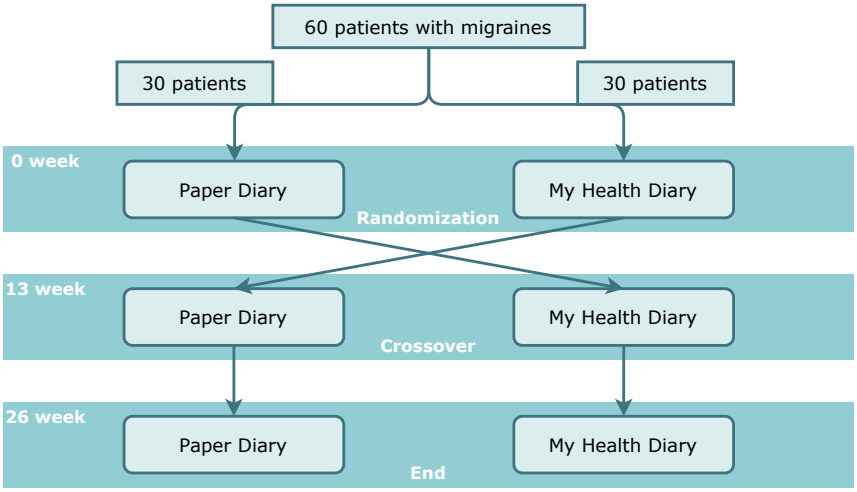


Figure 4.7: Study Timeline

Figure 4.7 presents the timeline of this clinical trial, as described below.

At week 0, when a patient initiates the process to participate in the study, it occurs the first moment through a meeting with the neurologists where they are introduced to the study, to the protocol, and where they will need to fill in the questionnaires 1, 3, 4, 5, and 6 from the list above. In this meeting, the professionals will also guarantee that the application is installed and running correctly, for the patients that will be using the My Health Diary application, and they will show the patients how to use the app. For the patients that will be using the paper diary, it is also presented the way to use this tool.

At week 13, the patients will meet the doctors again, and in this meeting, they will be submitted to the same questionnaires as before. However, the patients that have been using the mobile application will also need to answer the usability questionnaire - 7 on the list. At this time, the crossover will happen, which means that the patients that were using the paper diary will start to use the mobile application, and vice-versa. Therefore, the installation of the app, as well as the explanations on how to use both diaries, is presented to the new users of each tool.

At week 26, the patients will have a meeting with the neurologists, once more, and the same questionnaires from week 13 should be answered. Additionally, the patients will also need to fill in the second questionnaire on the list. This week marks the end of the study.

With these three moments, where patients will need to answer the same questionnaires, it is possible to see the evolution of the headaches for those patients.

In a normal situation, the neurologists could have all the patients in a room to initiate the study, being able to help and start all the patients at the same time. With the current pandemic situation,

the professionals needed to meet every single patient individually, and that delayed the process for starting the study.

At the time of writing, the clinical trial already has the participation of 20 patients, with 10 using the My Health Diary platform and the remaining 10 using the paper diary. More patients will continue to be added to the trial over time.

The pilot study was initiated on March 27th of 2021.

This clinical trial is an official trial [1] that was submitted to the United States database of clinical studies conducted around the world - clinicaltrials.gov.

4.5 Focus Group And Questionnaires

In order to collect the insights and opinions of the health professionals about the utilization of the system My Health Diary by the ULSM, a Focus Group activity was developed.

A Focus Group is a small group of people, who want to discuss a pre-determined topic, using open-ended questions to generate data on a topic. It is a qualitative research methodology, which focuses on defining answers to questions that cannot be answered with classical clinical research methods. They often focus on practical issues associated with unmeasurable variables.

This Focus Group was aimed at Physicians and Health Professionals who are considered relevant to the study. They should have experienced and know the platform to be discussed – My Health Diary.

The main objective of this Focus Group was to understand if the My Health Diary technology met the expectations initially presented for its day-to-day use. Conclusions would be drawn with the exploration of three topics within the theme:

- Adequacy of the application's use to the predefined objective;
- Future perspectives for using the application;
- Implications of using the application in clinical practice;

All data collected in the action served as a source of information and complement to the present dissertation.

A document was created containing the presentation of the activity as well as the questions to be raised. This document was previously sent to the physicians, so they could better prepare their answers and also streamline the process of gathering information and organizing the different points of view.

A total of eleven questions, divided by the three topics, were presented to the professionals and discussed during the meeting. The questions were as follows:

- Adequacy of the application's use to the predefined objective:

[1] Accessible through https://www.clinicaltrials.gov/ct2/show/NCT04828941?cntry=PT&city=matosinhos&draw=2&rank=1

  - What were the initial intentions that motivated the development of the technology?
  - How was the technology expected to benefit patients?
  - How do the features presented on the platform help/facilitate users to achieve the initially stipulated goals?
  - How is the technology being accepted by all users – patients and healthcare professionals?
  - Comments on concrete data already obtained: Is the data being generated useful? Are the data presented on the platform sufficient for clinical practice?
  - Are there any benefits already found for using this technology?
  - Doctors' opinion on the use of the platform.

- Future perspectives for using the application:
  - What changes are needed to the platform to improve the results obtained?
  - Other primary headaches for which it could be used.

- Implications of using the application in clinical practice:
  - How does the use of My Health Diary impacts the exercise of clinical practice?
  - Reorganization of headache consultation taking into account the remote control made with the application.

This activity took place on June 25th of 2021, via Zoom, and had the participation of three neurologists from ULSM who had direct contact with the system during the development phase, and also during the clinical trial.

Regarding questionnaires, two questionnaires were developed: one for health professionals, and one for the patients. Both questionnaires are displayed in the appendixes section - Appendix A, professionals questionnaire - A.8, and patients questionnaire - A.7.

Even though the questionnaires are called "Usability Questionnaire", they were used to get more information in addition to usability data. For example, the questionnaire for the health professionals is divided into three sections: the usability, the adequacy, and the usability of the patients' application. Moreover, the questionnaires for the patients also possess questions regarding the opinion of the patients in terms of the effectiveness of the platform.

All the questions from the questionnaires were made using the Likert scale, from "Discordo Completamente" to "Concordo Completamente", and they are written so that the higher is the answer from a user to a question the better is the performance of the scope of that question.

The questionnaires are being delivered to patients at the moment of writing, as the pilot study is crossing the mark of 13 weeks.

So far, two responses have been obtained in the questionnaire made available for the patients. The answers are represented in Appendix D - D.1. Regarding the questionnaire for the health

professionals, also two answers were obtained, and the answers are represented in the charts in D.2.

Chapter 5

Process Application

The main intention of this study is to understand how to carry out a Health Technology Assessment on the My Health Diary platform, in order to clarify whether the platform is more effective than the use of paper diaries, which is the tool currently used at ULSM, but also understand whether its use benefits both patients and physicians.

The study also intends to help in the decision regarding the adoption of the "My Health Diary" platform as the go-to tool for monitoring headaches in this local unit.

Health Technology Assessment is the systematic evaluation of properties, effects, and/or impacts of a health technology [18]. It comprises a transparent and multidisciplinary process that uses explicit state-of-the-art methods to assess a health technology at different points of its lifecycle, considering the best evidence available.

The process being used is divided into eleven domains that can fall into two different categories, category 1 - General HTA, and category 2 - Software Assessment. In the General HTA category, the 9 core domains of HTA will be considered because they are relevant to understand the impact that the technology has on patients, professionals, and the health system, and they go as follow: Health problem and current use of technology; Description and technical characteristics of technology; Safety; Clinical effectiveness; Costs and economic evaluation; Ethical analysis; Organizational aspects; Patients and social aspects; and Legal aspects.

The second category of the process - Software Assessment, is composed of two domains being both related to the assessment of software. These domains are Functional Requirements and Quality Attributes and correspond to the novelty presented in this new Health Technology Assessment process.

The current chapter will present the results of the application of the process described in chapter 3 following the alignment of the domains as explained in there, and therefore, there might be some repetition of what was presented in the previous chapters.

In the following sections, it should be noted the possible existence of inaccuracies in what was described regarding technology and the disease, as this is the first application of the process and

it was not possible to have the follow-up of specialists from all areas of this multi-disciplinary process.

5.1 Health problem and current use of technology

The first domain will mainly focus its analysis on trying to clarify three main aspects, which are: the Health Problem, defining the condition in the scope, the symptoms, the treatments and the diagnose process; the Target Population, by presenting an overview on the people that suffer from the condition and how will they be considered eligible to use the health technology; and, at last, it will explore the health technology targeted in the assessment, by presenting the technology, the reasons that motivated its use, and the possible alternative technologies that could be used.

My Health Diary, the health technology being assessed in this study, is a platform that intends to monitor patients' migraines as they will register information about each migraine in a calendar/diary, that can be accessed by health professionals.

Migraines is a chronic neurological disorder marked by exuberant episodes of headaches that may last from four hours to three days, and are spaced apart for periods without symptoms [39, 26].

In addition to headaches, one may experience symptoms such as nausea, sensitivity to light, noise, and/or some smells. Usually, the headache is pulsatile, as feeling the heartbeat inside the head. In terms of frequency, the migraines are very variable depending on the patients. Some patients may have two crises per week, and others may have only a few over the entire life [26].

The treatment of migraines relies mostly on symptomatic and prophylactic treatment. The symptomatic treatment should be applied during the episode. The patient should lay down on a dark and quiet spot and may apply cold or pressure to the pain site. Regarding medication, one should take painkillers, anti-inflammatories, or triptans, according to medical recommendation [26].

For the prophylactic treatment, one should use a calendar to identify triggering factors and assess the impact of migraines on quality of life. Avoiding triggering factors should be one measure of prophylactic treatment. Even though there is no specific medication to aid in migraine prophylactic treatment, some medications intended for other ends prove to be helpful like some antihypertensives, some antidepressants, some antiepileptics. The medication should be taken according to medical recommendations [26].

Regarding risk factors for migraines, they can be divided into non-modifiable and modifiable. The first type corresponds to factors like age and gender, as the disorder tends to affect more women than men, and is more frequent in people with ages between 20 and 40 [50]. Modifiable factors can be, for example, a sedentary lifestyle, obesity, caffeine abuse, medication abuse, anxiety and depression, etc. [44].

There are certain factors that can trigger migraine episodes, which are: hormonal factors in women, like menstruation, ovulation; emotional factors, like depression, anxiety, stress; Sleep disorders, like sleeping too little or sleeping too much; environmental factors, like weather changes,

long trips, exercise; and exposure to certain stimulation, that might be visual, sound, or olfactory, but also, prolonged fasting, drinking alcohol or excess caffeine [25].

Migraines can be categorized into two main subtypes, which are migraine without aura, and migraine with aura. A patient may also suffer from chronic migraines or other complications [59].

For each of these types of migraines, there are different diagnostic criteria that must be verified in order to categorize the patient's disorder [59].

Migraine without aura is a recurring disorder that has episodes lasting 4 to 72 hours. For a patient to be diagnosed with Migraines without aura he or she should meet the following criteria:

A. To have at least five episodes that fulfill criteria from B to D.

B. Episodes of headaches that last 4 to 72 hours.

C. The headache has at least two of the following characteristics:

    1. Pulsatile.
    2. Unilateral location.
    3. Moderate or severe pain.
    4. Routine physical activity is avoided or aggravates the episode.

D. During the episode of headache, one has at least one of the following:

    1. Nausea and/or vomiting.
    2. Photophobia and phonophobia.

E. The condition is not explained better by any other classification of ICHD-3 (International Classification of Headache Disorder)

Migraine with aura is a recurring disorder with episodes that last a few minutes. It is characterized as being unilateral and for having visual, sensitive, or other symptoms related to the central nervous system, totally reversible and followed by headache or other migraine symptoms. For a patient to be diagnosed with Migraines with aura he or she should meet the following criteria:

A. To have at least two episodes that fulfill criteria from B and C.

B. One or more of the following Aura symptoms:

    1. Visual.
    2. Sensitive.
    3. Speaking or language.
    4. Motor.
    5. Brainstem.
    6. Retinal.

C. At least three of the following characteristics:

    1. At least one aura symptom spreads gradually over 5 or more minutes.
    2. Two or more symptoms happen successively.
    3. Each aura symptom lasts 5 to 60 minutes.
    4. At least one aura symptom is unilateral.
    5. At least one aura symptom is positive.
    6. Aura is followed by 60 minutes of headache.

D. The condition is not explained better by any other classification of ICHD-3 (International Classification of Headache Disorder)

Regarding Chronic Migraines, this disorder has episodes of headaches occurring 15 or more days per month, for more than three months. Also, at least 8 days with headache episodes per month should have migraine characteristics. The diagnosis criteria are as follows:

A. Headache occurring 15 or more days per month, for more than three months, that fulfills criteria B and C.

B. It happens on a patient that has had at least five episodes fulfilling the criteria B to D from Migraine without aura, or B and C from Migraine with aura.

C. At least 8 days with headache episode per month, for more than three months, fulfilling any of the following:

    1. Criteria C and D from Migraine without aura.
    2. Criteria B and C from Migraine with aura.
    3. Patient's conviction that he has migraine at the beginning that is relieved by a triptan or ergotamine.

D. The condition is not explained better by any other classification of ICHD-3 (International Classification of Headache Disorder)

All information regarding diagnosis criteria was taken from "Classificação Internacional de Cefaleias", 2018 [59]

This disorder has a huge impact on society and on the economy. Martins et al., (2018) [44] state that studies were implemented all over the world (Europe, North America, South America, Asia, and Pacific) to understand the social and economic impact of migraines. According to the Global Burden of Disease Study 2015, migraines have been classified as the third cause of disability in the world for men and women under the age of 50 [59]. The studies demonstrated that the disorder brings a huge cost in terms of consumption of health care, in terms of medication, but also consultations, emergencies, exams, and more. The disorder also impacts negatively the labor

productivity, and the fact that it affects people in the most productive phase of their lives, brings huge costs at social, economic, and familiar levels [44, 26].

The technology being assessed in this study, My Health Diary, is intended to be used by the patients from ULSM that suffer from migraines. This health technology is going to be used to help the health professionals and the patients to monitor and understand the condition of these last, by keeping a diary with information regarding the headaches they have.

The diary keeps records of the following information about each headache:

- The type of headache: Migraine or tension;
- The intensity of pain: on a scale from 1 to 10;
- The painkillers usage: yes or no question;
- The triptans usage: yes or no question;
- If the patient is menstruating: yes or no question, in case patient is female;
- If the patient missed work: yes or no question;
- If the patient went to the emergency service: yes or no question;

Keeping a diary with this information is an asset for patients to understand better their migraines, and it is also a useful tool for professionals. This tool provides crucial information to help the health professional with the clinical decisions regarding treatment adjustments and others. Moreover, with the use of this tool one can perceive patterns in the headaches of the patients which can help in the prevention and management of its episodes.

As previously stated, My Health Diary has as target population the people that suffer from migraines and also belong to the Health Local Unit of Matosinhos (ULSM). According to the numbers provided by the neurologists, there are approximately 90 000 people suffering from headaches in ULSM, 30 000 of those suffer specifically from migraines on this local unit.

However, for the pilot study that is taking place at the time of writing, the target population was filtered through inclusion and exclusion criteria in order to find 60 eligible people to use the My Health Diary platform during the clinical trial period. The criteria to be eligible for the pilot study was previously described in Pilot Study Description Section - 4.4.

The alternative to the technology used until now in ULSM is the paper diary, which consists of a printed calendar where patients should register their occurrences of headaches. Although the diary presents advantages like the possibility to monitor the episodes of headaches, and the response to treatment in a more reliable way, than just relying on the memory of the patients, the limitations are also notorious, for example, the loss of the paper, or forgetting to bring the calendar to the medical appointment, or even the fulfillment of multiple registries in a biased way right before the appointments.

The My Health Diary application appears as a solution for the limitations presented by the paper diary. It is designed having the ULSM population and their needs as a basis, as it is adapted to

the reality of ULSM. The main motivation for this technology is the fact that the registries created by the patients in the My Health Diary system can be easily accessed by the health professionals, at any time, therefore the time dedicated to patients can be optimized, the clinical monitoring is improved, improving as well the accuracy of diagnostic and the adaption of therapeutic adjustments may be performed in a more rational and effective way.

There are more alternatives to My Health Diary in the digital field. However, the available options are mostly in English and are not validated. Also, as the technology in study was designed specifically for ULSM to use, the functionalities are fitted to the needs of the professionals. This is a huge advantage when compared to the existing options.

My Health Diary intends to replace the paper diary that is the current intervention used with migraine patients.

5.2 Description and technical characteristics of technology

This domain will provide information regarding the technology being targeted as it intends to enhance its purpose, features, and advantages and disadvantages. In addition, it will explore in more detail the alternatives to the health technology. Moreover, some other aspects should also be considered like the people who will use the technology, the way they will use it, and also the context of its development and the requirements for the adoption in terms of supplies or premises, as well as the necessary training to use this health technology.

My Health Diary is a system composed of two frontend applications and one backend application, that communicates with a database. One of the frontend applications is a Mobile application for the patients that have as main functionality a calendar where patients should register their headaches. The other frontend application is a Web application for health professionals where they can check the registries of the patients in the calendar. The backend application, not only communicates with the database, where every information is stored but also allows the two frontend applications to share data with each other.

In the mobile application, the patients have the possibility to create registries regarding their headaches on a calendar, register their future medical appointments in the calendar, consult the registries entered in the calendar, both headaches and appointments, access to a user manual with tutorials on how to use the application, and edit their own profile and change password.

The health professionals have the following functionalities at their disposal on the web application: to create an account for the patients, to associate and disassociate patients to their account, consult the registries that the patients add to their calendar, access to a summary regarding the patients' condition, and also to edit patients personal information.

Regarding My Health Diary, the system was developed last year by a group of students from FEUP and has been currently made available for the health professionals and patients selected for this study. The intention is to make it available to all patients that suffer from migraines in the ULSM, in case the system is proven effective.

This technology was completely idealized by the neurologists, to replace the method that is currently being used, a paper diary where patients register their headaches. The paper diary has been proven to be limited as the patients forget to fill it in or forget to bring it into the medical appointments. Another possible situation is the filling of multiple entries right before the medical appointments, which provides biased data to the professionals. This way health professionals cannot keep track of patients' headaches, and therefore, it is more difficult to manage and monitor the condition.

Other digital alternatives to My Health Diary already exist in the market. However, these alternatives were not suitable for the professionals' needs as they are mostly developed in English and do not provide the necessary information to health professionals, or, sometimes provide too much information, that is unnecessary for the management of headaches, and that might make them difficult to fill in.

As the health professionals idealized the My Health Diary system, they were able to define what information to gather from the patients, that is, the information that could be useful to monitor patients' headaches and understand the specific condition of the patients. This is an advantage over other technologies that already exist, because, although those technologies can provide some information, other data might not be collected. This technology was designed to fit the needs of professionals bridging existing flaws on the method that is being used - the paper diary.

For the pilot study, the system was deployed on the FEUP servers as this dissertation appears in its context. However, once the pilot study is finished, if the ULSM decides to adopt this technology and implement it as a tool for helping to monitor the migraines of patients, the system must be deployed on Hospital Pedro Hispano servers.

For the adoption of this platform, there is no need for specific premises or supplies.

However, to adopt the system, there is the need for a server with any operating system, that must have installed the following technologies: GIT, Apache, Java, Maven, and NPM, in order to run the backend and web applications. It is also needed the server where the database will run.

My Health Diary intends to be used by people that suffer from migraines in a context where there is a need to monitor and manage the frequency and intensity of the headaches, as well as the medication being taken and the work disability due to the headaches.

This technology will be made available for the patients by the neurologists. However, it will not be available for any patient that wants to use the system. The health professionals will only provide the system to patients that suffer from migraines, and that they consider that the use of the technology would be an asset for the management and treatment.

For a patient that suffers from migraines to have access to the application, a health professional will need to create an account for that patient. From this account creation, an email will be sent to the patient which contains the link for the download of the APK file, for the installation of the application, and the credentials to activate the account and further sign in.

In order to ease the process of learning for the patients, inside the application there is a section that contains nine tutorial videos on how to use the application, explaining its main features. Each video contains the utilization guide explaining all the steps to perform a functionality. In order to

ease the process of learning for the patients, inside the application there is a section that contains tutorial videos on how to use the application, explaining its main features. Each video contains the utilization guide explaining all the steps to perform a functionality.

Moreover, as the health professionals are the ones that may help the patients regarding the use of the application, a written manual of utilization was delivered to the professionals and can be consulted in Appendix E. In this manual, they can find a description and the steps to execute any action in the mobile application. Additionally, the manual also contains a description of the steps to every action of the web application, including explanations of error messages. The manual is all illustrated using prints of the screens of the applications for all the functionalities and error messages.

5.3 Safety

The domain of safety intends to identify risks and possible harms that the technology may cause to patients, health professionals, or the environment in general, analyzing the risk of harm happening, and the possibility of direct and indirect harms from technology use.

Thus, in this context, Safety will evaluate the manners in which My Health Diary may harm the patients, health professionals, or the environment.

My Health Diary is a technology that just intends to keep registries regarding the migraines of patients. The patients will only fill in the diary regarding their headaches and register information about their medication and their work incapacity or emergency service recurrence.

The platform does not intend to suggest medication for the patient, but register if the patient took medication. This matter was discussed with Health Professionals that confirmed that My Health Diary does not present any kind of risk to the patients, or people using it.

Therefore, considering all the information provided in regards to My Health Diary, one can say that this technology does not present direct harm to the patients, the health professionals, nor the environment in general.

5.4 Clinical effectiveness

This domain is one of the most important in the evaluation, as the information gathered here will be essential to understand whether the health technology brings benefits to users or not. It will try to understand the impact that the technology is having, which is usually evaluated through a Randomized Controlled Trial. Therefore it will present the expected benefits, comparing them with the actual benefits, as well as assessing the impacts on the health and quality of life of the patients.

My Health Diary platform, by itself, does not have an impact on the symptoms the patients are experiencing before and during the utilization of the platform. However, it is intended that

the symptoms show progress in the long term as health professionals make adjustments to the patients' medication, and find patterns on the registries, according to the information they acquire regarding headache monitoring.

With the adjustments of medication fitted to the patients' needs, and also with better knowledge about the own condition, it is expected the condition to become more manageable, with decreasing on the symptoms as well as improvement on the daily living activities and work ability.

The technology My Health Diary does not have an impact on mortality nor hospitalization.

In order to understand the clinical effectiveness that the platform can bring from its use by the ULSM patients and health professionals, a Crossover Randomized Controlled Trial is being implemented in this local unit. The trial involves sixty patients suffering from migraines.

This study intends to understand the effectiveness of the My Health Diary platform in comparison with the current method being used, the Paper calendar. Thus, half of the patients (30 people) will use My Health Diary for 13 weeks, and the other half will use the paper calendar. After this period of 13 weeks, the patients will swap the method of the registry. Thereby, all patients in the study will experience both methodologies.

The criteria to select the patients for the study was the following:

- Patient that is being followed on the neurology department for episodic or chronic migraine, with diagnostic of more than 6 months.
- Patient with at least 4 days of migraines per month.
- Patient with prophylactic medication.
- Patient with ages between 18 and 50, at the time of recruitment.
- User of Android smartphone.
- With informed consent.

Moreover, the study has as initial purpose to evaluate whether the adherence of migraine patients to the use of the electronic diary My Health Diary as a method of recording headache characteristics and defined treatment is superior to the adherence to the paper diary, by analyzing:

- Percentage of days with headaches in which the patient makes a registry;
- Percentage of patients that drop out of making headaches registries within the 13 weeks;

Additionally, the study also intends to analyze and evaluate the following aspects:

1. Comparison of quality of life using the questionnaire "HIT-6" evaluated at the baseline, after using each registry method.
2. Comparison of quality of life using the questionnaire "MSQ v2.1" evaluated at the baseline, after using each registry method.

3. Comparison of quality of life using the questionnaire "WHOQOL-BREF" evaluated at the baseline, after using each registry method.

4. Comparison of the number of days with migraines using data from the questionnaire filled at the baseline and the headache diaries, after using each registry method.

5. Comparison of the number of days of acute headache medication use using data from the questionnaire filled at the baseline and the headache diaries, after using each registry method.

6. Comparison of the number of days of prophylactic medication noncompliance using data from the questionnaire filled at the baseline and the headache diaries, after using each registry method.

7. Comparison of the number of days of incapacity using data from the questionnaire filled at the baseline and the headache diaries, after using each registry method.

8. Comparison of the number of visits to the emergency service using data from the questionnaire filled at the baseline and the headache diaries, after using each registry method.

9. Personal preference of the patients using the questionnaire "Questionário 2";

As the clinical trial is yet in an initial phase, there is not enough and concrete information that allows drawing robust conclusions. However, through the Focus Group, the answers to the questionnaires A.7 and A.8, and also from the continuous conversation with the professionals, some conclusions in terms of the clinical effectiveness can start to appear.

In terms of the evaluation indicators of the platform referred above, the data gathered is not conclusive because the clinical trial is reaching at the moment of writing the 13-week mark when the questionnaires would be delivered and answers would be obtained, and not all participants have met with the health professionals yet.

However, through the information already obtained, regarding the adherence of the tool, both tools are having a good performance, but some participants using the paper diary have stated that they keep losing the paper and it is quite complex to fill in.

Moreover, in the Usability Questionnaire for the patients - A.7, there were some questions regarding the opinion of the patients about the effectiveness of the application. The answers from patients to these questions are less positive than it would be hoped for, as can be seen in chart D.1.2. The patients have considered that the app allows the registry of relevant data regarding their headaches. However, they didn't experience much improvement in their headaches and quality of life.

Even though these results are not the desired, they are expected, as the study is still in an early stage, and the platform alone, does not bring that much change to the patients' lives, and in addition, even though it is expected the professionals to make adjustments on patients treatment, that is currently not being done on the clinical trial.

On the other hand, in the "Usability Questionnaire" for the professionals, on the section about the adequacy of the platform, the health professionals considered that the platform was useful and improved their access to information about the patients, the data provided was more accurate and reliable than the paper diary, and they also reinforce the usefulness of that data to monitor the patients' headaches.

Additionally, the professionals also considered a great benefit the remote monitoring of headaches, even though the application is not yet being used for therapeutic adjustment purposes.

Furthermore, some patients also provided feedback about the usefulness of the platform for them to better understand their condition, accept it, and comply with the treatment, as well as perceive some triggers.

5.5 Cost and economic effectiveness

The fifth domain intends to assess the impact of the technology but in terms of costs and economic efficiency. It should consider the resources required to deliver the technology, as well as the estimations of costs, and describing the differences of costs between the technology and its alternatives. Additionally, it should establish how the cost of the application might create differences in access to the technology.

In terms of costs, the technology My Health Diary will not have downsides as its acquisition and utilization does not have associated costs for patients nor the organization where it is going to be implemented.

In addition to the fact that the system does not incur costs, it is also expected that My Health Diary will reduce some internal costs in the organization through the reorganization of the consultations which will allow the expansion of the neurology teleconsultation and the reduction of the number of unnecessary appointments in this department. Moreover, with the improvement of the condition of the patients, it would be expected that the number of recurrences to the emergency department due to headaches and migraines is also reduced. Nevertheless, it would be necessary to measure these benefits through a more cost-oriented study, that would take more time to get results.

However, the organization will need to provide some resources in order to deliver the system. The necessary resources include a server where both the web application for health professionals and the business logic application could be deployed. It is also necessary for a server to host the database. There is the possibility for the hospital to host the applications in the already existing servers.

For the patients' application, as the application was not deployed in the Google Playstore, but instead the APK was made available through the health professionals application, its deployment does not have costs associated, also.

The utilization of the mobile application will be held on the users' personal smartphone that they already possess, thus, there are also no costs associated with the utilization of the mobile app.

However, a patient may be prevented from using the technology, not because it has an associated cost, but due to the resources that are necessary to run it, as it needs an Android smartphone to be used. This may cause differences in the access to the technology across patients.

When comparing My Health Diary to the alternative technologies presented in the section Description and Technical Characteristics, in terms of costs, these technologies also did not have costs associated with their use.

5.6 Ethical analysis

The Ethical Analysis will address the social and moral values that concern the technology, focusing on the consequences that the implementation of the technology will bring. It should focus the analysis understanding aspects like the impact the disease has in the life of patients, benefits, and harms that the technology has on the patients and on society, but also clarifying if the technology will impact human dignity, and the cultural, moral, and religious integrity of the patients, as well as to what extent it invades the privacy sphere. Moreover, this assessment should take into account the impact on healthcare delivery, and the factors that may deprive someone of using the technology.

As previously stated, My Health Diary is a health technology that intends to help patients that suffer from migraines to keep track of their condition, and also help the health professionals to monitor the patients' migraines, in order to help in the diagnosis or treatment adjustments.

Migraines are a pretty common disease that affects 1 in 7 adults, affecting people mostly between 20 and 40 years old. It is considered one of the most disabling diseases, being ranked as the third cause of disability in the world for men and women under the age of 50, according to the Global Burden of Disease Study 2015 [59]. The disorder also has great impacts on society, economy, and family as it affects people in the more productive ages of life [26].

This health condition has as the main symptom the headaches that are usually pulsatile, but one may also experience other symptoms like nausea, photophobia, and/or phonophobia or sensitivity to some smells. The frequency of the migraines may vary depending on the patients, from two crises per week to having only a few crises over the entire life [26].

A diary where patients can record their headaches is an important tool to understand the characteristics of the condition, and it helps the health professionals to supervise the headaches that the patient is having, in terms of intensity, and type of headache, but also to track the way the patient is dealing with them regarding medication, work incapacity, and emergency service recurrence. This monitoring intends to aid the professionals in the decision-making process so that they can provide adequate recommendations in terms of treatments and therefore improve the quality of life of the patients. It is expected that the work incapacity to be reduced as well as the emergency service recurrence due to the improvement on the condition of the patient. Therefore, in the long term, it is likely for the technology to bring these benefits to society and to the ULSM.

The platform is only accessible to patients to whom My Health Diary was recommended directly by the health professionals, as they need to create the patient's account. The patient must

belong to the ULSM, and also should suffer from migraines, for the professionals to recommend this technology. Moreover, the patient should know how to read and write in Portuguese, and also being able to fulfill the records independently. The last requirement to use the application is to have an Android smartphone as the app is not available for different operating systems.

Some of these limitations can be overcome with the implementation of some changes in the system, recommended by the professionals.

With the use of the My Health Diary, the health professionals will have access to more accurate information regarding the episodes of headaches that affect the patients over time. This might affect positively the way that healthcare is delivered because as the doctors possess information that is more reliable they can better adjust the treatments and diagnose the condition. Moreover, as the doctors have remote access to the patients' information, they are able to do a continuous follow up on their patients, to better understand the ones that are currently with adequate treatments, and possibly call the ones that need adjustments on their treatment for medical appointments sooner than expected.

My Health Diary does not impacts human dignity nor the cultural, moral, or religious integrity of the patient. Additionally, the technology will not affect the autonomy or capabilities of the patient, more than the disorder already does. In terms of privacy, there are some concerns regarding the technology.

At an initial phase, during the development, the application was intended to keep personal information about the patients that was not necessary for the application to work, like the health service id, the hospital id, the date of birth, to name a few. All the data that was not needed to be kept in the application was removed to diminish the private information being held.

However, the technology will still have records about the health conditions of patients, as well as some of their personal data, like e-mail. This information is crucial for the app to work, and therefore cannot be removed. In the system, each patient has an ID associated with their account, that is the only information that can allow the health professionals to trace the information to a specific person. The ID is composed of seven characters, being the first a letter that identifies the health center to which the patient belongs, followed by six digits of identification. This ID is not in any way related to the patients' hospital id, or health service id.

The only information that could allow tracing the data to a specific person is the e-mail address of the user that is necessary so that the patients could receive their credentials to sign in to the application. This e-mail is stored in the database of the system but in an encrypted form.

Regarding the credentials of the patients that are received by e-mail, in order for the patient to access their account for the first time, they should activate the account in the first place, using the credentials that were received by e-mail and changing the password to a different combination.

In addition, the professionals have personal information introduced into the application, like their name, password, and ULSM email address. This information is also encrypted in the database.

The right to privacy is a human right, and this technology tries to assure that this right is preserved at all costs, following the GDPR law.

More information regarding the privacy of the user information will be discussed and presented in a clearer way on the domain regarding Legal aspects.

5.7 Organizational aspects

This domain analyzes the implications that the implementation/adoption of the technology will bring to the organization and healthcare. It will take into consideration the modification to the work process of health professionals, the involvement that the technology requires, the training process, and the acceptance of the technology from patients and professionals.

My Health Diary, a technology that will help people with migraines to have better information about their condition, is also intended for health professionals to be able to help their patients in the best way possible, providing them with diagnosis, treatment, and recommendations that are suited for each patient.

The technology was designed for the Unidade Local de Saúde de Matosinhos, taking into consideration their needs and requirements, so that the technology being implemented could fit exactly its purpose.

The platform can only be used by patients to whom My Health Diary was recommended directly by the health professionals. The patient should belong to the ULSM, and also should suffer from migraines, for the professionals to recommend this technology. Additionally, it is important that the patient can read and write in Portuguese, and also being able to fulfill the records independently. The last requirement to use the application is to have an Android smartphone as the app is not available for different operating systems.

Moreover, for a patient to use the application, it is necessary that the health professional creates an account for the patient. This process of account creation will send an e-mail to the patient with the credentials to log-in, and also with a link to download the application to the smartphone.

As previously stated, this platform does not incur costs for the organization adopting it, nor to the patients that will use it.

In order to ease the use of the platform for health professionals, a user manual was written and made available with the platform. This manual contains an explanation on how to proceed with each available functionality of the web application, as well as the error messages that can occur, and how to deal with them. The manual also includes explanations for the patients' mobile application, so that the professionals can help them in case of need. The manual can be consulted in Appendix E. Moreover, the patients' application contains a section dedicated to the utilization guide, that contains explanatory videos on how to use the My Health Diary application.

This technology appears to have many benefits, however, in order for them to be achieved both professionals and patients need to commit to using the technology periodically and in the correct way. The patients should use the mobile application whenever they have a headache, registering its characteristics. On the other hand, health professionals must use the web app frequently, checking on the patients by consulting the information they are registering.

As the ULSM has the intention to adopt the My Health Diary technology, they wanted to assure that the system would really bring the advantages that were expected, and produce reliable information with quality, a clinical trial is being implemented using RCT methodology with crossover, where the My Health Diary is being put against the paper diary.

In terms of changes in the work process, the system does not yet manifest great changes other than the remote tracking of patients' registrations. However, it is expected that the system will help to reorganize the medical appointments allowing the following:

- Increase of neurology teleconsultations.
- Reduce unnecessary appointments for patients with controlled and stable disease.
- Carry out early pharmacological adjustments when symptoms worsen, in order to avoid a chronic headache.
- Improve the articulation between the Neurology consultation and Primary Health Care.
- Avoid the appearance of chronic headache factors such as medication abuse headache.
- Increase the rate of therapeutic effectiveness.
- Increase the rate of therapeutic compliance.

In general, the feedback that is being gathered regarding the platform is quite positive, both from patients and health professionals. However, the professionals have already come across situations that could be improved in order to ensure easier use of the web application.

5.8 Patient and social aspects

The domain of Patient and Social Aspects presents the points of view of the patients in regards to the technology and the condition. This perspective from patients is quite relevant as they will be the people that are most affected by the implementation of the technology. The assessment of social aspects must also analyze how the technology will affect the patient's life, how it will influence their daily routine, and how they will feel with the implementation of the technology.

Migraines are a disorder that can have a huge impact on society and on the economy, as it affects people in the most productive phase of their lives.

This condition also has a huge impact on the lives of the ones that suffer from it. Migraines can take control of the life of patients as they are so unexpected and disabling [14].

Living with migraines can be exhausting as the episodes can occur at any time, and can be painful and incapacitating. Additionally, and because they are unexpected, people might lose control of their own lives, they might have a hard time trying to plan the next days or weeks. Therefore patients can get really stressed, constantly waiting for the next episode of migraines [14].

The disorder takes over the life of the patients, not only on the personal side but also the work ability, as well as social and familiar aspects. Thus, sometimes patients start feeling guilty for constantly missing work or deadlines, for canceling social events and gatherings with friends, and also as they have less quality time with their families. It can take away patients' quality of life [14].

During an episode, the patient is suffering from a headache, which is usually pulsatile, as feeling the heartbeat inside the head. But they also can experience different symptoms like nausea, sensitivity to light, noise, and/or some smells [26].

The previous information regarding how migraines can affect the life of the patients living with it, as well as the burden they carry, was gathered from MiGRA Testimonies [14]. MiGRA is the Portuguese Association of Migraine and Headache Patients.

In terms of use of the technology, it was clarified in the Focus Group that the feedback from the patients has been quite positive, as the application has allowed a better understanding of the disease and its severity, as well as understanding periods of worsening and, sometimes, why they happen.

Also in the Focus Group were discussed the factors that could increase patients' adherence to registrations in the application, being the main factor to facilitate access to the platform on a day-to-day basis, without the patient having to put a password in every access they make.

As previously stated, My Health Diary is only accessible through recommendations from health professionals, who need to create the patient account. Moreover, the patient has to belong to the local unit and be diagnosed with migraines so that the health professional would recommend the technology. Additionally, patients who don't know how to read and write in Portuguese or that cannot fill the registry independently will not be able to use the system. Also, the patient needs to have an Android Smartphone to install the application.

5.9 Legal aspects

This domain intends to identify rules and regulations that should be considered when analyzing the technology. The assessment should concern legal information from the country and at an international level. The purpose is to understand if the health technology is compliant with the regulations that concern it.

In terms of legal aspects, My Health Diary appears to have two main concerns which are as follow:

- The nature of the system in terms of being a medical device.
- Data protection.

One should note the existence of inaccuracies in what was described in this section as there is no legal competence, and therefore the text was written through legal interpretations to which there is not enough knowledge.

In regards to the first concern of the platform being a medical device, it arises the need to verify and understand if the My Health Diary system is compliant with the Medical Devices regulation in force in Portugal. The regulations that are implemented in Portugal were stipulated according to the European Union regulations on Medical Devices.

The regulation that is currently in force is "REGULATION (EU) 2017/ 745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL - of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC" [52].

This Regulation presents the definition of a *Medical Device* as follows:

> " *'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:*
>
> *— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
>
> *— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
>
> *— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
>
> *— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,*
>
> *and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. (...)* "

Attending to this definition and comparing it with the My Health Diary system and its functionalities, one may think that My Health Diary is a medical device, as the system fits in the definition on "diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease".

However, further investigation was done, and the "Guidelines On The Qualification And Classification Of Stand Alone Software Used In Healthcare Within The Regulatory Framework Of Medical Devices - MEDDEV 2.1/6" [51] clarifies why My Health Diary is not considered a medical device. This guideline provides a decision diagram to assist in the qualification of software as a medical device.

My Health Diary complies with the first decision step: "the product is a software according to the definition of this document, then it may be a medical device; if the product is not a software according to the definition of this document, then it is not covered by the medical device directives." [51], and therefore should proceed to the second decision step.

The second decision step analyzes if the software "is stand alone software" in which case it should continue to decision step three [51].

It is on the third decision step that My Health Diary is no longer compliant with the medical device qualification, as in this step the guideline declares that "if the software does not perform an action on data, or performs an action limited to storage, archival, communication, 'simple search' or lossless compression (...) it is not a medical device.", being communication "The flow of information from one point, known as the source, to another, the receiver;". Even though My Health Diary is stand-alone software that helps to monitor headaches, the data that is inserted by the patients or by the health professionals will only be stored for monitoring purposes, and used/sent just as it is, in an embellished format, for the user requiring it.

As My Health Diary is not a medical device it does not need to comply with REGULATION (EU) 2017/ 745.

The second legal concern, which is data protection, refers to the need for the "My Health Diary" platform to be consistent with the policies on the users' data protection according to GDPR.

The rapid technological developments and globalization have created new challenges in terms of personal data protection. Thus, the GDPR or General Data Protection Regulation is a European Union law that was implemented on May 25, 2018. This law focuses on the protection, collection, and management of personal data, i.e. data about individuals and it enforces "obligations onto organizations anywhere, so long as they target or collect data related to people in the EU" [17, 15]. The violation of the GDPR can result in the application of fines with values that can go up to €20 million.

In order to analyze the GDPR compliance, the My Health Diary platform and its privacy policies were verified in comparison with a checklist provided by GDPR.eu, which is a resource for organizations and individuals researching on GDPR. The checklist used is called "GDPR checklist for data controllers" and it is available through `https://gdpr.eu/checklist/`.

Checklist items	**My Health Diary**
Lawful basis and transparency	

Conduct an information audit to determine what information you process and who has access to it.	Data collected and processed can include email, medication, disorders, and headache registries or medical appointments that are filled out daily. Health professionals, doctors, or nurses have access to the data, if and only when they need this access to provide the agreed service. No personal data of patients and users will be disclosed to third parties without their consent, except when required by law. The data collected by the My Health Diary application is kept for the time considered necessary during the hospital process between Hospital Pedro Hispano and the user/patient. In other cases, the data will be deleted after 5 years. The data collected by the My Health Diary application is saved on the Hospital Pedro Hispano intranet for as long as necessary during the hospital process between the hospital and the user/patient.
Have a legal justification for your data processing activities.	The My Health Diary app collects data from users/patients under legitimate interest. Data can include email and log information relating to headaches or medical appointments that are filled out daily. The data collected is intended to monitor the information in the diaries of users/patients. The use of the application is subject to prior consent by the data subject.
Provide clear information about your data processing and legal justification in your privacy policy.	The application that is intended for the patients contains a section reserved for the GDPR where it presents the privacy policy of the system.
Data Security	
Take data protection into account at all times, from the moment you begin developing a product to each time you process data.	When the system was implemented in the hospital, for the pilot study all aspects regarding the privacy of the data were already being taken into account.
Encrypt, pseudonymize, or anonymize personal data wherever possible.	In the My Health Diary system, all the personal data that is being gathered and that can be used to identify the person/user is encrypted to be stored in the database.

Create an internal security policy for your team members, and build awareness about data protection.	The system and the people who access or change it must have the hospital's policies in mind and follow them accordingly.
Know when to conduct a data protection impact assessment, and have a process in place to carry it out.	ULSM Responsibility to understand when it is necessary to perform impact assessment, and define the processes involved.
Have a process in place to notify the authorities and your data subjects in the event of a data breach.	ULSM Responsibility to notify authorities and users in case of data breaches.
Accountability and governance	
Designate someone responsible for ensuring GDPR compliance across your organization.	Comissão Local de Proteção e Segurança da Informação from ULSM will be the entity responsible on ensuring GDPR compliance
Sign a data processing agreement between your organization and any third parties that process personal data on your behalf.	N/A
If your organization is outside the EU, appoint a representative within one of the EU member states.	N/A
Appoint a Data Protection Officer (if necessary).	The Data Protection Officer that will be appointed in case the platform is adopted by the ULSM will be the DPO of the ULSM.
Privacy rights	
It's easy for your customers to request and receive all the information you have about them.	The functionality for the patient to be able to export their data from the app was implemented during the development phase, however, when tested in the context of this Dissertation bugs were found, that did not allow the data exportation to be completed. Additionally, the user is informed through the privacy policy present in the application, regarding the purposes, the time period that the data will be kept, and more.

It's easy for your customers to correct or update inaccurate or incomplete information.	At any time, a user/patient can access and change their personal data through the My Health Diary application. All information can be edited, including account information, headache registries, and appointments.
It's easy for your customers to request to have their personal data deleted.	At any time, a user/patient can access and delete their personal data. If they wish to be removed from the database, they can exercise this right from the application in the profile menu.
It's easy for your customers to ask you to stop processing their data.	At any time, a user/patient can access, change or delete their personal data. If they wish to be removed from the database, they can exercise this right from the application in the profile menu.
It's easy for your customers to receive a copy of their personal data in a format that can be easily transferred to another company.	The functionality for the patient to be able to export their data from the app was implemented during the development phase, however, when tested in the context of this Dissertation bugs were found, that did not allow the data exportation to be completed.
It's easy for your customers to object to you processing their data.	In order for a user/patient to object to the system processing their data, they should do so next to the health professionals. If the patient is disassociated with the health professional's accounts their data will still be stored, but will not be processed. The user can also delete their account, which will remove all associated data.
If you make decisions about people based on automated processes, you have a procedure to protect their rights.	N/A

Table 5.1: My Health Diary compliance with GDPR checklist

Additionally, in order to implement the case study, there was the need for the protocol of the study to be approved by the Comissão Local de Proteção e Segurança da Informação. This commission provided a favorable opinion on the study implementation.

5.10 Functional Requirements

This domain is intended to evaluate the health technology as a software product. The purpose of assessing the Functional Requirements is to assure that the requirements of the system correspond to the functionalities that it presents, understanding if the technology that is being added with

the intention to fulfill a need in healthcare, considering the needs, expectations, and constraints presented.

As mentioned in chapter 4.2, the requirements were presented to the developers/students of GPIE by the health professionals.

The requirements presented are as follows:

The system needed to comprise two applications, a mobile application for patients, and an application that could be accessed on a computer for the health professionals. Also, the two applications would need to exchange data with each other through the network.

Therefore, there are two types of users, the patients and the health professionals, and they both should have a profile. The patient's profile could only be created by the doctor, and it would be associated with an identification code. It should also keep track of some information about the patient like:

- Personal information - Name initials, Birthdate, Gender;
- Information about migraines - migraines with or without aura, migraines exclusively unilateral;
- Information about the treatments - If the patient is doing a symptomatic treatment, and which one; If the patient is doing a prophylactic treatment, which one, and when it started;
- Information about other comorbidities - depression, anxiety, insomnia, or other diseases.

The main functionality of the mobile application would be to record daily on a calendar headaches of the patients recording the following information about each headache:

- Type of headache (tension or migraine);
- Intensity on a scale from 1 to 10;
- Took a painkiller;
- Took a triptan;
- In case of the patient is woman, menstruation;
- Went to the emergency service;
- Work incapacity;
- Registry of future medical appointments;

Moreover, the patients must receive alerts in three different situations:

- In case the patient forgot to filled the diary for 3 days straight;

- In case the patient have a medical appointment in a week;
- In case the patient is taking too much medication:
  - Took painkillers more than 15 times on the past 30 days;
  - Took triptans more than 10 times on the past 30 days;

The health professionals also explicitly required that an instructions manual on how to use the mobile application and how to fill in the diary was necessary for the patients, to ease the learning process.

In regards to the health professionals' application, there should be a list of patients that are associated with the professional so that he/she can access the information of those patients. Additionally, the health professional should be able to add and remove patients from the list.

For each patient associated the health professional would be able to see a summary of the registries that contains the following information:

- Number of days with headaches per month;
- Number of days with migraines per month;
- Percentage of reduction on the number of days with headaches for the past three months;
- Number of days the patient took painkillers per month;
- Number of days the patient took triptan per month;
- Number of days the patient went to the emergency service per month;
- Number of days with work incapacity due to headaches per month;
- Maximum intensity of headache (from 1 to 10);

The health professionals also receive alerts regarding patients that belong to their list, in three situations:

- In case the number of days with headaches for a patient increases more than 20% on a month;
- In case the number of days that the patient needed to go to the emergency service increases in comparison with the previous month;
- In case the number of days with work incapacity due to headaches increases in comparison with the previous month;

The next two tables present these requirements as User Stories. The first table presents the user stories for Health Professionals Application and the second for the Patients Application.

ID	**User Story**

USHP1	**As** a Professional **I want to** be able to create an account **So that** I can keep track of my patients and their migraines evolution
USHP2	**As** a Professional **I want to** be able to login using e-mail address and password **So that** No one else can enter in my account but me
USHP3	**As** a Professional **I want to** to be able to edit my profile information **So that** my information is always updated
USHP4	**As** a Professional **I want to** be able to create an account for patients **So that** they can register their migraines allowing the professionals to have better monitoring of the condition
USHP5	**As** a Professional **I want to** to be able to edit the profile of my patients **So that** I can get updated information about the patient
USHP6	**As** a Professional **I want to** add patients to my list **So that** I can access their information easily and receive notifications about them
USHP7	**As** a Professional **I want to** remove patients from my list **So that** I won't see the records and won't receive notifications about patients that are no longer in my care
USHP8	**As** a Professional **I want to** receive a notification when the number of headaches of my patients rises 20% compared to the previous month **So that** I know if their condition is getting worst
USHP9	**As** a Professional **I want to** receive a notification if my patients goes to the emergency service more times than in the previous month **So that** I know if their condition is getting worst
USHP10	**As** a Professional **I want to** receive a notification if my patients miss work due to incapacity more times than in the previous month **So that** I know if their condition is getting worst
USHP11	**As** a Professional **I want to** consult the patient's last 3 months of records in the form of a graph or table **So that** my analysis is easier

USHP12	**As** a Professional **I want to** export the data registered by the patient on the last month into text format **So that** I can use the information with more efficiency
USHP13	**As** a Professional **I want to** to have access to my patients' calendar **So that** I can keep track of the patient diaries (migraines and medication)

Table 5.2: User Stories - Health Professionals Application

ID	**User Story**
USP1	**As** a Patient **I want to** to be able to activate my account after professional creates it **So that** I can configure my password and accept the privacy policy and terms and conditions
USP2	**As** a Patient **I want to** to be able to login with ID and password **So that** no one else can access to my account
USP3	**As** a Patient **I want to** to be able to edit my profile information **So that** my information is always updated
USP4	**As** a Patient **I want to** create registries of my headaches on a calendar **So that** I can keep track of my condition
USP5	**As** a Patient **I want to** create registries of my medical appointments on a calendar **So that** I know when my appointments will happen
USP6	**As** a Patient **I want to** receive a notification when I miss my calendar registration for 3 straight days **So that** I remember to use my calendar
USP7	**As** a Patient **I want to** receive a notification a week before my appointment **So that** I remember my appointments
USP8	**As** a Patient **I want to** receive a notification when I use painkillers 15 times or triptans 10 times in a month **So that** I don't abuse medication

USP9	**As** a Patient **I want to** have access to a manual **So that** I learn how to use the app

Table 5.3: User Stories - Patients Application

As defined in the process description, in order to evaluate and validate the Functional Requirements, all user stories presented will be tested with at least one acceptance test per user story. The Acceptance tests run are presented in Appendix B as well as the results obtained.

Looking at the Acceptance tests and results obtained that are presented in the Appendix B, one can perceive that the results obtained meet the expected results for every test that was performed.

However, some functionalities do not always work correctly. Two situations where this happens were noticed, which correspond to the functionalities of receiving notifications after three days without filling in the diary, and the sending of an e-mail with the credentials after the creation of an account for a patient.

Regarding the functionality of the notifications, the cause is still unknown, as the notifications are being scheduled correctly on the application.

The sending of the e-mail with the credentials fails in case the system has not accessed the email account for a long time.

A Gmail account for the My Health Diary system was created and it is connected to the system using the SMTP, Simple Mail Transfer Protocol, settings provided by Gmail, which allows the system to send e-mails through the Gmail account for all mail related functionalities.

This Gmail account was configured to allow access through "Less secure apps", and thus, this option was turned on, being "a less secure app (LSA) is an app that connects to Google accounts using only username and password verification for access and not OAuth" [13], which is the case with My Health Diary.

However, as Gmail is constantly praising for security, "Google will automatically turn this setting OFF if it's not being used". And, for this reason, when it passes too long without the system accessing this e-mail account, the option is turned off, and someone has to manually access the e-mail account and turn it on again so that the system can access Gmail as it is supposed to.

A solution to this problem could be changing the e-mail provider.

Even so, the system works correctly for most of the functionalities, and, moreover, the most crucial functionalities like a patient being able to register headaches, or a professional having access to those registries, are working as intended.

5.11 Quality Requirements

This domain of Quality Requirements intends to evaluate the My Health Diary platform in terms of the quality of the software.

It will analyze the Usability of the system, the Security measures implemented, and also the Functional Suitability presented by this platform.

5.11.1 Usability

As described in the HTA Process 3.11.1, the intention of assessing the usability of the system is to understand the degree of ease to use the product.

For that purpose, it is relevant to understand the position of the users of the system regarding its usability. Therefore, two questionnaires were developed (one for the health professionals and one for the patients) to inquire them in order to understand what is their opinion on this topic.

The questionnaire for the patients, which can be consulted in Appendix A - A.7, was designed to be printed out so that the patients could fill it in during the meeting with the health professionals, along with the other questionnaires.

On the other hand, the questionnaire for the health professionals was created using Google Forms, in order to facilitate access to the responses and to ease the sharing across the professionals. The questionnaire can be accessed through https://docs.google.com/forms/d/e/1FAIpQLSfAF-Yafl-z-Gfogr4vswCB4o_Z_6V7JqPmS-SozatB_0nLNA/viewform?usp=sf_link. It can also be consulted in Appendix A - A.8.

In terms of usability, the analysis should be divided between the mobile application and the web application.

According to the Usability Questionnaires referred to above, the mobile application is being evaluated in the questionnaire of the patients, and in one section of the questionnaire for the professionals.

As can be seen in D.1.1, that is the chart that represents the patients' answers, their answers regarding the usability of the mobile application vary between "Concordo" and "Concordo Completamente" answers.

In terms of Learnability, the patients "Strongly agree" that is easy to learn how to use the mobile app, and that the time they invested to learn was adequate. Additionally, they "Agree" that most people would be able to learn how to use the application. The health professionals, also provided positive opinions on the topic of learnability as they agree that the patients would be able to easily use the app.

Regarding the Aesthetics of the mobile app, the responses were also very positive in both questionnaires, as all patients "strongly agree" that the colors, font, and size of the font is adequate, also the layout is pleasant and adequate, and the overall aspect is to their liking. Professionals also have a positive opinion on this issue.

On the Operability and User error protection side, all users also provided very positive feedback as they considered the app easy to use, reactive, as it reacts when users perform actions, and easy to correct possible mistakes, they considered too that the time invested to use the application for headache registry was adequate. Moreover, the users also considered the app well organized and easy to access. Additionally, "the application is simple and intuitive, at this time we have not had patients who show difficulties in understanding its use.", according to one of the professionals.

In terms of Appropriateness recognizability, the professionals consider that the app is adequate to its purpose. However, the answers from patients in terms of this aspect are less positive, as can be seen in chart D.1.2. Even though they considered that the app allows the registry of relevant data regarding their headaches, they didn't experience that much improvement in their headaches and quality of life. One can believe that this happens, as the study is still in an early stage, and the application is not yet being used to help in the adjustment of medication.

Regarding the web application, that is currently being used by health professionals, in terms of usability, the application received quite positive feedback through the questionnaire, as can be seen in D.2.1.

The health professionals considered that it was also easy to learn how to use their application and that most of their peers would be able to learn and use it. The aesthetics also receive good opinions, with the professionals "Strongly agreeing" that the colors and fonts, as well as layout and organization of information, were pleasant and adequate.

The web app was also considered easy to use and to correct possible mistakes, reactive, organized, and easy to access. Moreover, the professionals believe the web app is fulfilling its purpose.

One should keep in mind that the conclusions drawn from this analysis are not final as the questionnaires from patients still only had the participation of 2 people, with the total number of participants being 30, therefore only 6.67% of participation. Regarding the questionnaires from health professionals, the two people that answered, correspond to the two active users of the platform, also responsible for the clinical trial.

Furthermore, it would have been a good addition to the study of usability to have had the opportunity to observe the population directly, assess the first interactions with the platform. This was not possible due to the current pandemic situation.

5.11.2 Security

The My Health Diary system was developed taking into account some security measures to ensure that the system is secure and does not violate the privacy of users, keeping their information safe.

This section on security intends to analyze the Security measures that were implemented in the system, and how they were implemented.

Additionally, and considering the security measures implemented, suggestions for improvement will then be presented.

The following security measures will be presented and described throughout this section:

- Authentication;
- Cryptography;
- JSON Web Tokens;

- Use of Data Transfer Objects;
- Logs;

One of the security measures implemented was **authentication**, which was implemented for both types of users - patients and health professionals.

Authentication is used to verify if the user is in fact who they declare themselves to be. In this situation, authentication is being used to validate the credentials of the user comparing them with the ones in the database, and make sure they can enter the system and have access to certain information.

In the My Health Diary system, the credentials for the health professionals are the e-mail and password used during the registration process. The e-mail must have as domain **ulsm.min-saude.pt**, and the password can be any combination of four or more characters, chosen by the health professional.

The credentials for patients correspond to the pair ID - Password, where the ID consists of the identification number of the patient, received by e-mail when the patient is registered on the platform, and the password can be any combination of four or more characters, chosen by the patient.

When patients are registered in the system, they receive an e-mail containing the ID and a provisional password. This set of credentials should be used so that the patient can activate their account and change the password to something that can be better remembered.

Thereby, the credentials that were received by e-mail cannot be used to sign in to the system, prior to the account activation, where the patient should alter the received password. Thus, in case the e-mail is compromised, those credentials that were sent will no longer be viable.

In this system, each kind of user can only be authenticated in the specific application, which means that the patients can only be authenticated in the mobile application, and the professionals on the web app.

Moreover, during the authentication in the system, the user will have access to their JWToken which will grant them access to make requests throughout the entire applications, as will be explained below.

Cryptography was another measure implemented to ensure security in the My Health Diary system, and it handles the encryption of information.

All encryption was implemented in the Business Logic application, that is the application that contains the business logic, allows the transmission of information across the web and mobile applications, and have direct access to the database.

The first type of encryption implemented uses the Interface PasswordEncoder from Spring Security, which is a password hashing mechanism [16]. The PasswordEncoder makes available two methods that are being used in the project: the encode(), which receives the raw password as a parameter and encodes it; and the matches(), which receives as parameter the raw password

and the encoded password obtained from storage and verifies if they match after encoding the raw password [11].

The My Health Diary system uses BCryptPasswordEncoder which is the class that implements the PasswordEncoder. It is an encoder that uses random 16 bytes of salt and bcrypt algorithm. This is used to encrypt the passwords of the users. The logs of the system are also being encrypted using this method.

The second type of encryption that the system is using implements the AES algorithm and is being used to encrypt and decrypt the email, username, and clinical name for the Professionals and the email for the Patients.

This encryption and decryption is being done using an automatic mechanism from SpringBoot, which is the annotation @Convert(converter = AttributeEncryptor.class), applied in the Entity fields that are intended to encrypt in the database. The AES symmetric key that is being used is hard coded in java, in the String secret.

Another security measure implemented in My Health Diary was **JSON Web Tokens** , also known as JWT.

JWT "is an open standard (RFC 7519) that defines a compact and self-contained way for securely transmitting information between parties as a JSON object. This information can be verified and trusted because it is digitally signed" [12]. The tokens can be signed with a public/private key pair with RSA or ECDSA or with a secret using the HMAC algorithm [12].

The way that it works is that when a user signs in to the system, the server creates a JWT for the user containing information about them, signs it with the secret, and returns it to the user. Then, whenever the user makes a request, the JWT must be included so that the server knows what user is making the request and can verify that the JSON Web Token was not modified since the sign-in. If the verification is correct the server can then send the response regarding the request made.

The JSON web Token has three distinct parts that are divided in the token with dots - ".":

- The header that determines the algorithm being used to encode the Token.
- The payload corresponds to the information stored in the token, that is, information about the user, when the token was created, or when it will expire.
- The signature that allows the verification of the integrity of the token during its utilization.

My Health Diary uses JWT signed with HS512, which is an abbreviation of HMAC using SHA-512.

When the user, patient, or health professional, sign-in on the system using their credentials, a JWToken is returned to that user. It must be sent in every request that is made inside the app to ensure authorization of the requests of the users.

In this system, the token's payload contains the user's username (ID for the patients and email for the professionals), expiring date, and the current date.

The token assigned to professionals does not allow access to patient requests and vice versa

For security purposes, the token was established to have a validity of five hours. Thus, if the token is taken by someone who should not have it, they will only be able to use the token to have access to the system, while the token is valid.

Another strategy used to ensure the security of the information from users was the use of **DTOs** or Data Transfer Objects. These are used when it is necessary to send an object to respond to a request, but the application requesting the object does not need to have access to all attributes on that specific object. For example, to obtain the professional profile, the app does not need to have access to the database id of the professional, or when the professionals' application makes a request to get the patients, it will not need to have access to the patients' passwords.

Thereby, the application is ensuring that the communication between apps will not transmit more information than necessary for the app requesting the data.

The system also **Logs** the actions of the users and saves them in the logs' table on the database. A log is a record of an event that occurs in the system.

This table of logs keeps records of all actions done in the system. Each log contains the time of the action, the user that performed it, as well as the action itself.

Keeping records of the actions provides information about the actions or events happening in the system, giving insights about its activity.

Moreover, as the logs provide information regarding actions occurring and who performed those actions, they become an asset for ensuring accountability on the system, as well as non-repudiation.

However, the logs of the system are being encoded before they are stored in the database, but as they are being hashed, using the PasswordEncoder, there is not a way to decode them and perceive the information they keep.

Even though the system is implementing these measures, some aspects to ensure security could be improved or developed.

One of the security concerns that affect this application is the fact that the password used for authentication only requires four characters, and does not need to include different types of characters like numbers or uppercase and lower case letters.

At an initial phase of development, the password was implemented to have nine characters, instead of the current four. But, for ease of access to the application, and to guarantee that the constant need to sign in was not an obstacle for the use of the application, the doctors asked to reduce the minimum number of characters to four.

This situation could be avoided if the system were to implement an automatic refresh on the JWT when it expires, keeping the assurance of security on the accesses and requests to the system.

The way to do this would be to implement a second token, Refresh Token, that could be used to get a new access token when it has expired.

Another suggestion is to keep the logs encoded but instead of using the PasswordEncoder, use the AES encryption, because this way the logs can be decrypted when there is a need to consult them for information, and they are still secured, and not readable at first sight.

Additionally, the secrets that are being used for the encryption methods, and for the JWT could be improved, as they are "easy". Taking a suggestion from the Project Handover, an option would be "the use of a Keystore to a better and more secure result".

5.11.3 Functional suitability

As headaches are one of the areas of greatest pressure in healthcare at ULSM, the main objective of the development of the My Health Diary application was to increase the adherence of migraine patients to filling out the headache diary, in order to increase the accuracy of diagnosis and monitor the evolution of symptoms.

This section intends to analyze the completeness, correctness, and appropriateness of My Health Diary.

The results to evaluate the suitability of the system will come mostly from health professionals, as they were the ones that idealize the system. They have a better understanding of the expected benefits, and therefore can better validate that the requirements were met and those benefits accomplished.

The opinions from health professionals on this matter will be gathered during the Focus Group, but also from the questionnaire A.8.

In terms of functional completeness, all the requirements that were presented by the health professionals were implemented, presenting all the expected functionalities in a system containing an application intended for the health professionals and one for the patients. Moreover, as presented in the domain of Functional Requirements, acceptance tests were created with the purpose to validate the system according to the requirements.

However, during the ongoing clinical trial, both health professionals and patients were faced with certain situations that raised new requirements and change requests to the applications. Some examples are presented as follows:

- The health professionals considered that is difficult to find one specific patient in the list of patients associated with the professional because the only field that can be used to search is the ID number. In this phase, all the IDs are quite similar as they all have many "0" in a row because the IDs are being distributed orderly.

- Patients expressed that they did not appreciate the fact that each time they enter the application they have to log in. This situation can become an obstacle to the daily register of headaches.

- Patients also considered it relevant to include some more information in the registry questionnaire, for example, they feel the need to register when they cannot do their daily activities. This could be defined in terms of disability to perform >50% of their daily living activities due to headaches. Another example is the possibility to not only register the use of painkillers on a given day but also how many and which ones (sometimes more than one).

Regarding the functional correctness of the software, My Health Diary is a technology used to track patients' headaches. A patient makes registries in their application and then the health professional can access the registries and monitor the condition and the patient. Thus, the application is used to keep records of the patients' headaches, making it possible for the health professional to access that information remotely through their application. The information that is being transmitted to the professionals corresponds exactly to what the patient filled in their registry.

Moreover, to assure that patients would not be able to make multiple biased registries right before the medical appointments, the patient can only fill in registries of headaches up to a week before the current day. This is an overcome to one of the paper diary's limitations, which improves the accuracy and reliability of the data about the headaches.

In relation to functional appropriateness, the data was based on the Focus Group and supported by the answers of the questionnaire presented in D.2.2. This data showed that during the clinical trial, the system has proven to be useful to achieve the objectives that motivated its development. In addition, according to the health professionals, My Health Diary is a more attractive and pleasant tool for the patients to record the symptoms they experience in each episode when compared to the paper diary. This is an important factor to assure adherence to the technology, which is one of the main motivations to use this tool.

Another important factor is the reliability and accuracy that the records presented in the platform, which better reflect the reality of the headaches in comparison with the paper calendar. Furthermore, one of the objectives was also the remote access to the information registered by patients in the application. This objective is being also achieved, being the main benefit of the use of the app that was already noted during the clinical trial.

Additionally, My Health Diary is also achieving the objective of overcoming some of the limitations of the paper diary, as the information contained in these diaries cannot be lost by the patient, and the diary is accessed remotely, thus even though the patient doesn't bring their smartphone to the appointment, the health professional would still be able to access the registries. Likewise, these diaries cannot be filled in by the patient just before the appointment, increasing their reliability, as previously stated.

5.12 Overview

From the application of the Health Technology Assessment process described in chapter three, one can easily perceive that all the eleven domains that were used to analyze the My Health Diary technology bring relevant aspects to the table when it comes to assessing this health technology.

One should also keep in mind that the main purpose of performing this assessment was to help clarify and reach conclusions for the three main intentions that were set regarding the adoption/use of this technology by this local unit:

- Is My Health Diary more effective than the paper diary?
- Does the use of My Health Diary bring benefits to patients and health professionals?
- Should My Health Diary be considered the go-to tool adopted to monitor the headaches of patients from this local unit?

The following table 5.4 intends to summarize the analysis of each domain analyzed

Domain	Description of Domain	Analysis of My Health Diary according to the Domain
Health Problem and Current Use of Technology	The domain will focus its analysis on three main aspects: the Health Problem, defining the condition in the scope, the symptoms, the treatments and the diagnose process; the Target Population, by presenting an overview on the people that suffer from the condition and how will they be considered eligible to use the health technology; and, at last, it will explore the health technology targeted in the assessment, by presenting the technology, the reasons that motivated its use, and the possible alternative technologies that could be used.	The first domain provides a motivation for the use of the technology by the Unidade Local de Saúde de Matosinhos, presenting the disease/condition, the target population as well as a brief description of the technology itself. The disease and its symptoms are explored in this domain, as well as the respective diagnosis process and treatment options, being one of the prophylactic treatments the use of a headache diary. Here one can understand the impact that migraines can have on the life of people, and recognize how My Health Diary could be an asset helping to monitor the condition, gathering useful information for the health professionals, and overcoming some limitations of the paper diary.
Description and Technical Characteristics	This domain will provide information regarding the technology being targeted as it intends to enhance its purpose, features, and advantages and disadvantages. In addition, it will explore in more detail the alternatives to the health technology. Moreover, some other aspects should also be considered like the people who will use the technology, the way they will use it, and also the context of its development and the requirements for the adoption in terms of supplies or premises, as well as the necessary training to use this health technology.	The application of the process continues to the next domain, this one looking at the technical characteristics of the technology. Here, My Health Diary is described, presenting the main features of the technology, the context of design and development, and the context of its utilization. Moreover, there is a presentation of the advantages in comparison with alternative tools, also explaining why is My Health Diary a better fit for ULSM. It is a better fit as the professionals idealized the technology to exactly correspond to the needs of the local unit, being able to define the information to be gathered that would be useful to monitor patients' headaches and understand the specific condition of the patients, and also to have remote access to the information filled by the patients.

Safety	The domain of safety intends to identify risks and possible harms that the technology may cause to patients, health professionals, or the environment in general, analyzing the risk of harm happening, and the possibility of direct and indirect harms from technology use.	In terms of safety, My Health Diary does not present any kind of risk for patients, health professionals, or the environment. Therefore, this domain can be assessed positively.
Clinical Effectiveness	This domain is one of the most important in the evaluation, as the information gathered here will be essential to understand whether the health technology brings benefits to users or not. It will try to understand the impact that the technology is having, which is usually evaluated through a Randomized Controlled Trial. Therefore it will present the expected benefits, comparing them with the actual benefits, as well as assessing the impacts on the health and quality of life of the patients.	Regarding Clinical Effectiveness, there is not enough information yet to draw conclusions on this topic, because the clinical trial is still in an early stage. From the data that was already gathered, it is possible to understand already that My Health Diary brings advantages over the paper calendar, as some patients stated that they lose the paper and it is hard to fill in. Also, the remote access brought by the platform is a great benefit, according to the professionals. They also considered that the app is fulfilling its purpose of providing more accurate and reliable data. However, according to patients' answers, patients do not have experienced improvements in their condition and quality of life. This aspect could be expected, as the platform is not yet being used to adjust the patients' treatment and the platform alone is just a monitorization tool.

Cost and Economic Effectiveness	The fifth domain intends to assess the impact of the technology but in terms of costs and economic efficiency. It should consider the resources required to deliver the technology, as well as the estimations of costs, and describing the differences of costs between the technology and its alternatives. Additionally, it should establish how the cost of the application might create differences in the access to the technology.	Also in the domain of Cost and Economic effectiveness, the technology can have a positive assessment as its acquisition and utilization does not present any kind of costs to the organization or to the patients using it. Thus, the cost-benefit analysis presents a positive decision, as the use of the application presents some benefits at no costs, and it might reduce internal costs with the reorganization of appointments and reduction of the number of emergency service recurrences due to headaches.
Ethical Analysis	The Ethical Analysis will address the social and moral values that concern the technology, focusing on the consequences that the implementation of the technology will bring. It should focus the analysis understanding aspects like the impact the disease has in the life of patients, benefits, and harms that the technology has on the patients and on society, but also clarifying if the technology will impact human dignity, and the cultural, moral, and religious integrity of the patients, as well as to what extent it invades the privacy sphere. Moreover, this assessment should take into account the impact on healthcare delivery, and the factors that may deprive someone of using the technology.	Regarding the Ethical Analysis, this domain explored the impacts that the condition has on the patients, like the symptoms and how disabling it can be, which motivates the use of a headache diary - My Health Diary. It then presents the benefits that the use of the diary has on patients, but also on society in general, through the fact that, in the long term, it will improve the quality of life and reduce the incapacity to work. Additionally, there is also a description of how the technology will affect healthcare delivery. Here there is also clarification on how My Health Diary will not impact the cultural, moral, and religious integrity of the patients, it will not affect the autonomy. Still, in the ethical domain, the privacy of the information of users in the application is also discussed. The ethical analysis raises pertinent aspects that bring a positive perception to the assessment.

Organizational Aspects	This domain analyzes the implications that the implementation/adoption of the technology will bring to the organization and healthcare. It will take into consideration the modification to the work process of health professionals, the involvement that the technology requires, the training process, and the acceptance of the technology from patients and professionals.	In terms of organizational aspects, this platform that was idealized by the health professionals from ULSM, can be seen as an asset for this local unit. The organization would benefit from its use, as it is expected My Health Diary to help in the reorganization of medical appointments. Also, this system is being targeted in a clinical trial in order to assure the expected quality from its results. In addition, My Health Diary, which can only be used by patients to whom it was recommended, is having positive feedback from its users, but, for it to reach the goals initially set both health professionals and patients should commit to its use. Furthermore, tutorial videos were shared in the mobile application to demonstrate to patients how to use the application, and a utilization manual was made available for the professionals, to help them use both applications.
Patient and Social Aspects	The domain of Patient and Social Aspects presents the points of view of the patients in regards to the technology and the condition. This perspective from patients is quite relevant as they will be the people that are most affected by the implementation of the technology. The assessment of social aspects must also analyze how the technology will affect the patient's life, how it will influence their daily routine, and how they will feel with the implementation of the technology.	In terms of Social Aspects, the assessment looks at how difficult it is for patients to live with a condition that is as disabling as migraines. Moreover, the application has enabled patients to better understand their disease, better accept it, and notice some situations that could trigger an event of migraines. Still in this domain, patients have shown positive feedback towards the application, however the need to log in every time they enter the system has been a downside for the use of My Health Diary.

Legal Aspects	This domain intends to identify rules and regulations that should be considered when analyzing the technology. The assessment should concern legal information from the country and at an international level. The purpose is to understand if the health technology is compliant with the regulations that concern it.	With regard to the domain of Legal Aspects, the assessment had its focus on two main considerations. The first one concerns the European regulations of medical devices and intends to understand if My Health Diary fits the definition of medical device, and therefore if it needs to follow the regulations in terms of safety. The conclusions on this concern were that My Health Diary is not a medical device because it takes no action on the collected data other than recording and transmitting them across applications. The second consideration analyzed in the Legal Aspects domain has to do with the General Data Protection Regulation, and to analyze this the My Health Diary platform and its privacy policies were compared to a checklist on GDPR provided by GDPR.eu. The technology complied with the majority of the items on the checklist.
Functional Requirements	This domain is intended to evaluate the health technology as a software product. The purpose of assessing the Functional Requirements is to assure that the requirements of the system correspond to the functionalities that it presents, understanding if the technology that is being added with the intention to fulfill a need in healthcare, considering the needs, expectations, and constraints presented.	In terms of Functional Requirements, the analysis of the domain starts with the description of the requirements as they were delivered to the developers, with the presentation of the functionalities. Then the requirements are presented as user stories. In a second step, all the requirements presented were put to test through the acceptance tests that were designed to validate the functionalities, and are presented in Appendix B, as well as the results obtained in each test. All the functionalities passed on the acceptance tests, however, two situations were verified in which the functionality, sometimes, fails the test. Even so, in regards to the Functional Requirements, the system showed a positive performance.

Quality Attributes	This domain is also intended to evaluate the health technology as a software product, with the intention to understand it in terms of the quality of the product to be used. Three quality attributes were selected, according to the intention of the study: Usability - to assess the ease of use of the product, assessed through questionnaires; Security - to assess the degree to which the software can reduce the prospect of suffering an accidental or malicious attack, as well as the theft or loss of data, by analyzing the security measures that were implemented.; and Functional Suitability - to assess the degree to which a software product provides useful functions that meet the needs for which it was developed.	The Quality Attributes also provided good insights regarding the quality of the software product. From the analysis of the **usability**, evaluated through questionnaires answered by patients and professionals, it was possible to understand that the system is quite usable, gathering positive opinions on learnability, aesthetics, Operability, and User error protection. In terms of Appropriateness recognizability, the system received positive feedback from the professionals, but from the patients, the feedback was less positive, which can be explained by the early stage of the study, and by the fact that the platform is not yet being used to adjust medication from patients. In terms of **security**, the system is implementing several security measures like Authentication, JWToken, Cryptography, DTOs, and table of Logs. But, even though the system is implementing these measures, there are still some aspects that could be improved, like the implementation of a refresh token on JWT, and the secrets used in cryptography could also be improved. Regarding **functional suitability**, the information was gathered through the questionnaire and the Focus Group. In terms of completeness, the system has implemented all requirements initially defined, validated in the Functional Requirements domain. However, during the clinical trial, new requirements and change requests were raised. In regards to the correctness, the data inserted in the applications is transmitted exactly as it is, and the mobile application also allowed to decrease the biased registries before a medical appointment. In terms of appropriateness, the system has achieved the objectives that motivated its development like increasing reliability and accuracy of the data, remote access to registries, and overcoming limitations of the paper diary.

Table 5.4: HTA process - summary of the process application to My Health Diary

The overall evaluation for this health technology, taking into consideration all the domains analyzed is quite positive, as the system showed a good performance in each of the domains considered.

Additionally, My Health Diary proved to be more efficient, more practical, and more pleasant to use than the paper diary tool, as it was expected.

The system also brought many benefits for both patients and doctors. Some patients were able to notice some triggering factors for their condition, and better monitor their migraines, information that made them better understand their condition and be able to accept it better. The professionals were able to keep track of their patients and their conditions remotely and were provided with accurate and reliable information about the patients' headaches. This information represents the metrics they would use to monitor the responses to the treatment, for later adjustments.

For this reason, My Health Diary is a good option to be adopted as the go-to tool for monitoring the headaches in ULSM.

However, even though the data that has already been obtained and presented here, can be used to get an idea of the impact that the My Health Diary technology is having, this data does not allow us to draw final conclusions, as the clinical trial is still at an early stage, and the answers to the questionnaires are few.

Chapter 6

Conclusions and Future Work

6.1 Conclusions

This dissertation has as its objective the development of a Health Technology Assessment process that would be suitable to evaluate digital health technologies, and that could be used to assess the adoption of the My Health Diary platform by the Unidade Local de Saúde de Matosinhos.

The first step was the analysis of the current state-of-the-art. From this analysis, it was possible to learn the main concepts involved with the topics, and that, even though there is no specific, standard methodology that fits all assessments, some methodologies are being used frequently to carry out an HTA study, like Systematic Reviews, Randomized Controlled Trials, EUnetHTA Core Model®, Multiple Criteria Decision Analysis. However, when the intention is to assess a digital health technology, some changes should be done in the process as this kind of technology presents some characteristics that should be taken into account during the assessment process.

Therefore, a new process for HTA was designed, using the EUnetHTA Core Model®as the foundation, with the addition of two more domains specific for the assessment of the software aspects of the technology, assessing the Functional Requirements, and three Quality Attributes - Usability, Security, Functional Suitability.

The process described was designed to assess the technology My Health Diary, created to be used in the ULSM, and therefore, for it to be applied to different technologies, there might be a need to adapt the process to the health technology and to the objectives set for the assessment.

In order to validate the process developed, as well as evaluate the impact of the platform My Health Diary, a pilot study was implemented in Unidade Local de Saúde de Matosinhos. This pilot study was put into practice with the support of health professionals who also intended to analyze the impact of the use of the health technology - My Health Diary.

My Health Diary, a technology fully idealized by the health professionals from ULSM, developed in partnership between the ULSM and FEUP, on the GPIE course in 2020. The platform

consists of a mobile application intended for patients, a web application for health professionals, and a Business Logic application with a REST API that allows the data to flow from one application to the other, with access to the database.

To implement the Pilot Study, it was necessary to make some modifications on the platform, and also make it available for the users. Therefore, the system was deployed on the FEUP servers.

The pilot study was then implemented, a randomized controlled trial, developed at the ULSM, and with the participation of 60 patients from the neurology service who had been diagnosed with migraines. The study, which is still ongoing, was designed in such a way that the use of My Health Diary could be compared with the use of the tool currently in place at this local unit, the paper diary. In the study, each participant will experience each of the tools for a period of 3 months after which they will have to switch to the other tool, with the study having a total duration of 6 months. Recruitment of participants has been done over time, and at this moment, 20 people are already included in the clinical trial.

The HTA process was applied to the platform My Health Diary in order to validate the process, and also to help clarify and reach conclusions for the three main intentions that were set regarding the adoption/use of this technology by this local unit:

- Is My Health Diary more effective than the paper diary?
- Does the use of My Health Diary bring benefits to patients and health professionals?
- Should My Health Diary be considered the go-to tool adopted to monitor the headaches of patients from this local unit?

However, the data already obtained and presented do not allow us to draw final conclusions, as the clinical trial is still at an early stage, and responses to the questionnaires are few. Moreover, the system is not yet being used to provide information to better adjust the medication of the patients.

Taking this into consideration, as well as all the domains analyzed, the overall assessment of this health technology is quite positive, as the system showed a good performance in each of the domains considered.

Additionally, My Health Diary has shown to be more efficient, more practical, and more pleasant to use than the paper diary tool, as was expected.

The system has also brought many benefits to patients and physicians. Some patients were able to perceive some triggering factors of their condition and better monitor their migraines, information that helped them to better understand their condition and to accept it better. Professionals were able to monitor their patients and their condition remotely and received accurate and reliable information about patients' headaches.

For this reasons, My Health Diary is a good option to be adopted as the go-to tool for monitoring the headaches in ULSM.

Nevertheless, the current pandemic situation that the world is facing was a huge limitation to this work, especially as the topic is related to the health field, and involved a clinical trial. It delayed the beginning of the clinical trial and kept delaying it as the professionals would need

to meet each participant alone, a situation that would be eased in normal circumstances, with a general meeting for all participants. The recruitment to the study was also impaired as the patients were not able to use the medical facilities for this kind of trial for a period of time.

Furthermore, it would have been a good addition to the study of usability to have had the opportunity to observe the population directly, assess the first interactions with the platform. This was also not possible due to the current pandemic situation.

Other limitations are also relevant to refer as is the case of the lack of experience in HTA application, with the need to learn and analyze with more detail certain aspects that would be clear for someone with experience on the topic. A further limitation is related to the need to make conclusions based on the interpretation of medical documents, and laws and regulations from the legal department, to which there was not enough knowledge to.

The biggest conclusion that can be drawn from this analysis is the fact that the platform is an asset to the hospital, but it still has some aspects to be improved and features to develop, in order to be exactly the tool that health professionals and patients need.

6.2 Further Work

In terms of Future Work, there are several aspects that are relevant to work on, which will be discussed below.

At the moment of finalization of this dissertation, the clinical trial only reaches half of the time for the first group of 20 participants, being the study composed of a total of 60 patients. Therefore, one of the main aspects of future work is the continuation of the follow-up to the study.

This follow-up will allow consolidating the results and conclusions that were taken as there are more people using the system and additional answers to the questionnaires, therefore, providing more concrete information on the results.

Another important aspect of the follow-up is the answers to the "Questionário 2" that will provide the opinion of the patients after using both methods, which means that they can then choose knowingly one of the tools over the other. Moreover, the answers to all the other questionnaires will also bring crucial information to the study, that will allow to meet the stipulated objectives.

The next step in this work could also be the implementation of additional features, fixes, and adjustments on the platform, that were presented by the doctors at meetings and also during the Focus Group.

One of the suggestions was to add the possibility for the My Health Diary to gather the information that would be useful to keep track and monitor more types of primary headaches, not just migraines. This way, anyone with headaches could use the system, in order to be able to better understand their condition and make a more reliable diagnosis, as the main way to diagnose primary headaches is through historical information and headache registries. This would be useful to understand possible causes and triggers.

Another suggestion provided by the doctors was to include more questions that would help to better categorize the type of condition, on the patient categorization, in the patient profile. Questions like “Alivia com triptanos”, “Precedida de Aura”, “Habitualmente unilateral”, or “Habitualmente pulsátil” are just some examples of the questions that could be added.

Moreover, some suggestions for future implementations, from the point of view of the author, would also be relevant for this platform.

An example of that is the suggestions presented in the Security section on the Quality Attributes domain, during the Process Application chapter, which go as follow:

- At an initial phase of development, the password was implemented to have nine characters, instead of the current four. But, for ease of access to the application, and to guarantee that the constant need to sign in was not an obstacle for the use of the application, the doctors asked to reduce the minimum number of characters to four. This situation could be avoided if the system were to implement an automatic refresh on the JWT when it expires, keeping the assurance of security on the accesses and requests to the system. The way to do this would be to implement a second token, Refresh Token, that could be used to get a new access token when it has expired.

- Another suggestion is to keep the logs encoded but instead of using the PasswordEncoder, use the AES encryption because this way the logs can be decrypted when there is a need to consult them for information, and they are still secured, and not readable at first sight.

- Additionally, the secrets that are being used for the encryption methods, and for the JWT could be improved, as they are easy. Taking a suggestion from the Project Handover, an option would be “the use of a Keystore to a better and more secure result”.

Appendix A

Questionnaires

A.1 Questionário 1

Questionário 1

A preencher com a ajuda do investigador

Nº do doente:

Escolaridade:

Profissão:

Medicação profilática que realiza:

1.
2.

Medicação analgésica que realiza:

1.
2.

Quantos dias de dor de cabeça teve, em média por mês, nos últimos 3 meses? _____

Quantos dias de dor de cabeça teve no último mês? _____

Quantos dias se esqueceu de tomar a sua medicação profilática por mês, em média, nos últimos 3 meses? _____

Quantos dias se esqueceu de tomar a sua medicação profilática no último mês? _____

Quantos dias se esqueceu de tomar a sua medicação profilática na última semana? _____

Quantos dias tomou medicação analgésica no último mês? _____

Quantos dias tomou medicação analgésica por mês em média nos últimos 3 meses? _____

Já alguma vez foi ao Serviço de Urgência por causa da sua Enxaqueca? Sim Não

Se sim, quantas vezes nos últimos três meses? _____

Já alguma vez foi à consulta aberta do Centro de Saúde por causa da sua Enxaqueca?
Sim Não

Se sim, quantas vezes nos últimos três meses? _____

A.2 Questionário 2

Questionário 2

Qual foi o diário que gostou mais de usar?

Papel My Health App

Durante as 13 semanas que utilizou o calendário em papel, em algum momento deixou de o preencher?

Sim Não

Se sim, após quanto tempo? _____

Durante as 13 semanas que utilizou a My Health App, em algum momento deixou de a preencher?

Sim Não

Se sim, após quanto tempo? _____

Numa escala de 1 a 5, sendo 1 “discordo completamente” e 5 “concordo completamente”, marque a opção que melhor se adequa à sua opinião.

Selecione na escala a resposta que mais se adequa para si em relação ao uso do diário em **PAPEL**:

1.	Foi um incómodo ter de o usar.	1	2	3	4	5
2.	Consumia demasiado do meu tempo.	1	2	3	4	5
3.	Foi demasiado complicado usá-lo.	1	2	3	4	5
4.	Foi fácil de usar.	1	2	3	4	5
5.	O tempo que dispendia a utilizá-lo era adequado.	1	2	3	4	5
6.	Recomendaria o seu uso a outras pessoas.	1	2	3	4	5
7.	Foi difícil lembrar-me de o usar.	1	2	3	4	5
8.	Permitiu-me perceber melhor a minha dor de cabeça.	1	2	3	4	5
9.	Este método é útil para monitorizar a minha dor de cabeça.	1	2	3	4	5
10.	Este método ajudou-me a controlar melhor a dor de cabeça.	1	2	3	4	5

Selecione na escala a resposta que mais se adequa para si em relação ao uso da **My Health App**:

1.	Foi um incómodo ter de a usar.	1	2	3	4	5
2.	Consumia demasiado do meu tempo.	1	2	3	4	5
3.	Foi demasiado complicado usá-la.	1	2	3	4	5
4.	Foi fácil de usar.	1	2	3	4	5
5.	O tempo que dispendia a utilizá-la era adequado.	1	2	3	4	5
6.	Recomendaria o seu uso a outras pessoas.	1	2	3	4	5
7.	Foi difícil lembrar-me de a usar.	1	2	3	4	5
8.	Permitiu-me perceber melhor a minha dor de cabeça.	1	2	3	4	5
9.	Este método é útil para monitorizar a minha dor de cabeça.	1	2	3	4	5
10.	Este método ajudou-me a controlar melhor a dor de cabeça.	1	2	3	4	5

A.3 MiDAS

MiDAS (The Migraine Disability Assessment Test)

Instruções:
Por favor, responda às seguintes perguntas sobre TODAS as cefaleias que teve nos últimos 3 meses.
Escreva a sua resposta a seguir a cada pergunta.
Escreva 0 (zero) se não efetuou a atividade referida nos últimos 3 meses. (Se necessário, recorra a um calendário).

Nota: O score ignora A e B

1 – Em quantos dias nos últimos 3 meses teve de faltar à escola ou ao emprego devido às cefaleias?

_____

2 – Quando ainda conseguiu ir à escola ou trabalhar, em quantos dias, em quantos dias nos últimos 3 meses a sua produtividade esteve reduzida a metade ou mais, devido às cefaleias? (sem contar os dias que considerou na pergunta 1).

_____

3 – Em quantos dias, nos últimos 3 meses, teve de deixar de fazer os seus trabalhos domésticos por causa das cefaleias?

_____

4 – Quando ainda foi capaz de fazer os seus trabalhos domésticos, em quantos dias, nos últimos 3 meses, esteve a sua produtividade reduzida a metade ou mais devido à enxaqueca? (sem contar os dias que considerou na pergunta 3).

_____

5 – Em quantos dias, nos últimos 3 meses, teve de faltar a atividades com a sua família, atividades sociais ou de tempos livres por causa das cefaleias?

_____

A – Quantos dias de dor de cabeça teve nos últimos 3 meses?

_____

B – De 0 a 10 quão dolorosa é, em média, a sua dor de cabeça?
(0 – sem dor, 10 – a maior dor que possa imaginar)

_____

A.4 HIT-6

HIT-6 (Teste do Impacto da Dor de Cabeça)

Este questionário foi elaborado para o/a ajudar a descrever e comunicar o modo como se sente e o que não consegue fazer devido às dores de cabeça.

Para cada pergunta, por favor selecione uma resposta.

1 – Quando tem dor de cabeça, com que frequência é que a dor é muito forte?

nunca raramente às vezes muito frequentemente sempre

2 – Com que frequência as dores de cabeça limitam a sua capacidade de realizar as suas atividades diárias regulares, incluíndo trabalho doméstico, trabalho, estudos, ou relacionamentos sociais?

nunca raramente às vezes muito frequentemente sempre

3 – Quando tem uma dor de cabeça, com que frequência gostaria de poder deitar-se para descansar?

nunca raramente às vezes muito frequentemente sempre

4 – Durante as últimas 4 semanas, com que frequência sentiu-se demasiado cansado(a) para trabalhar ou para realizar as suas atividades diárias devido às suas dores de cabeça?

nunca raramente às vezes muito frequentemente sempre

5 – Durante as últimas 4 semanas, com que frequência sentiu-se farto(a) ou irritado(a) devido às suas dores de cabeça?

nunca raramente às vezes muito frequentemente sempre

6 – Durante as últimas 4 semanas, com que frequência as suas dores de cabeça limitaram a sua capacidade de se concentrar no seu trabalho ou nas suas actividades diárias?

nunca raramente às vezes muito frequentemente sempre

A.5 MSQ V2.1 - Quality of life questionnaire specific for migraines

QUESTIONÁRIO DE QUALIDADE DE VIDA ESPECÍFICO PARA ENXAQUECAS (VERSÃO 2.1)

INSTRUÇÕES PARA O PACIENTE:

Preencha este questionário. Irá ajudar-nos a compreender os efeitos das enxaquecas nas suas atividades diárias.

O questionário foi concebido de modo a poder ser preenchido rápida e facilmente. Assinale uma só resposta para cada questão. Deve responder a todas as questões.

Obrigado pela sua colaboração!

Ao responder às questões seguintes, pense em ***todas as enxaquecas*** que teve ***nas últimas 4 semanas***.

1. Nas últimas 4 semanas, com que frequência as suas enxaquecas **influenciaram** a sua relação com a família, amigos ou outras pessoas que lhe são próximas? (Selecione apenas **uma** resposta.)

   $_1$❑ Nunca
   $_2$❑ Muito poucas vezes
   $_3$❑ Algumas vezes
   $_4$❑ Bastantes vezes
   $_5$❑ A maior parte do tempo
   $_6$❑ Sempre

2. Nas últimas 4 semanas, com que frequência as suas enxaquecas **interferiram** nos seus tempos livres, tais como ler ou fazer exercício? (Selecione apenas **uma** resposta.)

   $_1$❑ Nunca
   $_2$❑ Muito poucas vezes
   $_3$❑ Algumas vezes
   $_4$❑ Bastantes vezes
   $_5$❑ A maior parte do tempo
   $_6$❑ Sempre

3. Nas <u>últimas 4 semanas</u>, com que frequência sentiu **<u>dificuldade</u>** em trabalhar ou realizar atividades diárias como consequência de sintomas de enxaqueca? (Selecione apenas **<u>uma</u>** resposta.)

$_1$❑ Nunca

$_2$❑ Muito poucas vezes

$_3$❑ Algumas vezes

$_4$❑ Bastantes vezes

$_5$❑ A maior parte do tempo

$_6$❑ Sempre

4. Nas <u>últimas 4 semanas</u>, com que frequência as enxaquecas foram **<u>impedimento</u>** para a realização de tarefas profissionais ou domésticas? (Selecione apenas **<u>uma</u>** resposta.)

$_1$❑ Nunca

$_2$❑ Muito poucas vezes

$_3$❑ Algumas vezes

$_4$❑ Bastantes vezes

$_5$❑ A maior parte do tempo

$_6$❑ Sempre

5. Nas <u>últimas 4 semanas</u>, com que frequência as enxaquecas **<u>limitaram</u>** a sua capacidade de concentração no trabalho ou em atividades diárias? (Selecione apenas **<u>uma</u>** resposta.)

$_1$❑ Nunca

$_2$❑ Muito poucas vezes

$_3$❑ Algumas vezes

$_4$❑ Bastantes vezes

$_5$❑ A maior parte do tempo

$_6$❑ Sempre

6. Nas <u>últimas 4 semanas</u>, com que frequência as enxaquecas o **<u>deixaram demasiado cansado</u>** para trabalhar ou realizar atividades domésticas? (Selecione apenas **<u>uma</u>** resposta.)

$_1$❑ Nunca

$_2$❑ Muito poucas vezes

$_3$❑ Algumas vezes

$_4$❑ Bastantes vezes

$_5$❑ A maior parte do tempo

$_6$❑ Sempre

7. Nas <u>últimas 4 semanas</u>, com que frequência as enxaquecas **<u>limitaram</u>** o número de dias em que se sentiu com energia? (Selecione apenas **<u>uma</u>** resposta.)

$_1$❑ Nunca

$_2$❑ Muito poucas vezes

$_3$❑ Algumas vezes

$_4$❑ Bastantes vezes

$_5$❑ A maior parte do tempo

$_6$❑ Sempre

8. Nas <u>últimas 4 semanas</u>, com que frequência teve de **<u>cancelar</u>** trabalho ou atividades diárias devido a uma enxaqueca? (Selecione apenas **<u>uma</u>** resposta.)

$_1$❑ Nunca

$_2$❑ Muito poucas vezes

$_3$❑ Algumas vezes

$_4$❑ Bastantes vezes

$_5$❑ A maior parte do tempo

$_6$❑ Sempre

9. Nas <u>últimas 4 semanas</u>, com que frequência **<u>precisou de ajuda</u>** para tratar de tarefas rotineiras, tais como lides domésticas, resolver assuntos, fazer compras ou tratar de pessoas devido a uma enxaqueca? (Selecione apenas **<u>uma</u>** resposta.)

1❑ Nunca

2❑ Muito poucas vezes

3❑ Algumas vezes

4❑ Bastantes vezes

5❑ A maior parte do tempo

6❑ Sempre

10. Nas <u>últimas 4 semanas</u>, com que frequência teve de **<u>interromper</u>** trabalho ou atividades diárias para lidar com os sintomas de uma enxaqueca? (Selecione apenas **<u>uma</u>** resposta.)

1❑ Nunca

2❑ Muito poucas vezes

3❑ Algumas vezes

4❑ Bastantes vezes

5❑ A maior parte do tempo

6❑ Sempre

11. Nas <u>últimas 4 semanas</u>, com que frequência não **<u>foi capaz de ir</u>** a atividades sociais, tais como festas, jantar com amigos, devido a uma enxaqueca? (Selecione apenas **<u>uma</u>** resposta.)

1❑ Nunca

2❑ Muito poucas vezes

3❑ Algumas vezes

4❑ Bastantes vezes

5❑ A maior parte do tempo

6❑ Sempre

12. Nas <u>últimas 4 semanas</u>, com que frequência **sentiu** saturação ou frustração por causa das enxaquecas? (Selecione apenas **uma** resposta.)

$_1$❑ Nunca

$_2$❑ Muito poucas vezes

$_3$❑ Algumas vezes

$_4$❑ Bastantes vezes

$_5$❑ A maior parte do tempo

$_6$❑ Sempre

13. Nas <u>últimas 4 semanas</u>, com que frequência **sentiu** que era um fardo para as outras pessoas por causa das suas enxaquecas? (Selecione apenas **uma** resposta.)

$_1$❑ Nunca

$_2$❑ Muito poucas vezes

$_3$❑ Algumas vezes

$_4$❑ Bastantes vezes

$_5$❑ A maior parte do tempo

$_6$❑ Sempre

14. Nas <u>últimas 4 semanas</u>, com que frequência sentiu **receio** de desapontar as outras pessoas por causa das suas enxaquecas? (Selecione apenas **uma** resposta.)

$_1$❑ Nunca

$_2$❑ Muito poucas vezes

$_3$❑ Algumas vezes

$_4$❑ Bastantes vezes

$_5$❑ A maior parte do tempo

$_6$❑ Sempre

A.6 WHOQOL- BREF

Instruções

Este questionário procura conhecer a sua qualidade de vida, saúde, e outras áreas da sua vida.

Por favor, responda a todas as perguntas. Se não tiver a certeza da resposta a dar a uma pergunta, escolha a que lhe parecer mais apropriada. Esta pode muitas vezes ser a resposta que lhe vier primeiro à cabeça.

Por favor, tenha presente os seus padrões, expectativas, alegrias e preocupações. Pedimos-lhe que tenha em conta a sua vida nas **duas últimas semanas**.

Por exemplo, se pensar nestas duas últimas semanas, pode ter que responder à seguinte pergunta:

	Nada	Pouco	Moderadamente	Bastante	Completamente
Recebe das outras pessoas o tipo de apoio que necessita?	1	2	3	4	5

Deve pôr um círculo à volta do número que melhor descreve o apoio que recebeu das outras pessoas nas duas últimas semanas. Assim, marcaria o número 4 se tivesse recebido bastante apoio, ou o número 1 se não tivesse tido nenhum apoio dos outros nas duas últimas semanas.

Por favor leia cada pergunta, veja como se sente a respeito dela, e ponha um círculo à volta do número da escala para cada pergunta que lhe parece que dá a melhor resposta.

		Muito Má	Má	Nem Boa Nem Má	Boa	Muito Boa
1 (G1)	Como avalia a sua qualidade de vida?	1	2	3	4	5

		Muito Insatisfeito	Insatisfeito	Nem satisfeito nem insatisfeito	Satisfeito	Muito Satisfeito
2 (G4)	Até que ponto está satisfeito(a) com a sua saúde?	1	2	3	4	5

As perguntas seguintes são para ver até que ponto sentiu certas coisas nas duas últimas semanas.

		Nada	Pouco	Nem muito nem pouco	Muito	Muitíssimo
3 (F1.4)	Em que medida as suas dores (físicas) o(a) impedem de fazer o que precisa de fazer?	1	2	3	4	5
4 (F11.3)	Em que medida precisa de cuidados médicos para fazer a sua vida diária?	1	2	3	4	5
5 (F4.1)	Até que ponto gosta da vida?	1	2	3	4	5
6 (F24.2)	Em que medida sente que a sua vida tem sentido?	1	2	3	4	5
7 (F5.3)	Até que ponto se consegue concentrar?	1	2	3	4	5
8 (F16.1)	Em que medida se sente em segurança no seu dia-a-dia?	1	2	3	4	5
9 (F22.1)	Em que medida é saudável o seu ambiente físico?	1	2	3	4	5

As seguintes perguntas são para ver **até que ponto** experimentou ou foi capaz de fazer certas coisas nas duas últimas semanas.

		Nada	Pouco	Moderadamente	Bastante	Completamente
10 (F2.1)	Tem energia suficiente para a sua vida diária?	1	2	3	4	5
11 (F7.1)	É capaz de aceitar a sua aparência física?	1	2	3	4	5
12 (F18.1)	Tem dinheiro suficiente para satisfazer as suas necessidades?	1	2	3	4	5
13 (F20.1)	Até que ponto tem fácil acesso às informações necessárias para organizar a sua vida diária?	1	2	3	4	5
14 (F21.1)	Em que medida tem oportunidade para realizar actividades de lazer?	1	2	3	4	5

		Muito Má	Má	Nem boa nem má	Boa	Muito Boa
15 (F9.1)	Como avaliaria a sua mobilidade [capacidade para se movimentar e deslocar por si próprio(a)]?	1	2	3	4	5

As perguntas que se seguem destinam-se a avaliar se se sentiu **bem ou satisfeito(a)** em relação a vários aspectos da sua vida nas duas últimas semanas.

		Muito Insatisfeito	Insatisfeito	Nem satisfeito nem insatisfeito	Satisfeito	Muito Satisfeito
16 (F3.3)	Até que ponto está satisfeito(a) com o seu sono?	1	2	3	4	5
17 (F10.3)	Até que ponto está satisfeito(a) com a sua capacidade para desempenhar as actividades do seu dia-a-dia?	1	2	3	4	5
18 (F12.4)	Até que ponto está satisfeito(a) com a sua capacidade de trabalho?	1	2	3	4	5
19 (F6.3)	Até que ponto está satisfeito(a) consigo próprio(a)?	1	2	3	4	5
20 (F13.3)	Até que ponto está satisfeito(a) com as suas relações pessoais?	1	2	3	4	5
21 (F15.3)	Até que ponto está satisfeito(a) com a sua vida sexual?	1	2	3	4	5
22 (F14.4)	Até que ponto está satisfeito(a) com o apoio que recebe dos seus amigos?	1	2	3	4	5
23 (F17.3)	Até que ponto está satisfeito(a) com as condições do lugar em que vive?	1	2	3	4	5
24 (F19.3)	Até que ponto está satisfeito(a) com o acesso que tem aos serviços de saúde?	1	2	3	4	5
25 (F23.3)	Até que ponto está satisfeito(a) com os transportes que utiliza?	1	2	3	4	5

As perguntas que se seguem referem-se à **frequência** com que sentiu ou experimentou certas coisas nas duas últimas semanas.

		Nunca	Poucas vezes	Algumas vezes	Frequentemente	Sempre
26 (F8.1)	Com que frequência tem sentimentos negativos, tais como tristeza, desespero, ansiedade ou depressão?	1	2	3	4	5

A.7 Usability Questionnaire for Patients

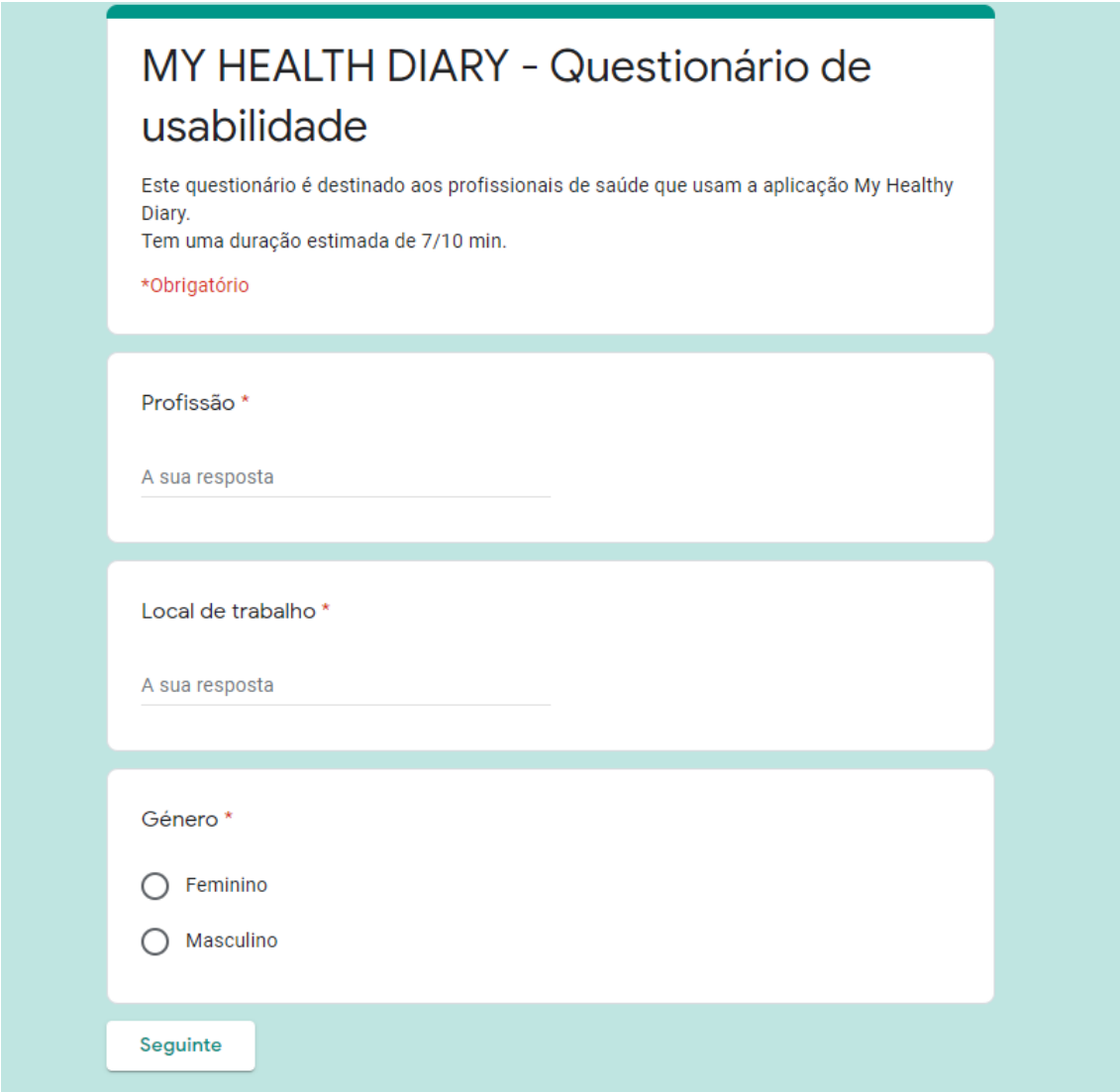
Numa escala de 1 a 5, sendo 1 "discordo completamente" e 5 "concordo completamente", marque a opção que melhor se adequa à sua opinião.

1	É fácil aprender a usar a aplicação.	**1**	**2**	**3**	**4**	**5**
2	A aplicação é fácil de usar.	**1**	**2**	**3**	**4**	**5**
3	O tempo que investi para aprender a utilizar a aplicação foi adequado.	**1**	**2**	**3**	**4**	**5**
4	O tempo que investi na utilização da aplicação foi adequado.	**1**	**2**	**3**	**4**	**5**
5	Considero que a maioria das pessoas seria capaz de aprender a usar a aplicação.	**1**	**2**	**3**	**4**	**5**
6	A informação está bem organizada e é fácil de aceder.	**1**	**2**	**3**	**4**	**5**
7	A aplicação funciona corretamente e não apresenta erros ou problemas durante a sua utilização.	**1**	**2**	**3**	**4**	**5**
8	A aplicação permite registar dados importantes sobre as minhas dores de cabeça.	**1**	**2**	**3**	**4**	**5**
9	Quando a aplicação vai de um ecrã para outro, as informações que introduzi não são perdidas, e consigo voltar a vê-las.	**1**	**2**	**3**	**4**	**5**
10	A aplicação funciona bem à medida que vou efetuando ações.	**1**	**2**	**3**	**4**	**5**
11	Durante a utilização da aplicação, quando me enganei numa ação, foi fácil e rápido de corrigir.	**1**	**2**	**3**	**4**	**5**
12	As cores usadas são atrativas e o tamanho e tipo de letra é adequado.	**1**	**2**	**3**	**4**	**5**
13	A forma como os elementos são apresentados na aplicação é agradável e adequa-se ao propósito da aplicação.	**1**	**2**	**3**	**4**	**5**
14	De um modo geral, o aspeto da aplicação é do meu agrado.	**1**	**2**	**3**	**4**	**5**
15	Consigo aceder à aplicação e aos seus dados a qualquer momento.	**1**	**2**	**3**	**4**	**5**
16	A aplicação é mais adequada e fácil de usar do que o registo do diário em papel.	**1**	**2**	**3**	**4**	**5**
17	A utilização da aplicação ajudou a melhorar a minha saúde.	**1**	**2**	**3**	**4**	**5**
18	A aplicação é útil para eu fazer o acompanhamento da minha saúde.	**1**	**2**	**3**	**4**	**5**
19	Os dados pedidos/tratados pela aplicação representam bem o meu problema de saúde – dores de cabeça.	**1**	**2**	**3**	**4**	**5**
20	A aplicação melhorou o meu acesso a tratamentos eficazes para a minha dor de cabeça.	**1**	**2**	**3**	**4**	**5**
21	A aplicação permite descrever os dados importantes sobre a minha dor de cabeça.	**1**	**2**	**3**	**4**	**5**
22	A aplicação ajudou-me a melhorar as minhas dores de cabeça.	**1**	**2**	**3**	**4**	**5**

23	Com a utilização da aplicação, tive mais oportunidades de interagir com o meu médico e enfermeiro de família e neurologista.	**1**	**2**	**3**	**4**	**5**
24	Estou confiante que os dados introduzidos na aplicação foram recebidos pelo meu médico e enfermeiro de família e neurologista.	**1**	**2**	**3**	**4**	**5**
25	Tenho melhor qualidade de vida por usar a aplicação.	**1**	**2**	**3**	**4**	**5**

Tem algum comentário final sobre a aplicação?

A.8 Usability Questionnaire for Health Professionals



MY HEALTH DIARY - Questionário de usabilidade

Este questionário é destinado aos profissionais de saúde que usam a aplicação My Healthy Diary.
Tem uma duração estimada de 7/10 min.

*Obrigatório

Profissão *

A sua resposta

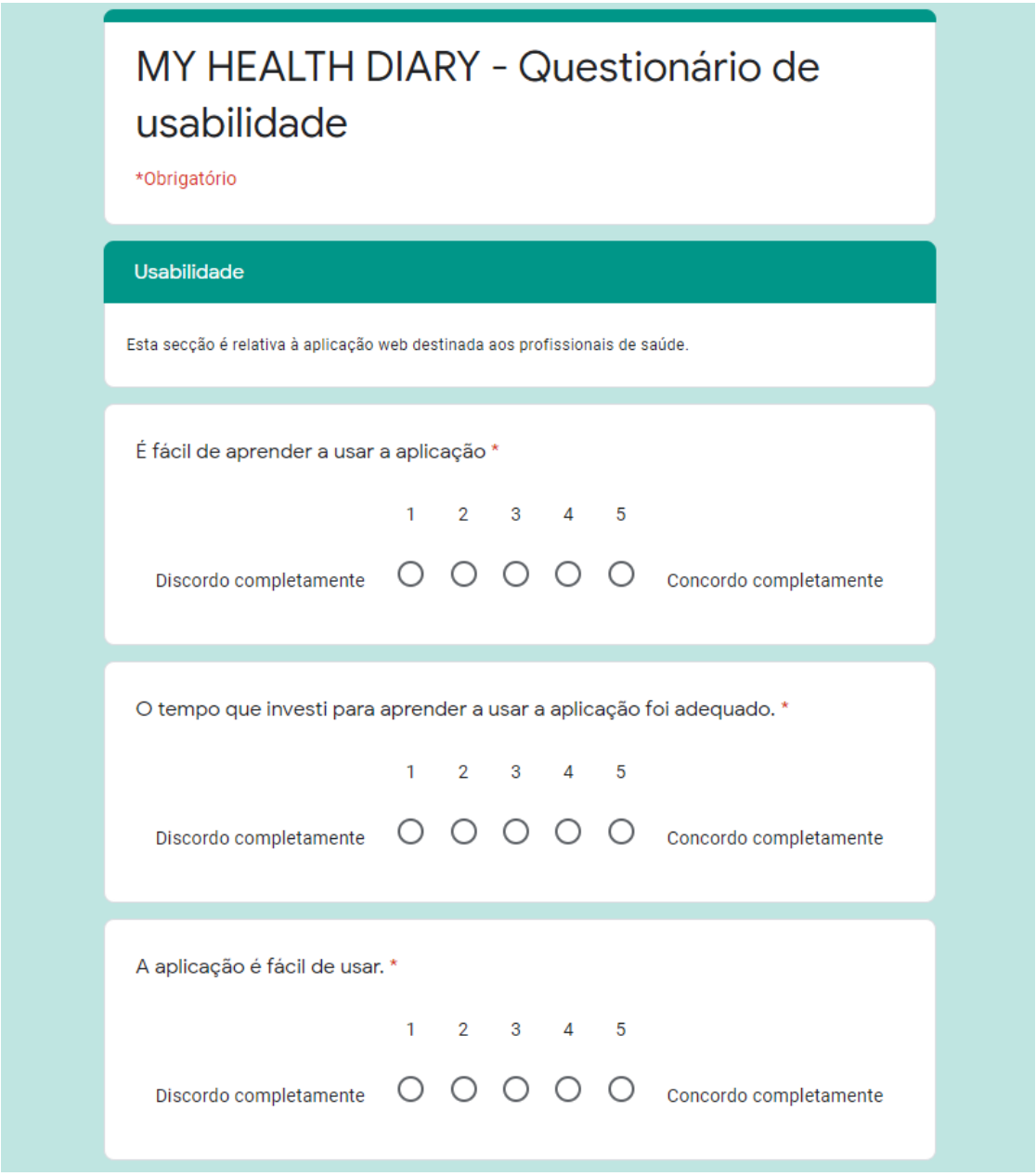
Local de trabalho *

A sua resposta

Género *

- Feminino
- Masculino

Seguinte



MY HEALTH DIARY - Questionário de usabilidade

*Obrigatório

Usabilidade

Esta secção é relativa à aplicação web destinada aos profissionais de saúde.

É fácil de aprender a usar a aplicação *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

O tempo que investi para aprender a usar a aplicação foi adequado. *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

A aplicação é fácil de usar. *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

O tempo que investi na utilização da aplicação foi adequado. *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

Considero que a maioria dos meus pares seria capaz de aprender a usar a aplicação. *

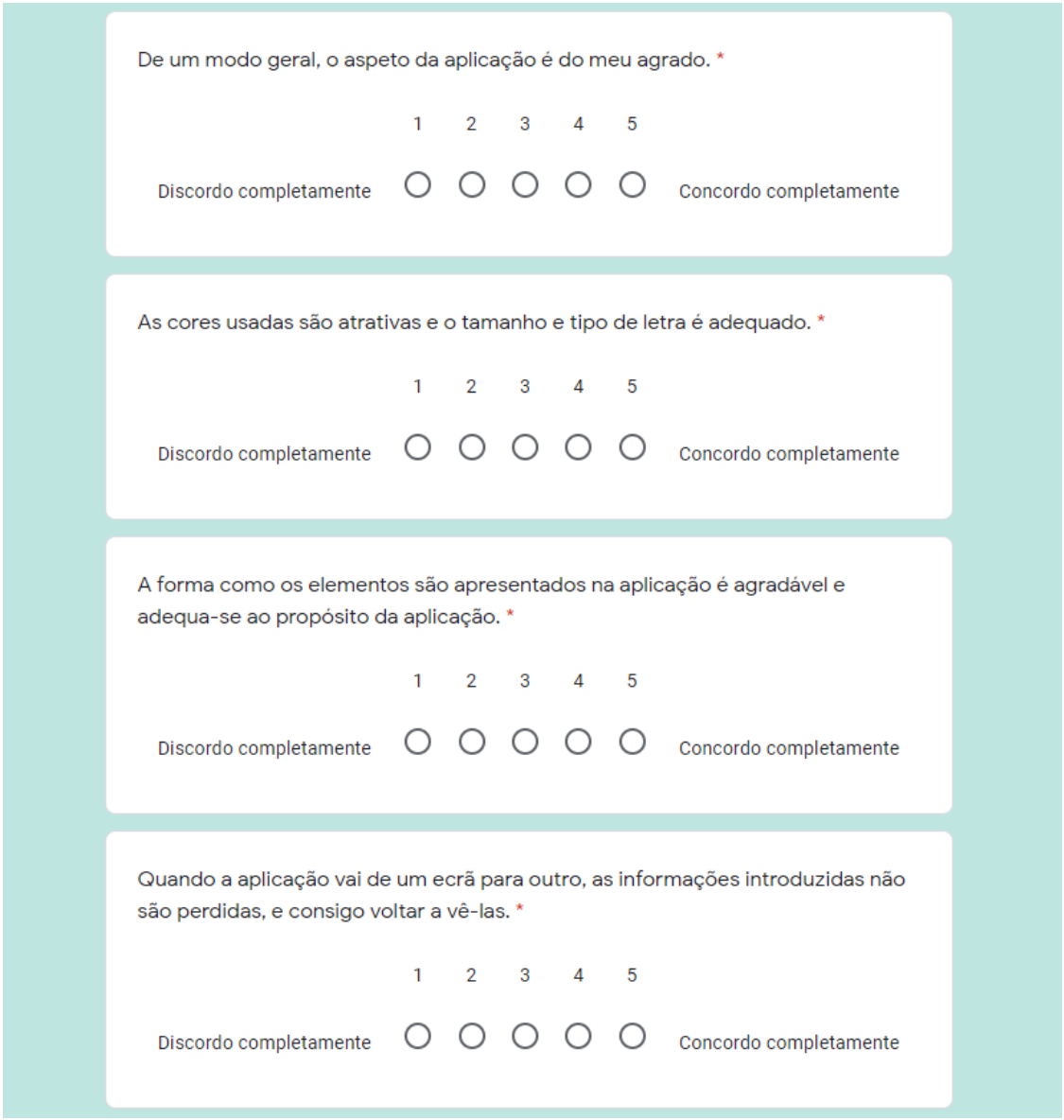
	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

A informação está bem organizada e é fácil de aceder. *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

A aplicação funciona corretamente e não apresenta erros ou problemas aquando da sua utilização. *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente



De um modo geral, o aspeto da aplicação é do meu agrado. *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

As cores usadas são atrativas e o tamanho e tipo de letra é adequado. *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

A forma como os elementos são apresentados na aplicação é agradável e adequa-se ao propósito da aplicação. *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

Quando a aplicação vai de um ecrã para outro, as informações introduzidas não são perdidas, e consigo voltar a vê-las. *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

A aplicação funciona bem à medida que vou efetuando ações. *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

Durante a utilização da aplicação, quando me enganei numa ação, foi fácil e rápido de corrigir. *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

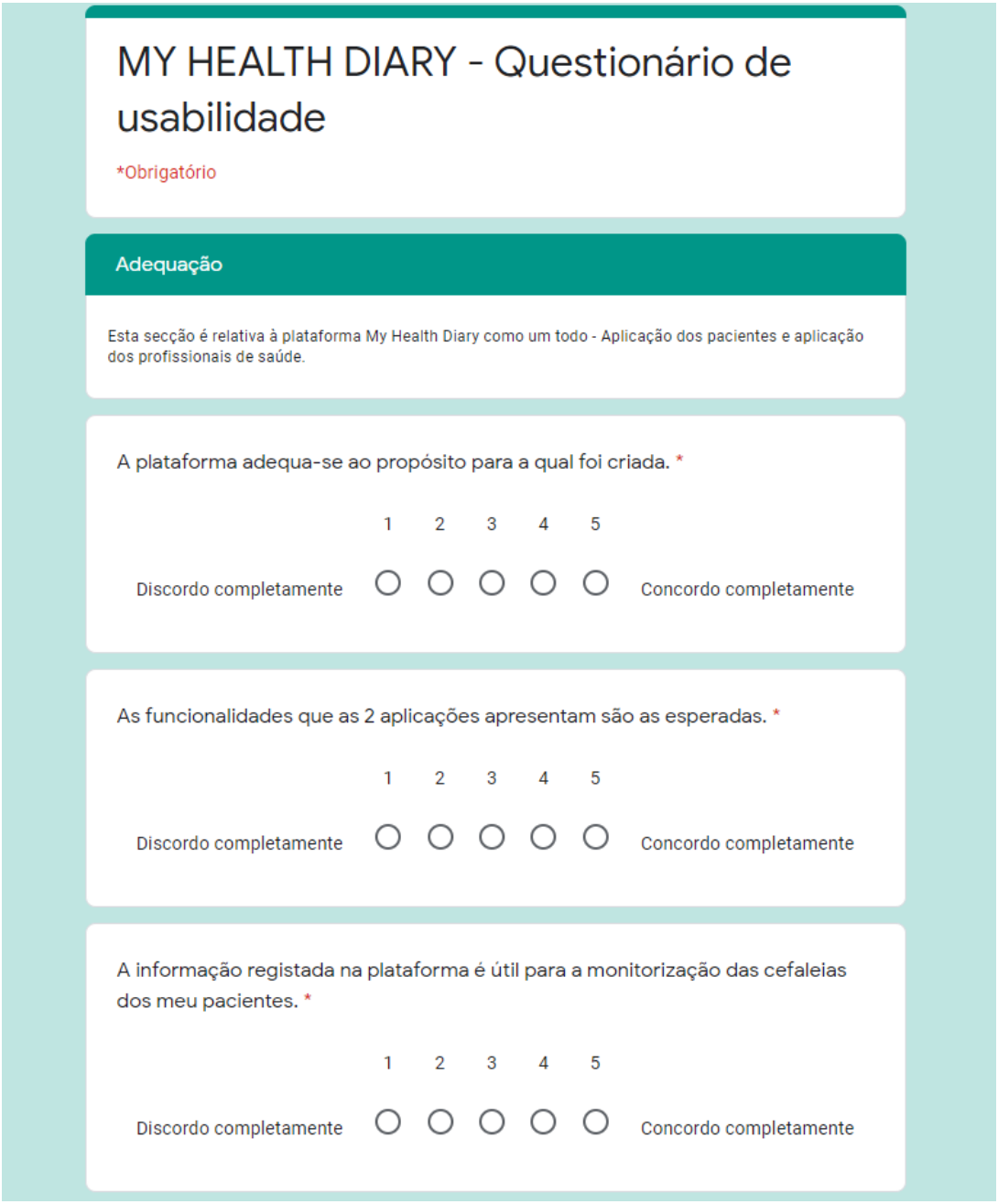
Consigo aceder à aplicação e aos seus dados a qualquer momento. *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

Tem algum comentário sobre a usabilidade da aplicação?

A sua resposta

Anterior Seguinte



MY HEALTH DIARY - Questionário de usabilidade

*Obrigatório

Adequação

Esta secção é relativa à plataforma My Health Diary como um todo - Aplicação dos pacientes e aplicação dos profissionais de saúde.

A plataforma adequa-se ao propósito para a qual foi criada. *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

As funcionalidades que as 2 aplicações apresentam são as esperadas. *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

A informação registada na plataforma é útil para a monitorização das cefaleias dos meu pacientes. *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

Os dados inseridos na plataforma são suficientes para a monitorização das cefaleias dos meus pacientes. *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

A plataforma melhorou o meu acesso a informações relevantes sobre os meus pacientes. *

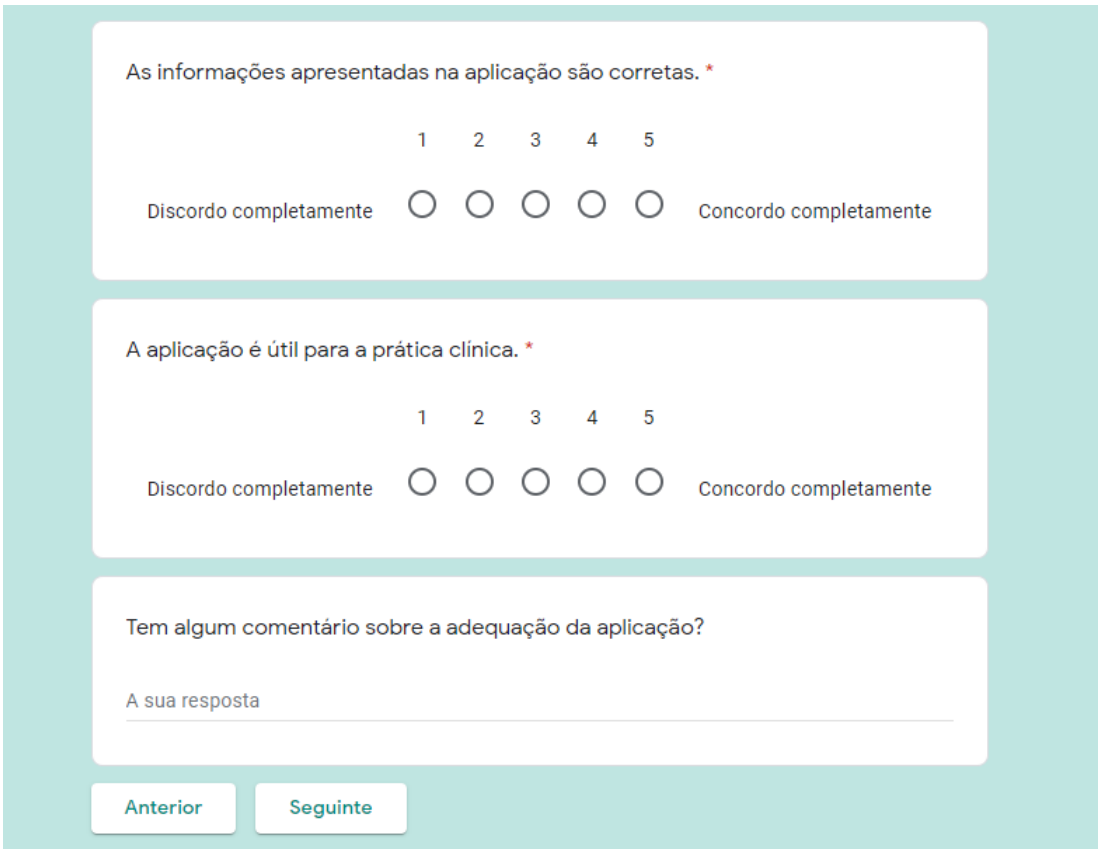
	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

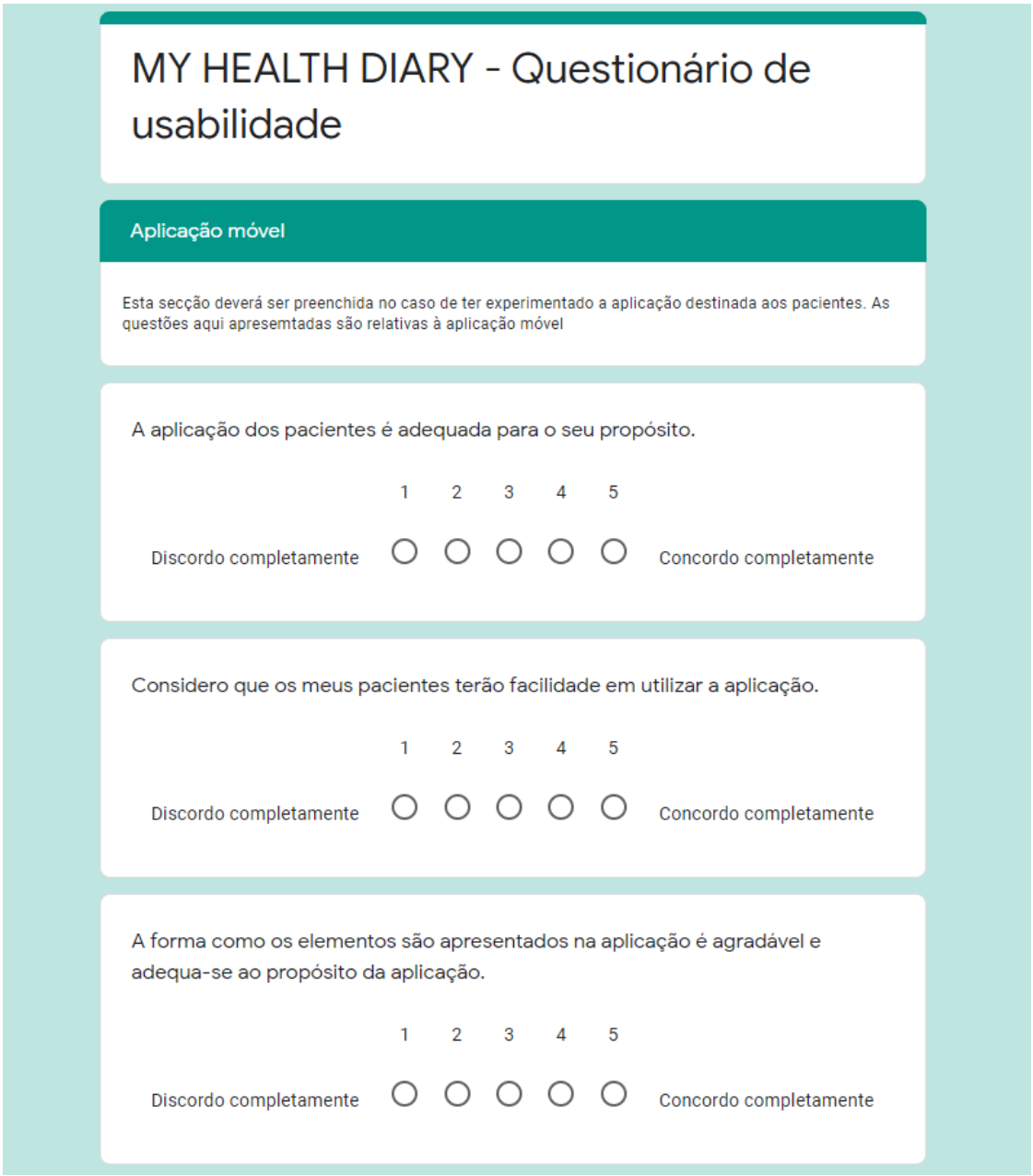
A aplicação permite que os pacientes tenham acesso a tratamentos mais eficazes. *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

A aplicação fornece dados mais fiáveis relativamente às cefaleias dos meus pacientes do que o diário em papel. *

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente


As informações apresentadas na aplicação são corretas. *
1 2 3 4 5
Discordo completamente
Concordo completamente
A aplicação é útil para a prática clínica. *
1 2 3 4 5
Discordo completamente
Concordo completamente
Tem algum comentário sobre a adequação da aplicação?
A sua resposta
Anterior
Seguinte



MY HEALTH DIARY - Questionário de usabilidade

Aplicação móvel

Esta secção deverá ser preenchida no caso de ter experimentado a aplicação destinada aos pacientes. As questões aqui apresemtadas são relativas à aplicação móvel

A aplicação dos pacientes é adequada para o seu propósito.

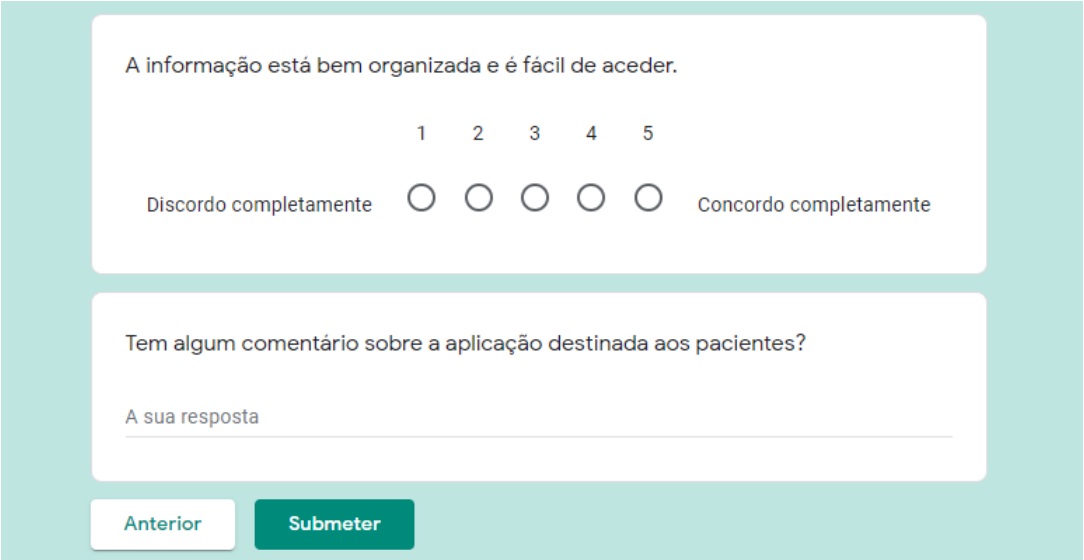
	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

Considero que os meus pacientes terão facilidade em utilizar a aplicação.

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente

A forma como os elementos são apresentados na aplicação é agradável e adequa-se ao propósito da aplicação.

	1	2	3	4	5	
Discordo completamente	○	○	○	○	○	Concordo completamente


A informação está bem organizada e é fácil de aceder.
1 2 3 4 5
Discordo completamente
Concordo completamente
Tem algum comentário sobre a aplicação destinada aos pacientes?
A sua resposta
Anterior
Submeter

Appendix B

Acceptance tests for My Health Diary

B.1 Web application - for Health Professionals

Table B.1: User Story USHP1 - Create a health professional account

User Story USHP1
Scenario: Open page for account creation. **Given** Professional is in the initial page. **When** Professional clicks “Criar conta”. **Then** A new page with text fields for account creation is shown.
Result obtained

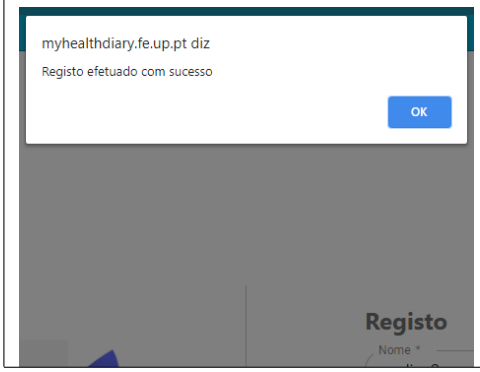
Scenario: Create Health Professional Account **Given** Professional is in the create account page **When** Professional fills the text fields with the following information about himself: Name: "Nome do Medico" Email: "medico@ulsm.min-saude.pt" Medical specialty: "Neurologista" Place of Work: "Hospital Pedro Hispano" Password: "123456789" Confirm password: "123456789" **And** Clicks "Criar" button. **Then** Presentation of successful message.


Table B.2: User Story USHP2 - Health Professional Login.

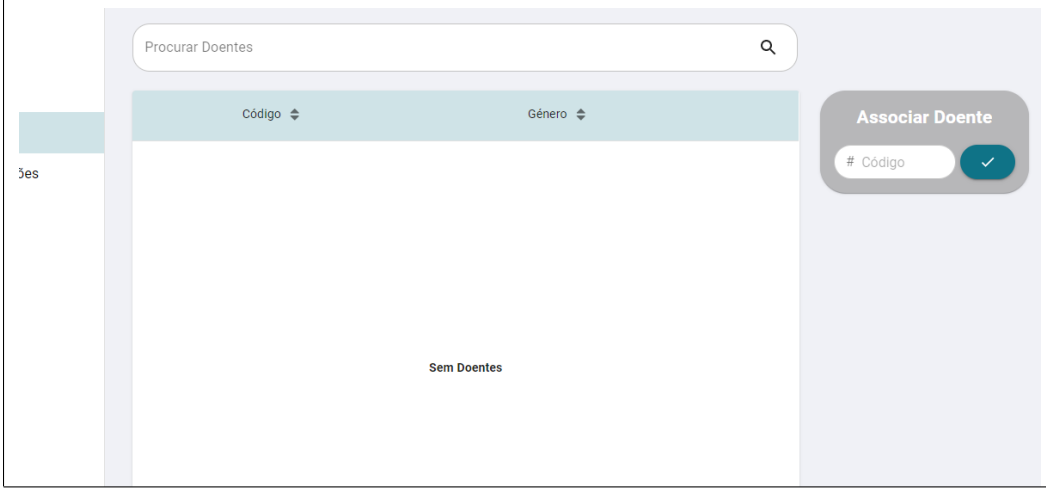
User Story USHP2
Scenario: Login. **Given** Professional is in the initial page. **When** Professional inserts credentials - email and password used on account creation Email: "medico@ulsm.min-saude.pt" Password: "123456789" **And** Clicks “Iniciar Sessão” button. **Then** Go to page of the list of patients associated with the health professional.
Result obtained


Table B.3: User Story USHP3 - Edit Health Professional profile.

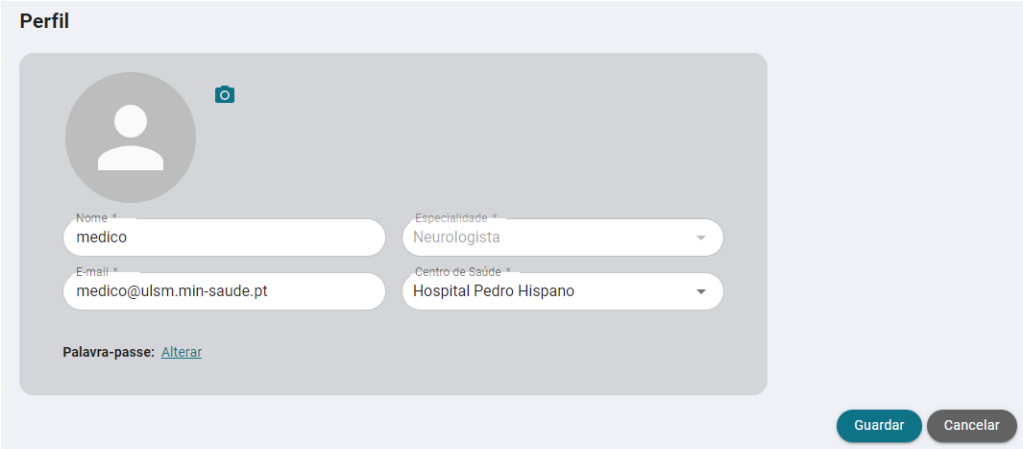
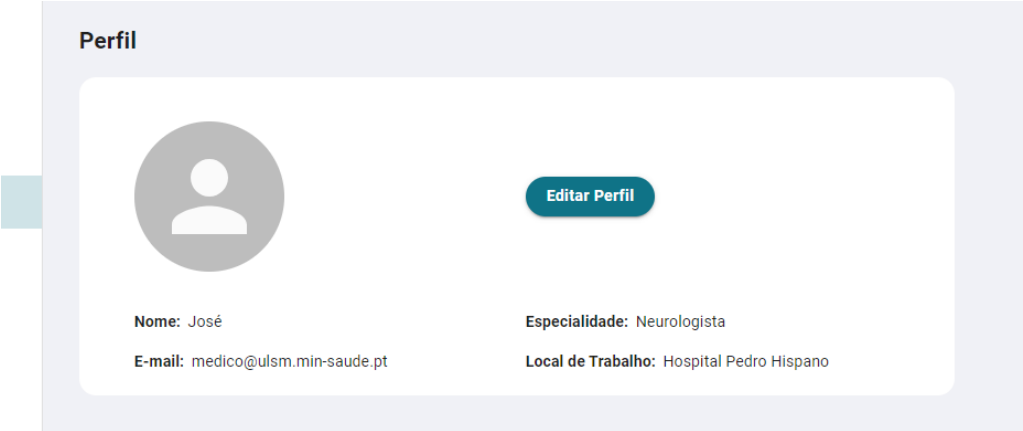
User Story USHP3
Scenario: Open edit profile page. **Given** Professional is in the profile page. **When** Professional clicks “Editar Perfil” button. **Then** The page with text fields for account editing is opened, with the text fields filled with information about professional.
Result obtained

Scenario: Edit Profile. **Given** Professional is in the Edit Profile page. **When** Professional changes the text field “Nome”para “José” **And** Clicks “Guardar”. **Then** Go back to the profile page, and the name shown should be the one inserted now.


Table B.4: User Story USHP4 - Create Patients' Account.

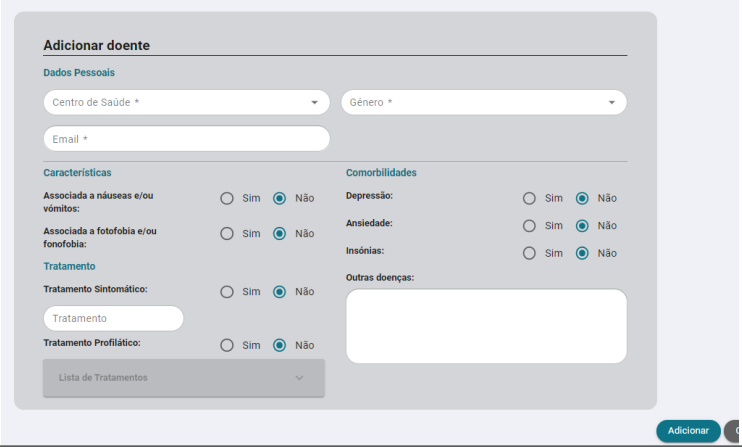
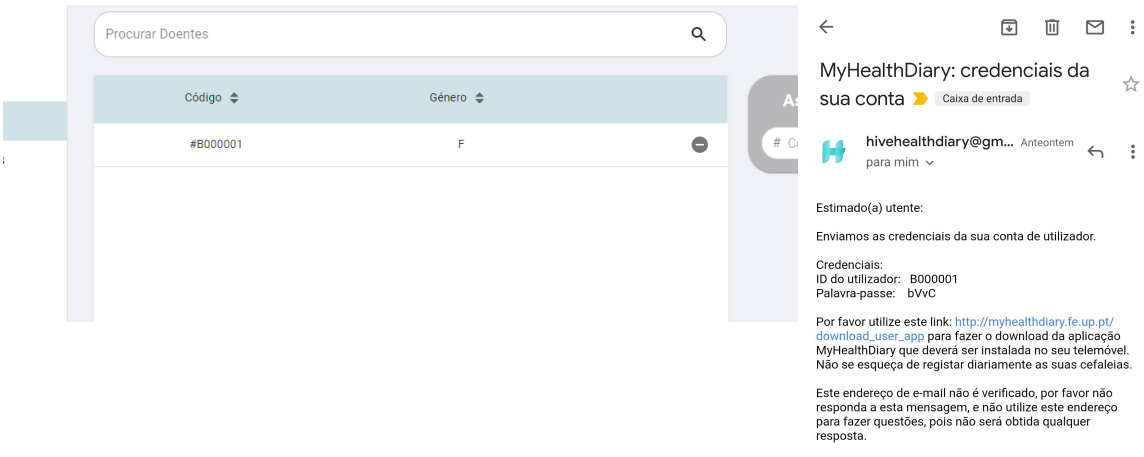
User Story USHP4
Scenario: Open page for account creation. **Given** Professional is in the page of the list of patients associated with the health professional. **When** Professional clicks "Adicionar Doente" button. **Then** A new page with fields for account creation is opened.
Result obtained

Scenario: Create Patients' Account. **Given** Professional is in the page for Patient account creation. **When** Professional fills in the text fields with data about the patient Health Center: "USF MARESIA" Email: "mcarolinarosa96@gmail.com" Gender: "Feminino" **And** Clicks "Adicionar". **Then** Go back to page of the list of patients associated with the health professional. **And** a new patient was added to the list. **And** an email is sent to the address inserted in e-mail field, with the credentials, and link to download app.


Table B.5: User Story USHP5 - Edit Patients' Account.

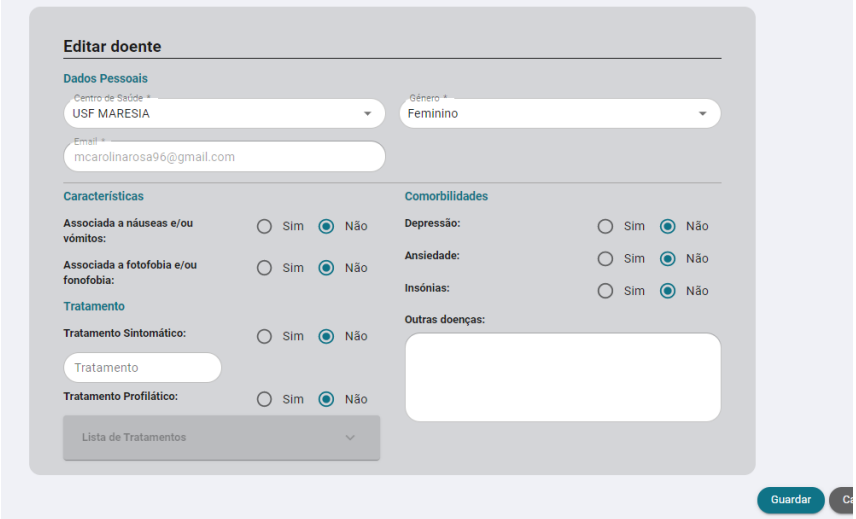
User Story USHP5
Scenario: Open edit patients' account page. **Given** Professional is in the patients' account information page. **When** Professional clicks "Editar" button. **Then** The page with fields for patients' account editing, with fields filled in with information about the patient, is opened.
Result obtained

Scenario: Edit Patient Account. **Given** Professional is in the page for Patient account editing. **When** Professional changes the values of the fields Anxiety: "Yes" Associated with photophobia/phonophobia: "Yes" **And** Clicks "Guardar". **Then** Go back to the patients' account information page with the fields that were changed with the new data.


Table B.6: User Story USHP6 - Associate Patient to Health Professional.

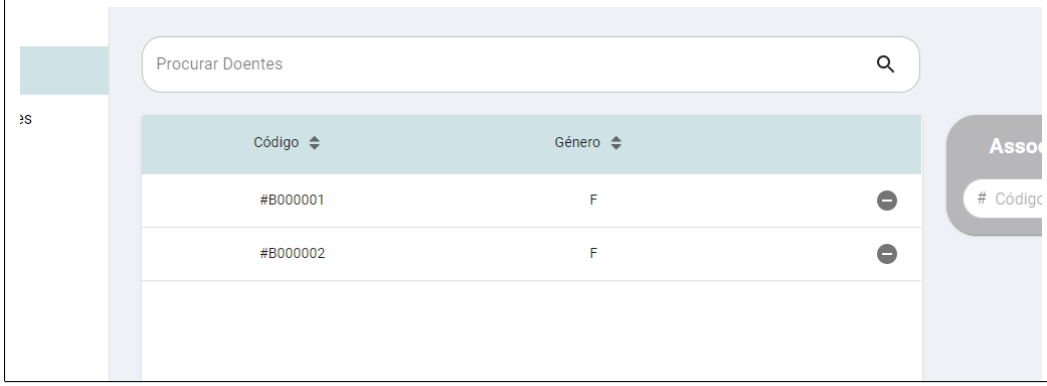
User Story USHP6
Scenario: Associate Patient to Health Professional. **Given** Professional is in the page of the list of patients associated with the health professional. **When** Professional add a patient using the box next to the list. Patient ID: "B000002" **Then** The patient is added to the professional's list.
Result obtained


Table B.7: User Story USHP7 - Disassociate Patient to Health Professional.

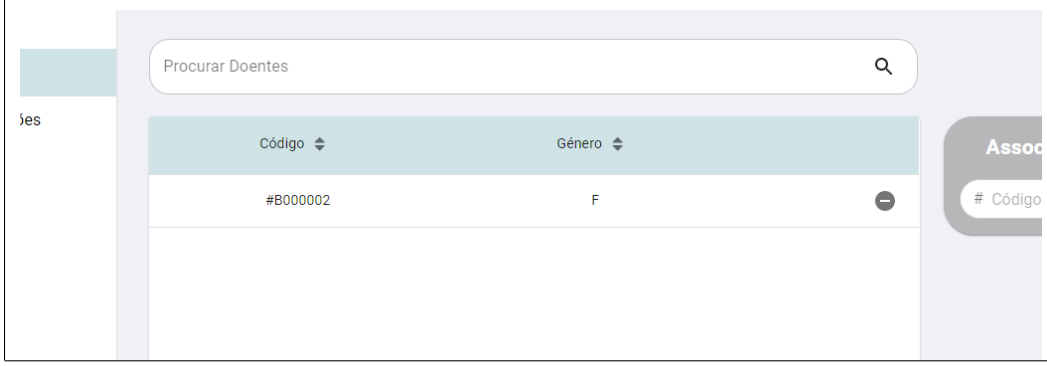
User Story USHP7
Scenario: Disassociate Patient to Health Professional. **Given** Professional is in the page of the list of patients associated with the health professional. **When** Professional clicks in the icon - ⊖- at the end of patient B000001 row. **Then** The patient is removed from the professional's list.
Result obtained


Table B.8: User Stories USHP8, USHP9, USHP10 - Notifications.

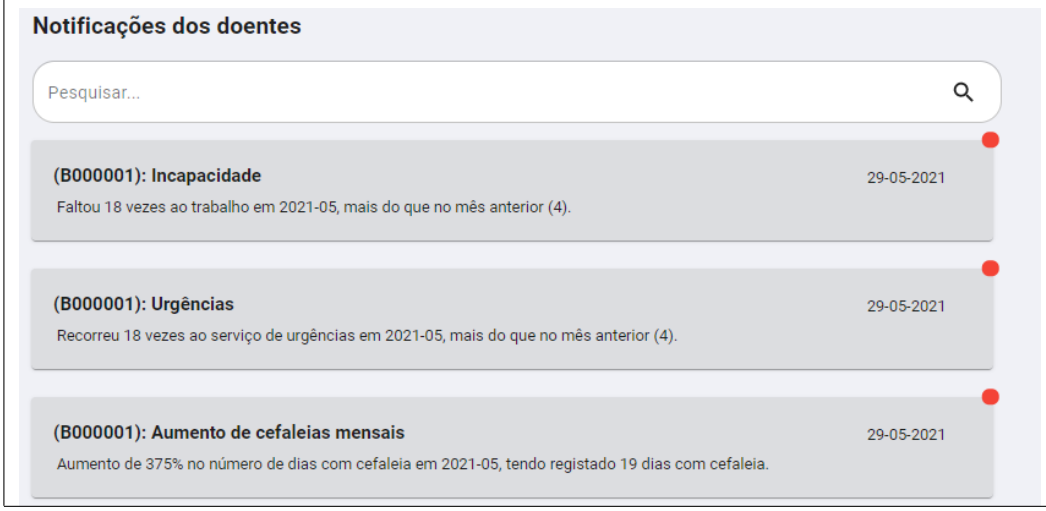
User Stories USHP8, USHP9, USHP10
Scenario: Receive notifications about the patient. **Given** The patient increases the number of headaches registered on >20% in comparison to the previous month. **Or** The patient increases the number of days with work incapacity in comparison to the previous month. **Or** The patient increases the number of days with emergency room recurrence in comparison to the previous month. **And** The professional is logged-in. **When** Professional clicks on "Notificações" on the left menu. **Then** The professional will be able to seethe notifications regarding the patients associated with them. **Note:** In order to test these functionalities, data was inserted directly in the database.
Result obtained


Table B.9: User Story USHP11 - Consult Patients' records.

User Story USHP11
Scenario: Consult Patients' records. **Given** Professional is in the page of the list of patients associated with the health professional. **When** Professional clicks in the patient B000001 row. **Then** A page with patients' records is opened. **Note:** Professional can consult records from previous months by clicking on the row beside the calendar.
Result obtained

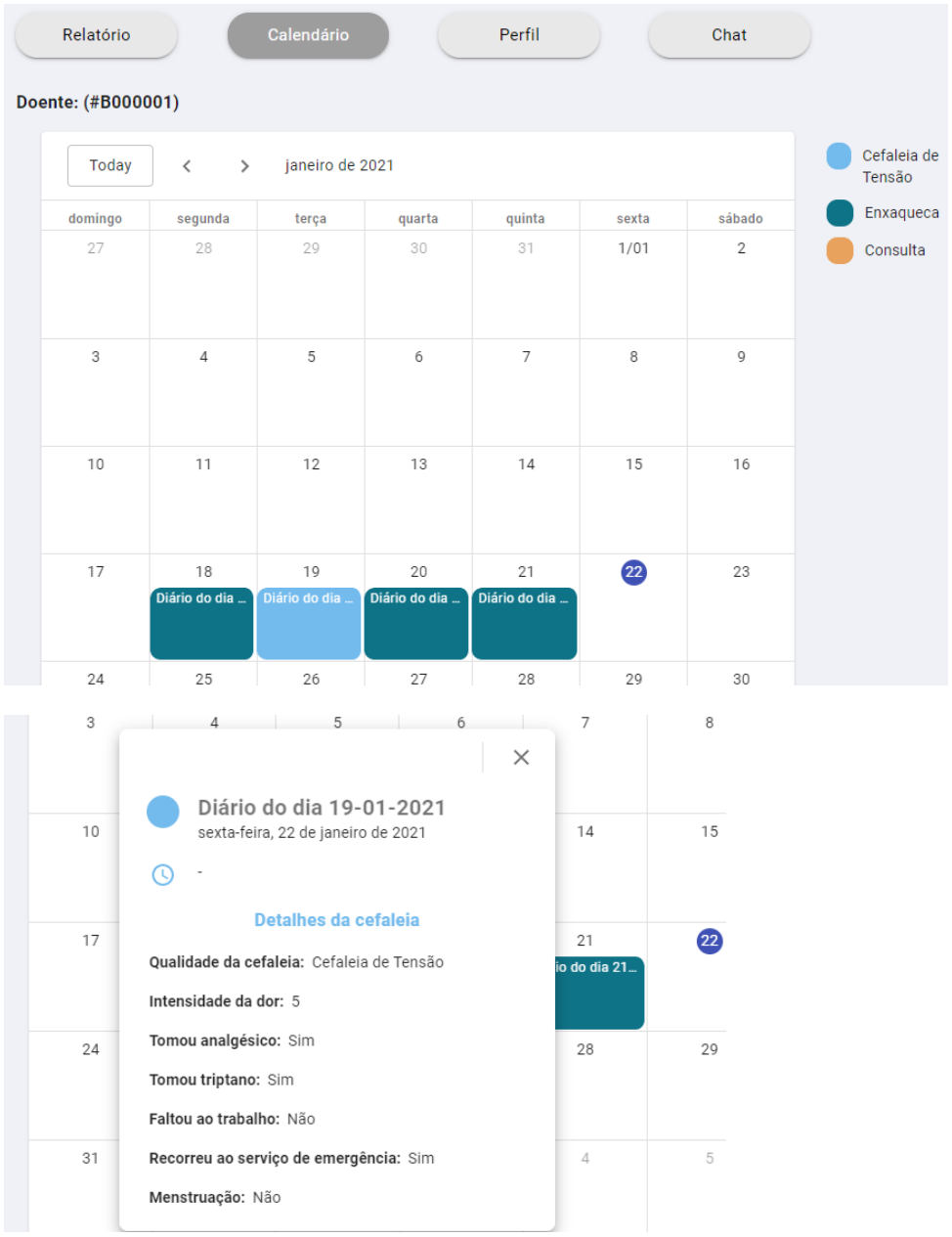

Table B.10: User Story USHP12 - Export Patients' records.

User Story USHP12
Scenario: Export Patients' records. **Given** Professional is in the page of the patients' records. **When** Professional clicks in the "Exportar Dados" button. **Then** The data from the record is copied to the clipboard.
Result obtained

Pasted in the notepad:
 	
`| Mês | 2021-01 |`
`| Evolução (%) nº dias cefaleias | 0% |`
`| Nº dias cefaleia | 4 |`
`| Nº dias enxaqueca | 3 |`
`| Nº dias med. analgésica | 2 |`
`| Nº dias med. triptanos | 3 |`
`| Intensidade máxima cefaleia | 8 |`
`| Nº idas urgências | 2 |`
`| Nº dias abstinência laboral | 2 |`

Table B.11: User Story USHP13 - Consult Patients' calendar.

User Story USHP13
Scenario: Consult Patients' calendar. **Given** Professional is in the page of the patients' records. **When** Professional clicks in the "Calendário" button. **Then** The calendar page will show up, with the registries from the patients.
Result obtained



When hover on a day with registry.

B.2 Mobile application - for Patients

Table B.12: User Story USP9 - Check the utilization manual.

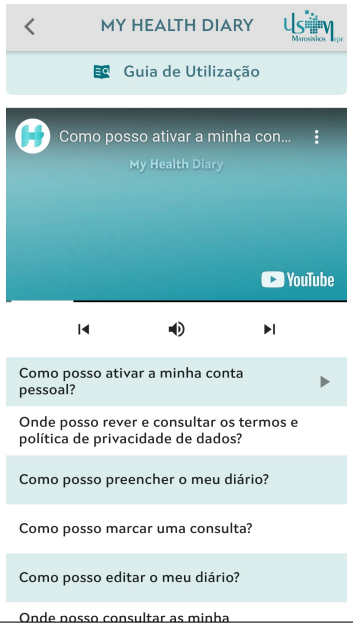
User Story USP9	**Result obtained**
Scenario: Check the manual. **Given** Patient is in the initial page or calendar page. **When** Patient clicks in the menu button. **And** Clicks on “Guia de utilização” **Then** Open a new page with all tutorial videos explaining how the application works.	

Table B.13: User Story USP1 - Activate user account.

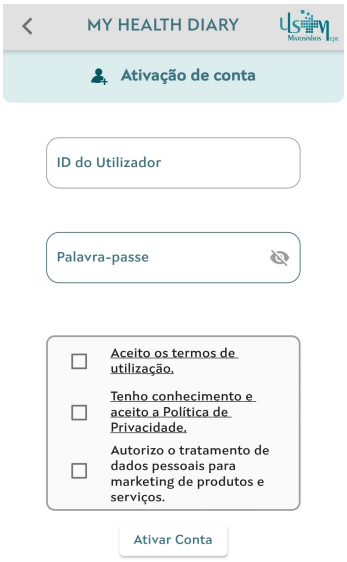
User Story USP1	**Result obtained**
Scenario: Open account activation page **Given** Patient is in the initial page. **When** Patient clicks on "Ativar conta" button. **Then** Open activate account page.	
Scenario: Activate the account **Given** Patient is in the Account activation page. **When** Patient inserts id and password received by e-mail, after account creation. User: B000001 Password: bVvC **And** Checks the boxes regarding consent of privacy policies and terms of use. **And** Presses "Ativar Conta". **Then** Go to the next page to change the temporary password.	
Scenario: Change temporary password **Given** Patient is in the change temporary password page. **When** Patient inserts the new password twice to replace the password received by e-mail, and confirm it. Password: 1234 Confirm Password: 1234 **And** Press "Continuar". **Then** "Conta Ativada com Sucesso" message should appear on the screen.	

Table B.14: User Story USP2 - Login.

User Story USP2	**Result obtained**
Scenario: Login **Given** Patient is in the initial page. **When** Patient inserts id and password in the respective fields. User: B000001 Password: 1234 **And** Clicks “Iniciar Sessão”. **Then** Open the Calendar page.	

Table B.15: User Story USP3 - Edit patients' account.

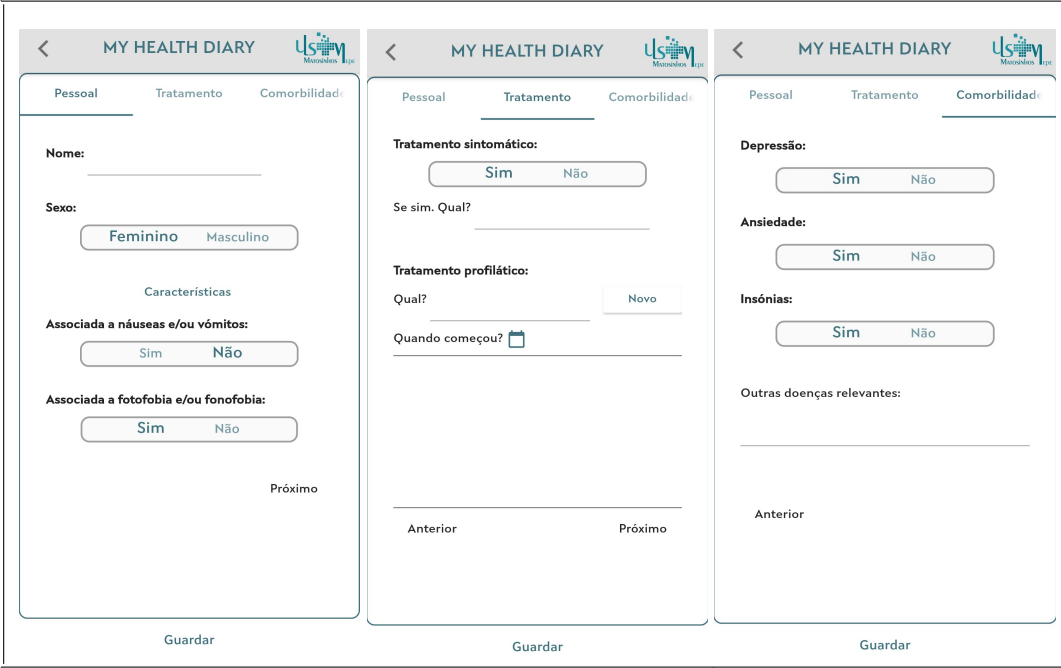
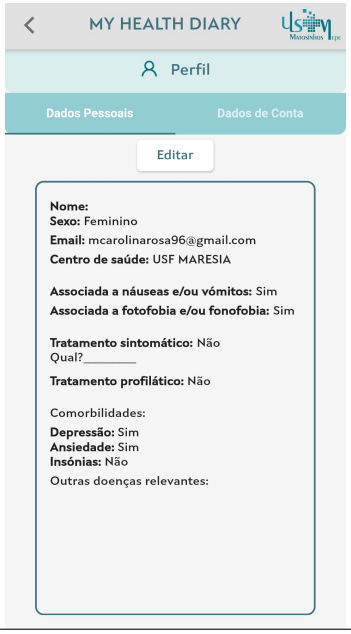
User Story USP3
Scenario: Enter in edit patient's account page. **Given** Patient is in the account page. **When** Patient clicks in "Editar" button **Then** Open the edit account page.
Result obtained

Scenario: Edit account **Given** Patient is in the edit account page. **When** Patient changes the fields: Associated with nausea or vomit: "Yes" Depression: "Yes" **And** Clicks "Guardar". **And** Also clicks "Guardar" on the confirmation pop-up. **Then** Go back to the profile page, with the alterations on the respective fields.	

Table B.16: User Story USP4 - Register Headache.

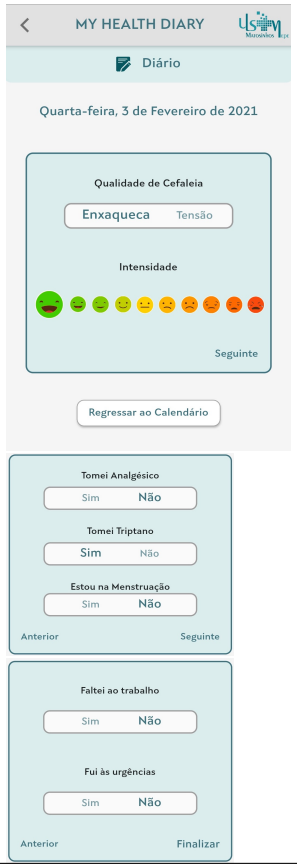
User Story USP4	**Result obtained**
Scenario: Create new registry **Given** Patient is in the calendar page. **When** Patient clicks on the day chosen to register a headache. Day: February 3rd. **And** Press "+ Diário". **Then** Open the Add Diary page.	
Scenario: Register Headache: type, intensity, medication, menstruation, missed work, and went to emergency room **Given** Patient is in the Add Diary page. **When** Patient selects the information regarding the headache felt in February 3rd. Type: "Enxaqueca" Intensity: 5th face from the left Painkiller: "Não" Triptan: "Sim" Menstruation: "Não" Miss work: "Não" Went to emergency room: "Sim" **And** Clicks "Finalizar". **Then** Return to calendar with success message and a dot underneath the day in calendar	

Table B.17: User Story USP4 - Consult headache registry.

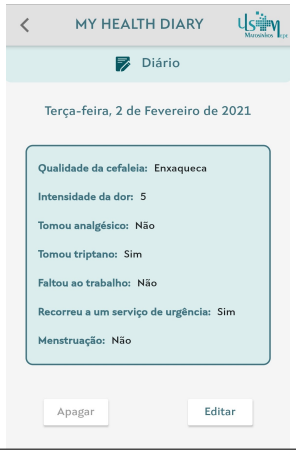
User Story USP4	**Result obtained**
Scenario: Consult headache registry **Given** Patient is in the calendar page. **When** Patient selects the day February 3rd. **And** Presses "Ver Diário". **Then** Open the Diary page on February 3rd.	

Table B.18: User Story USP5 - Register medical appointment.

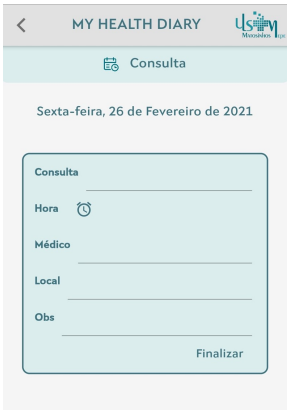
User Story USP5	**Result obtained**
Scenario: Register medical appointment **Given** Patient is in the calendar page. **When** Patient clicks on the day chosen to register a headache. Day: February 26th. **And** Press "+ Consulta". **Then** Open the add appointment page.	
Scenario: Register the information about the appointment **Given** Patient is in the add appointment page. **When** Patient writes the information regarding the medical appointment and select the time. Consult: "neurologia" Time: "10h31" Doctor: "José Silva" Place: "Hospital Pedro Hispano" Obs: "levar exames médicos" **And** Presses "Finalizar". **Then** Return to calendar with success message and a dot underneath the day in calendar - February 26th.	

Table B.19: User Story USP5 - Consult medical appointment registry.

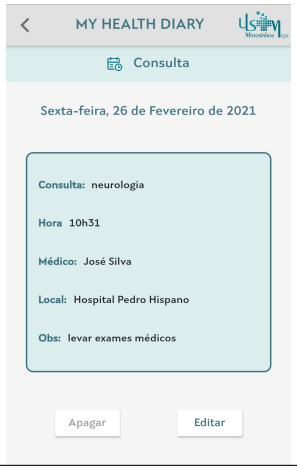
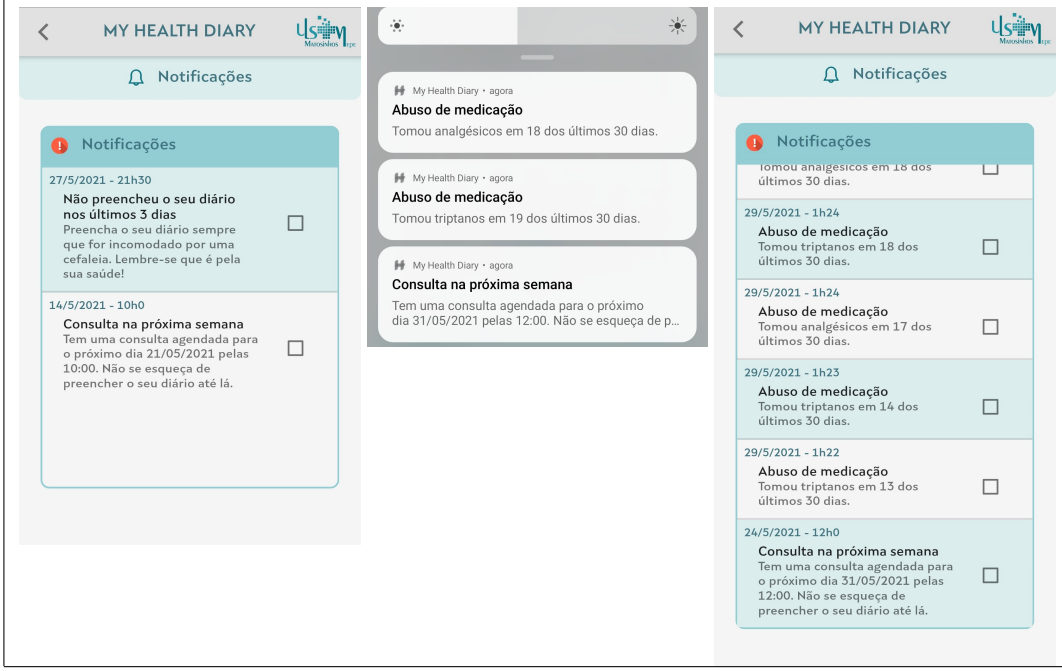
User Story USP5	**Result obtained**
Scenario: Consult medical appointment registry. **Given** Patient is in the calendar page. **When** Patient selects the day February 26th. **And** Presses “Ver Consulta”. **Then** Open the Appointment page on February 26th.	

Table B.20: User Story USP6, USP7, and USP8 - Patient receive notifications.

User Story USP6, USP7, and USP8
Scenario: Receive notifications regarding the registries. **Given** The patient has made a registry. **When** patient does not make new registries for 3 days straight. **Given** The patient has registered a medical appointment on the calendar. **When** There is a week left for the appointment. **Given** The patient has registered the use of triptans for more than 10 times in a month. **When** Patient creates a new registry with the use of triptan. **Given** The patient has registered the use of painkillers for more than 15 times in a month. **When** Patient creates a new registry with the use of painkiller. **Then** The patient should receive a push notification on the smartphone. **And** The patient can also consult it on the notification section of the app. **Note:** In order to test the functionalities regarding medication use, data was inserted directly in the database.
Result obtained



Appendix C

Paper diary

Número do doente: **Mês:** **Ano:**

Dia	1. Enxaqueca	2. Cefaleia Tipo Tensão	3. Medicação SOS	4. Escala de dor	5. Faltou ao trabalho	6. Recorreu ao SU
1				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
2				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
3				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
4				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
5				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
6				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
7				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
8				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
9				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
10				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
11				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
12				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
13				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
14				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
15				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
16				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
17				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
18				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
19				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
20				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
21				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
22				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
23				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
24				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
25				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
26				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
27				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
28				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
29				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
30				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		
31				0 – 1 – 2 – 3 – 4 – 5 – 6 – 7 – 8 – 9 – 10		

Instruções de uso:

1. Marque X na secção “Enxaqueca”, nos dias de ocorrência de enxaqueca

2. Marque X na secção “Cefaleia Tipo Tensão”, nos dias de ocorrência de cefaleia tipo tensão

3. Marque X na secção “Medicação SOS”, se nesse dia tomou medicação SOS

4. Na secção “Escala de Dor” selecione com uma cruz o número que corresponde à sua dor no dia da Cefaleia correspondente, sendo 0 sem dor e 10 a pior dor imaginável.

5. Marque X na secção “Faltou ao trabalho”, se nesse dia faltou ao trabalho por causa da sua Cefaleia

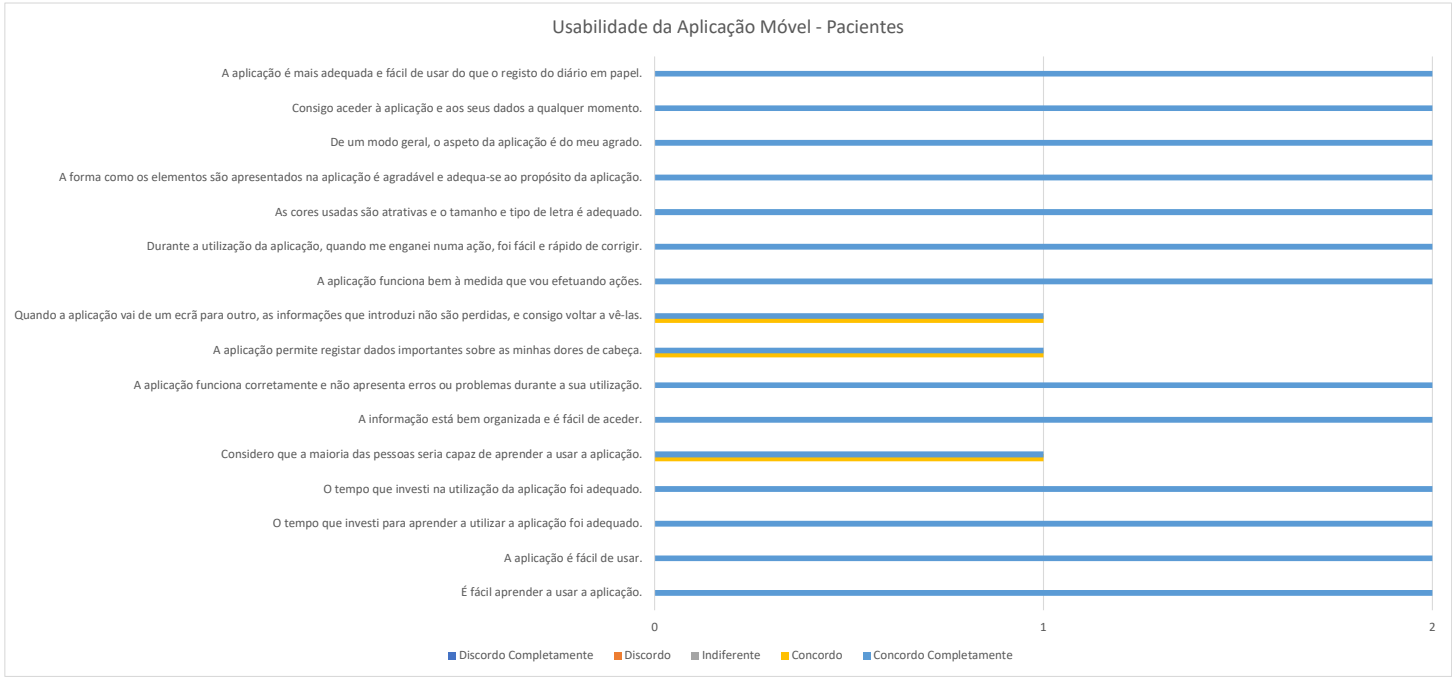
6. Marque X na secção “Recorreu ao SU”, se nesse dia recorreu ao SU por causa da sua cefaleia

Appendix D

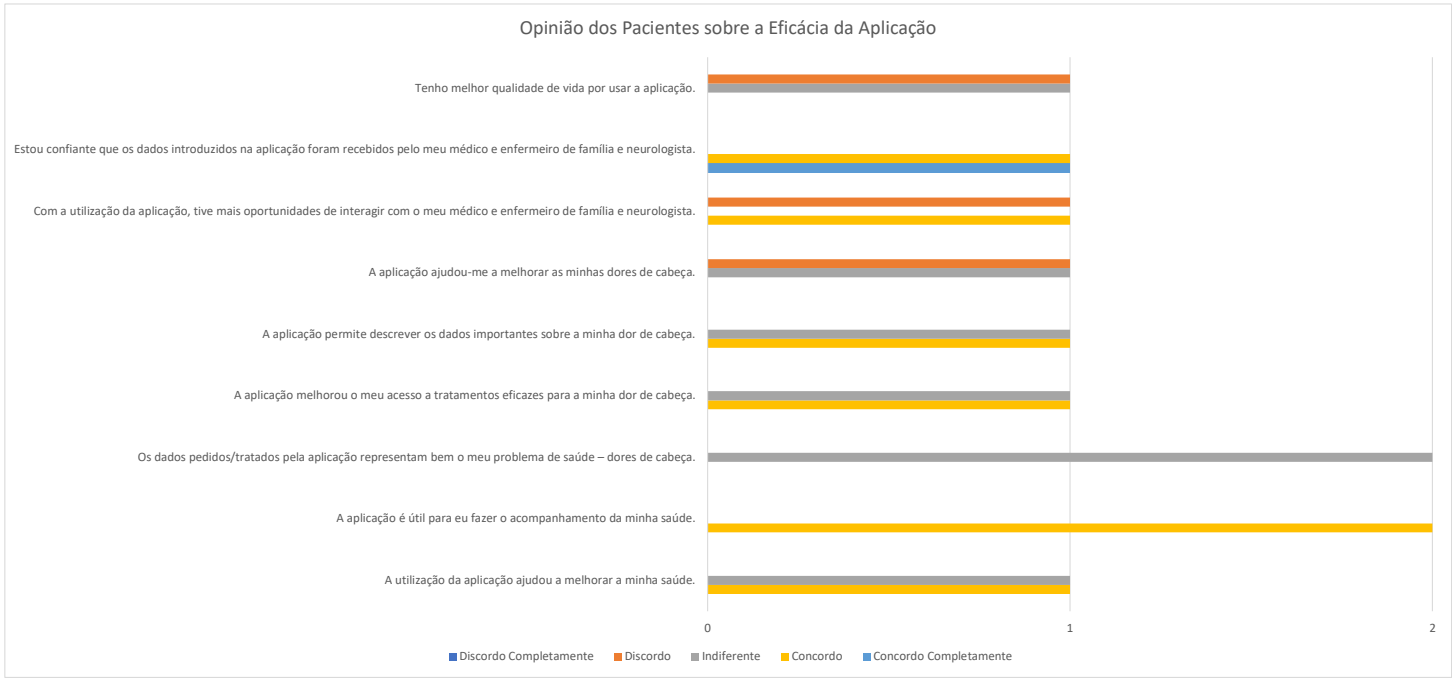
Results from Usability Questionnaires

D.1 Usability Questionnaire for Patients

D.1.1 Usability Questionnaire regarding the mobile application answered by Patients

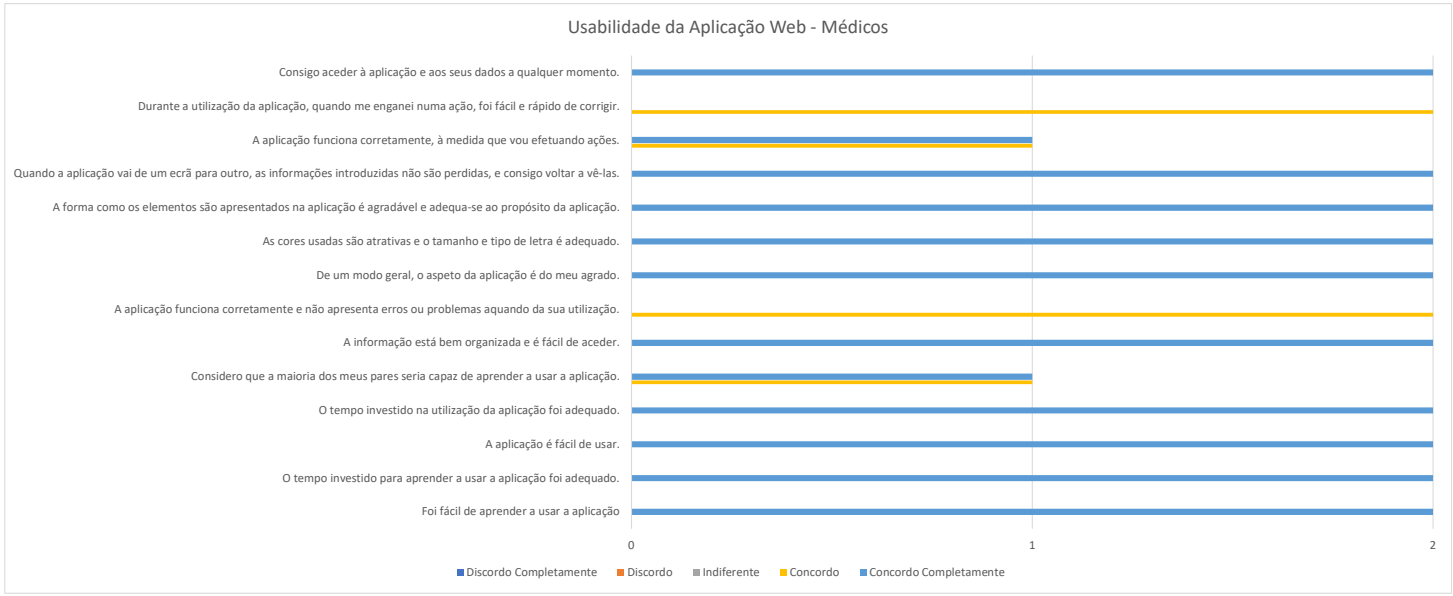


D.1.2 Patients opinions regarding effectiveness of the application

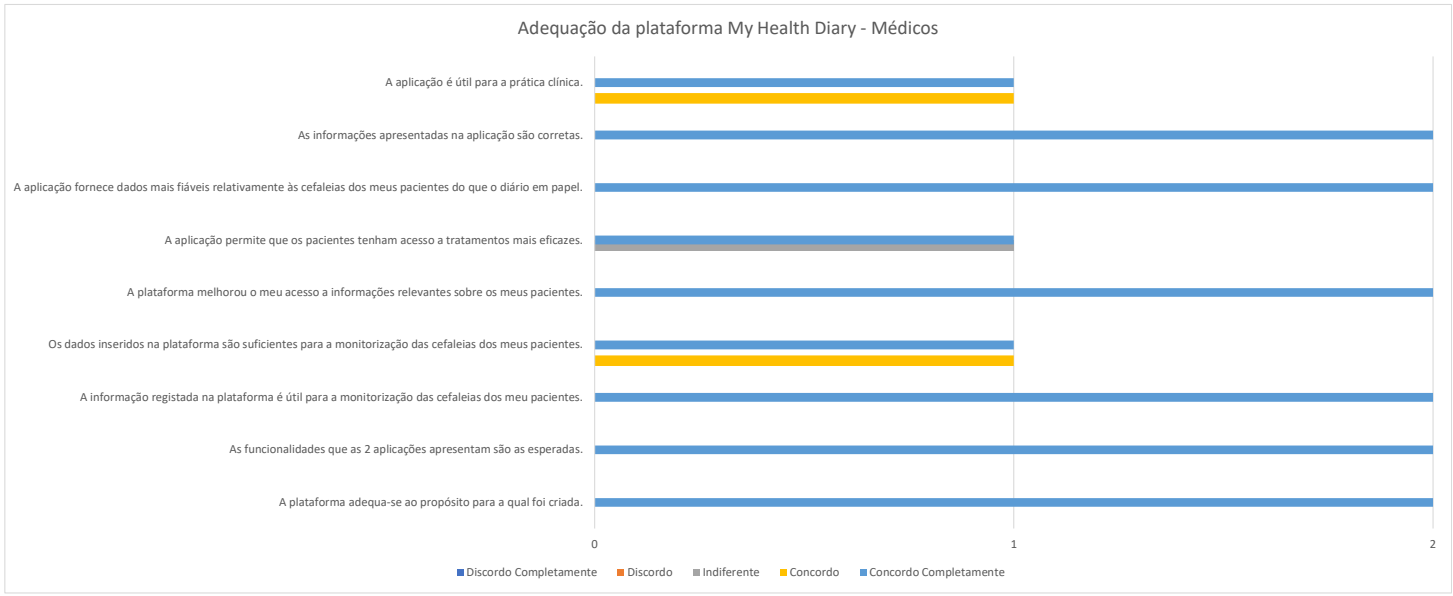


D.2 Usability Questionnaire for Health Professionals

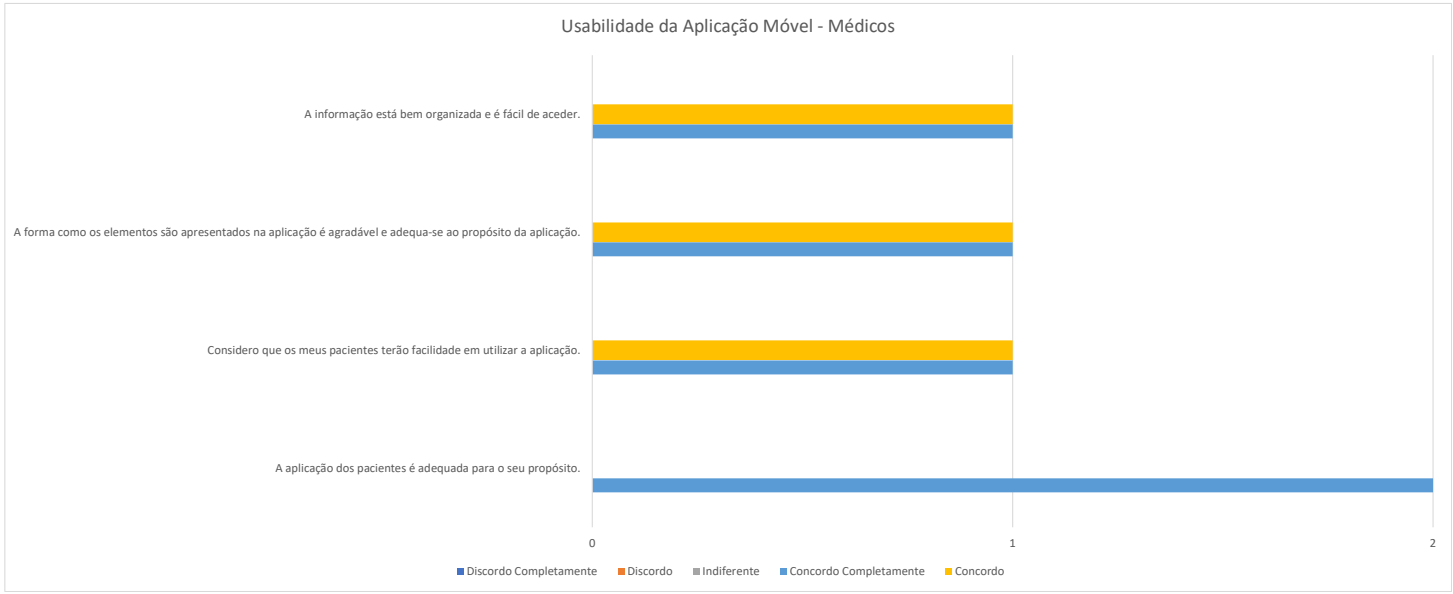
D.2.1 Usability Questionnaire regarding the web application answered by health professionals



D.2.2 Adequacy questionnaires



D.2.3 Usability Questionnaire regarding the mobile application answered by health professionals



Appendix E

Utilization Manual

My Health Diary

Manual de Utilização

Conteúdo

Lista de Figuras

1 Aplicação para médicos

A aplicação web para médicos está disponível em http://myhealthdiary.fe.up.pt, a partir do qual todas as operações estão disponíveis.

1.1 Criar conta

Para criar uma conta, o médico tem de, primeiramente, carregar no botão "Criar Conta", que se encontra no canto superior direito da página inicial. Será, então, redirecionado para a página de Registo onde deverá preencher todos os campos.

O ecrã de Criação de conta é mostrado em Fig.1.

Fig. 1. Criar uma conta

O endereço de email inserido deverá ter como domínio **ulsm.min-saude.pt**, isto significa que tem de ser do tipo ***utilizador*@ulsm.min-saude.pt**. Deverá ser válido, e o médico precisa de lhe ter acesso.

Relativamente aos campos de "Especialidade" e "Local de Trabalho", estes estão ligados, no sentido em que um "Neurologista" só poderá selecionar como local de trabalho o "Hospital Pedro

Quanto à palavra-passe, esta deverá ter pelo menos 4 caracteres.

Quando todos os campos estiverem preenchidos, o médico deverá selecionar o botão de “Criar”.

Uma mensagem informativa do browser aparecerá no topo da página , informando que o registo foi efetuado com sucesso. Deverá carregar em “Ok”para prosseguir - Fig.2.

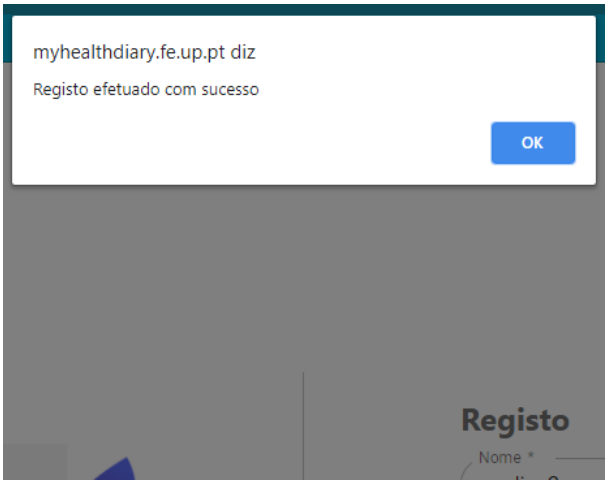


Fig. 2. Registo efetuado com sucesso

Será, então, reencaminhado para a página inicial, onde poderá iniciar sessão.

1.1.1 Situações de erro

- No caso de o médico tentar criar uma conta utilizando como e-mail um endereço que já esteja associado a outra conta, ao selecionar o botão ”Criar”, surgirá uma mensagem de erro do browser ”Username já existe.” - Fig.3.

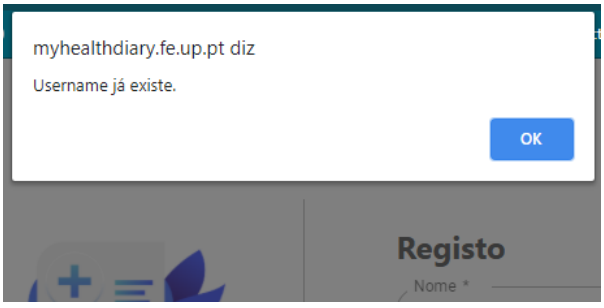


Fig. 3. E-mail já usado

Para solucionar esta situação de erro, o médico deverá criar a sua conta utilizando um endereço de e-mail diferente.

- No caso de o médico tentar criar a sua conta utilizando um e-mail cujo domínio seja diferente de "ulsm.min-saude.pt", uma mensagem de erro surgirá por baixo deste campo informando que o e-mail não é válido - Fig.4.

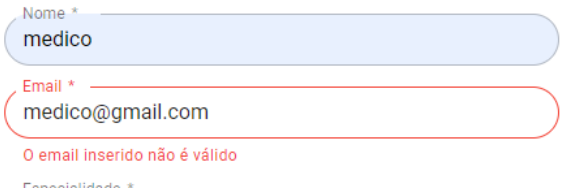


Fig. 4. E-mail inválido

O e-mail deverá ser substituído por outro que seja válido, isto é, cujo domínio seja "ulsm.min-saude.pt".

- No caso de o médico tentar criar a sua conta utilizando uma palavra passe com menos de 4 caracteres, os campos relativos à palavra passe ficarão a vermelho seguidos de uma mensagem solicitando para que defina uma palavra-passe com pelo menos 4 caracteres - Fig.5.

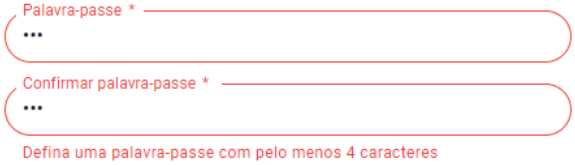


Fig. 5. Palavra-passe com pelo menos 4 caracteres

A palavra-passe deverá ser substituída por outra que contenha pelo menos 4 caracteres.

1.2 Iniciar sessão

Para um médico iniciar sessão, basta preencher o e-mail e palavra-passe, de acordo com a sua conta, criada anteriormente.

O ecrã de Início de sessão é mostrado em Fig.6.

Depois de iniciar sessão, o médico terá acesso a todas as funcionalidades disponíveis da aplicação web.

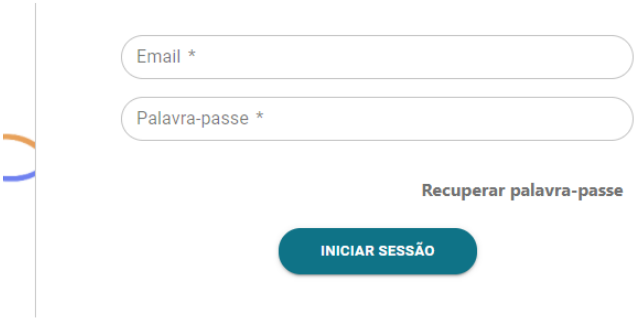


Fig. 6. Iniciar Sessão

1.2.1 Situação de erro

- No caso de o médico se enganar a escrever o e-mail ou a palavra-passe, uma mensagem de erro surgirá por baixo dos campos informando que o e-mail ou a palavra-passe é inválido - Fig.7. O mesmo acontece se tentar iniciar sessão utilizando credenciais que ainda não foram registadas.

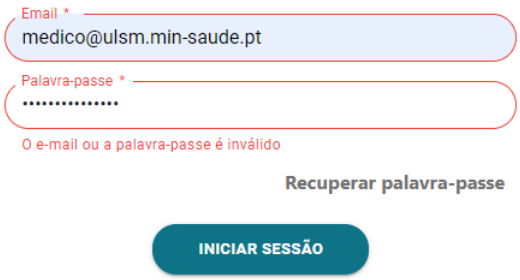


Fig. 7. O e-mail ou a palavra-passe é inválido

Para solucionar esta situação de erro, caso se tenha enganado a escrever as credenciais, deverá corrigi-las para as corretas. Caso tenha tentado iniciar sessão com credenciais que ainda não foram registadas, deverá Criar uma conta, seguindo os passos em 1.1.

1.2.2 Recuperação da palavra-passe

No caso de ter esquecido a palavra-passe, deverá selecionar "Recuperar palavra-passe", por baixo dos campos de preenchimento. Será então reencaminhado para a

página de "Recuperar a palavra-passe", onde deverá inserir o e-mail associado à sua conta. Então, será enviada uma mensagem para o e-mail inserido com a sua nova palavra-passe - Fig.8.

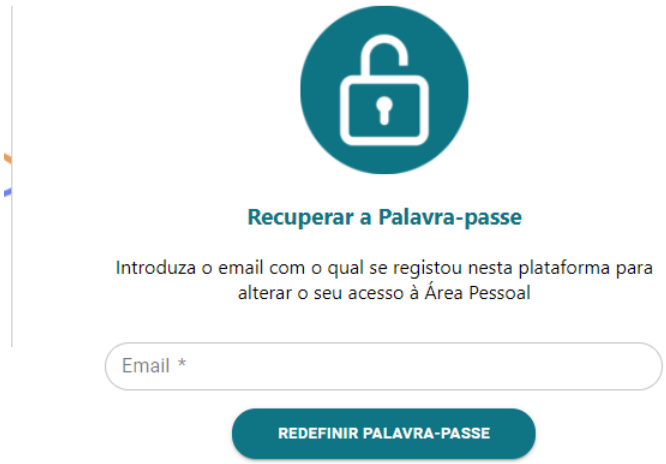


Fig. 8. Recuperar palavra-passe

Então, deverá regressar ao ecrã de Iniciar sessão e utilizar o seu e-mail e a palavra-passe que lhe foi enviada para entrar na sua conta. Esta palavra-passe poderá ser alterada, como será mostrado em 1.7.1.

Situação de erro

- No caso de o médico se enganar a escrever o e-mail ou inserir um e-mail que ainda não foi registado, uma mensagem de erro do browser informará que o e-mail inserido não existe - Fig.9.

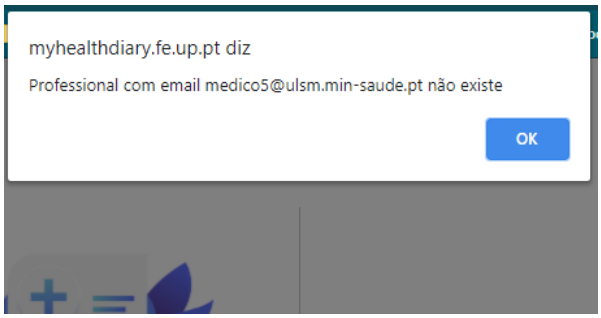


Fig. 9. Professional com email * não existe

Para solucionar, deverá corrigir o e-mail inserido.

1.3 Criar novo paciente

A criação de uma nova conta para um paciente/utilizador tem de ser efetuada pelo médico.

Para isso, o médico, na sua página principal, deve verificar que a opção "Doentes", no menu lateral, do lado esquerdo, está selecionada. Então, deve carregar no botão "Adicionar Doente", que se encontra no fundo da página, do lado direito, como se pode ver na - Fig.10. Será, então, reencaminhado para a página de criação de um doente.

Fig. 10. Adicionar um doente

O ecrã para Adicionar um paciente é mostrado em Fig.11.

Nesta página, os três campos iniciais, "Centro de Saúde", "Género" e "Email" estão assinalados com * pois são campos de preenchimento obrigatório para a criação do

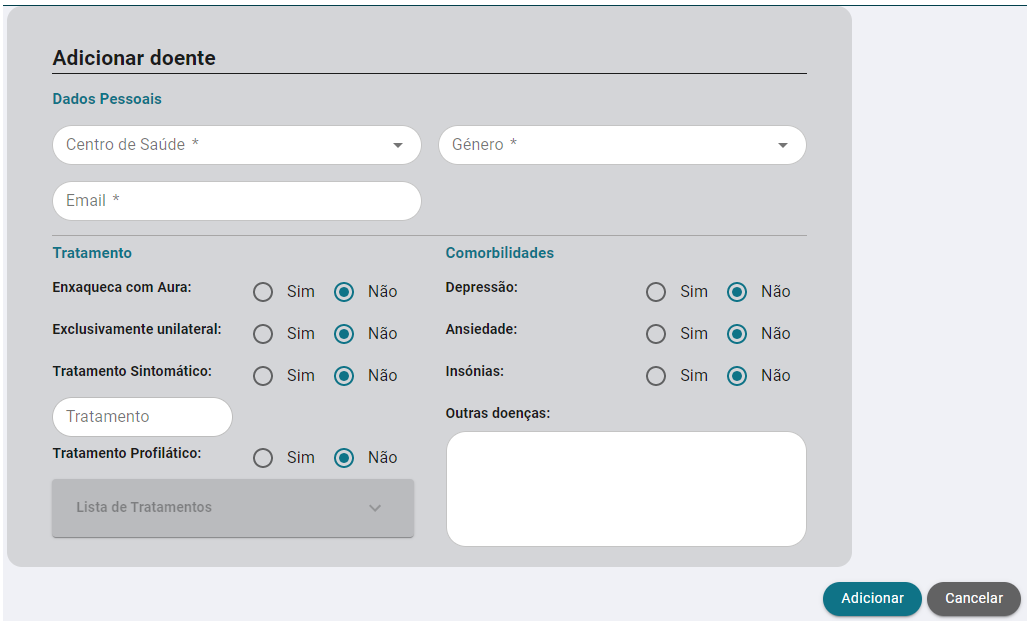


Fig. 11. Ecrã para adicionar doente

doente.

Todos os restantes dados, são de preenchimento opcional no momento da criação da conta. Têm um valor inicial de "não", e podem ser editados a qualquer momento, tanto pelo médico, como pelo paciente, na app.

O campo "Tratamento Profilático", quando está marcado com "sim" tem como campo obrigatório a descrição e a data de início do tratamento, que se encontram em "Lista de Tratamentos". É também possível adicionar mais do que um tipo de tratamento profilático, em "Adicionar Tratamento" - Fig.12.

Fig. 12. Adicionar tratamento profilático

Para finalizar a operação, é preciso carregar no botão de Adicionar, no canto inferior direito da página.

1.3.1 Situação de erro

- Caso o médico tente adicionar um paciente sem preencher o endereço de email ou sem selecionar o centro de saúde ou o género, não conseguirá concluir a ação recebendo um aviso para preencher o(s) campo(s) em falta - Fig.13.

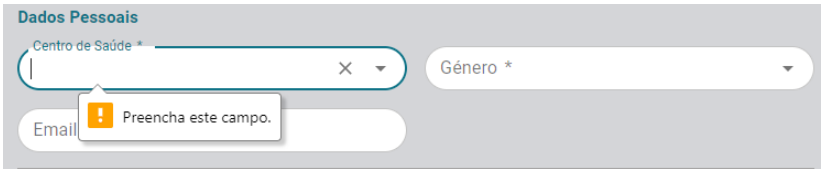


Fig. 13. Campos por preencher

- Caso o médico tenha selecionado "Sim" em "Tratamento profilático", não tenha preenchido a data de início ou a descrição deste tratamento e tente adicionar o paciente, não conseguirá, também, concluir a ação recebendo um aviso para preencher o(s) campo(s) em falta - Fig.14.

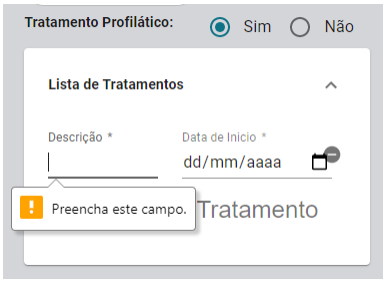


Fig. 14. Tratamento profilático por preencher

- No caso de o médico se enganar a escrever o e-mail do paciente e clicar em "Adicionar", vai conseguir concluir a ação, mas o paciente não vai ter acesso às credenciais para si criadas.

  Nesta situação, o médico terá de criar uma nova conta para o paciente, e deverá desassociar o código de paciente criado por engano da sua conta.

1.4 Associar e desassociar pacientes da conta do médico

Para associar um paciente à sua conta, o médico tem de escrever o código de identificação do doente na caixa cinzenta "Associar Doente", e clicar no botão de ✓- Fig.15.

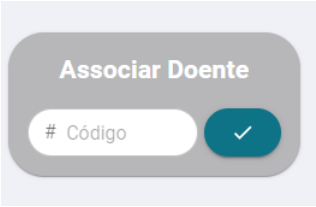


Fig. 15. Associar um doente

Para desassociar um doente da sua conta, o médico deverá localizar o doente na lista de pacientes a si associados, e clicar no último ícone da linha - Fig.16.

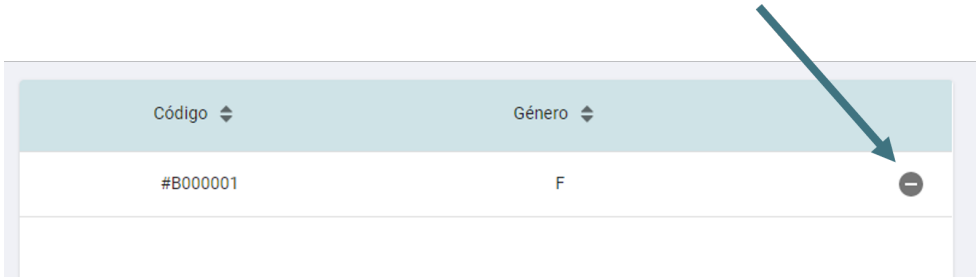


Fig. 16. Desassociar um doente

1.4.1 Situação de erro

- Caso o médico tente associar à sua conta um paciente que já lhe esteja associado, uma mensagem de erro do browser surgirá, informando que o Paciente já tinha sido adicionado anteriormente - Fig.17.

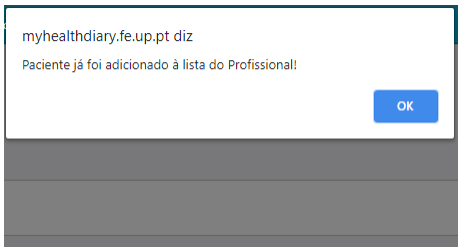


Fig. 17. Paciente já adicionado

- Caso o médico tente associar à sua conta um paciente com um código que não exista no sistema, uma mensagem de erro do browser surgirá, informando que o Paciente não existe - Fig.18.

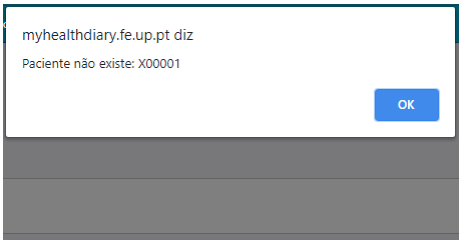


Fig. 18. Paciente não existe

1.5 Consultar dados de um paciente

Na página principal, o médico tem acesso aos doentes que estão associados à sua conta. Poderá consultar a informação respeitante a um doente, clicando no código de identificação que aparece na lista de todos os doentes a si associados. Poderá filtrar os pacientes por código de identificação, utilizando a barra de pesquisa, logo acima da lista.

Será redirecionado, assim para a página do doente. Aqui, poderá consultar um relatório relativo aos dados inseridos, comparando-o com os dados de meses anteriores, no caso de "Relatório" estar selecionado - Fig.19.

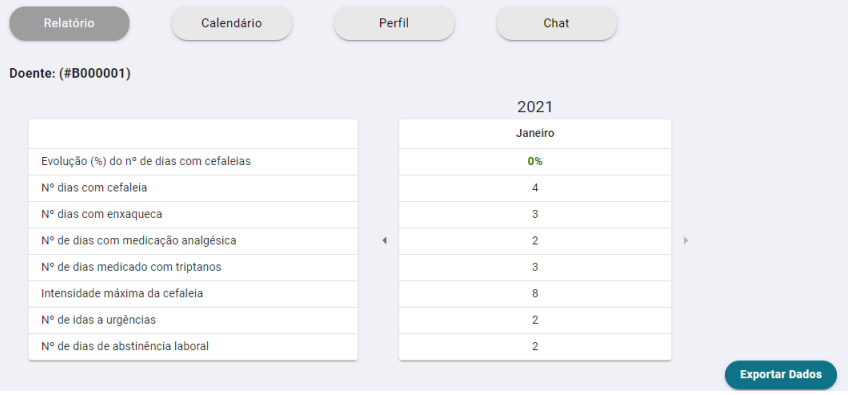


Fig. 19. Relatório

Nesta secção, o médico tem opção de exportar os dados do relatório, que serão copiados para o clipboard, e prontos a colar, no seguinte formato - Fig.20.

Poderá, também, ver os registos diários do paciente, apresentados num calendário, se "Calendário" está selecionado- Fig.21.

```
| Mês                          | 2021-01 |
| Evolução (%) nº dias cefaleias |      0% |
| Nº dias cefaleia             |       4 |
| Nº dias enxaqueca            |       3 |
| Nº dias med. analgésica      |       2 |
| Nº dias med. triptanos       |       3 |
| Intensidade máxima cefaleia  |       8 |
| Nº idas urgências            |       2 |
| Nº dias abstinência laboral  |       2 |
```

Fig. 20. Exportar dados

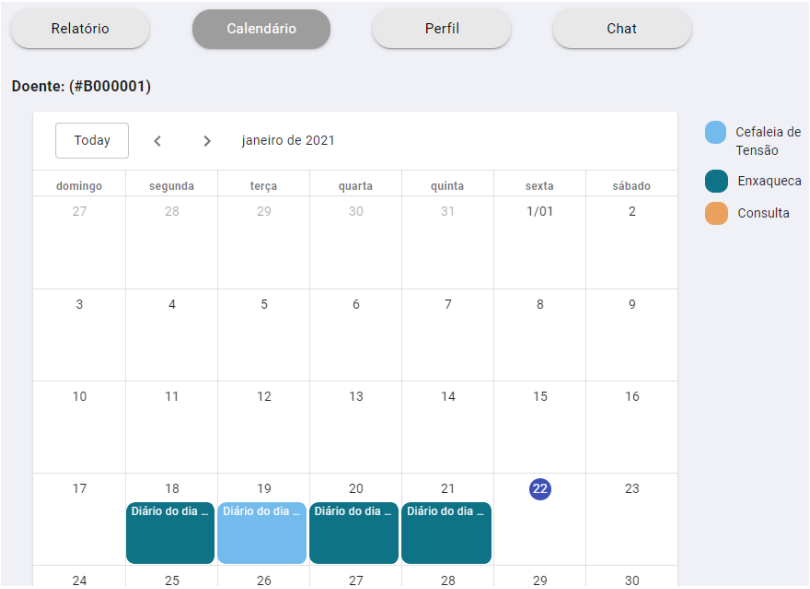


Fig. 21. Calendário

Selecionando um dia que tenha uma entrada associada, o médico poderá ver a informação registada pelo paciente, relativamente às suas cefaleias nesse dia - Fig.22.

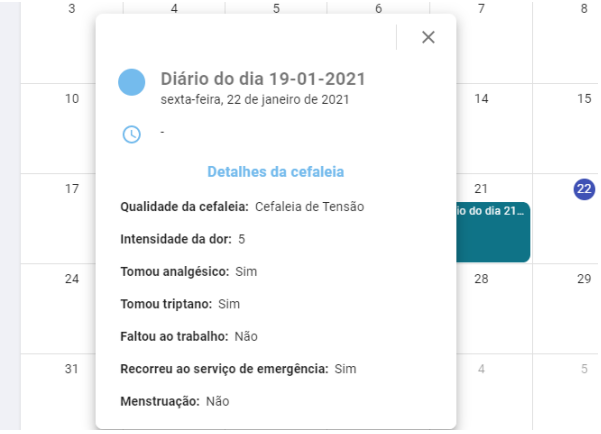


Fig. 22. Informação de cefaleia

Ainda, tem acesso ao perfil do doente, com as informações pessoais do doente, bem como o seu tratamento e comorbilidades. Estes dados podem ser editados por um médico, carregando no botão "Editar", que se encontra no canto inferior direito da página - Fig.23.

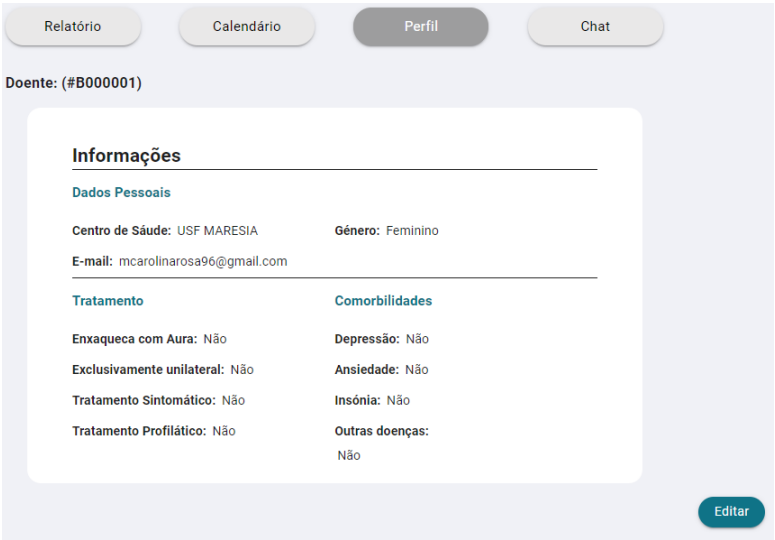


Fig. 23. Perfil

1.6 Notificações

O médico poderá receber notificações relativamente aos pacientes que tem associado à sua conta. Estas notificações poderão ser acedidas em "Notificações", na barra lateral, do lado esquerdo.

O ecrã Notificações é mostrado em Fig.24.

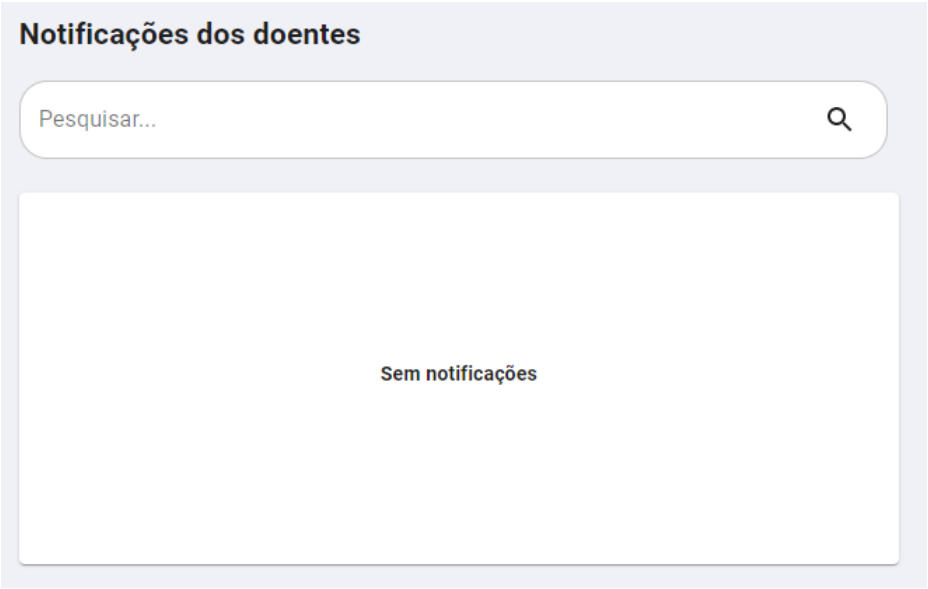


Fig. 24. Ecrã de notificações

As notificações dizem respeito ao dados preenchidos pelos pacientes relativamente às suas cefaleias. Pretendem alertar os médicos para o aumento de dias com cefaleia, aumento de dias em que o paciente faltou ao trabalho ou recorreu ao serviço de urgência, relativamente ao mês anterior.

Através da barra de pesquisa, logo acima da caixa de notificações o médico pode pesquisar as notificações por código de paciente ou por assunto da notificação, utilizando palavras da notificação, como por exemplo, "incapacidade" ou "urgência".

1.7 Editar perfil do médico

Para editar os seus dados, o médico deverá aceder a "Perfil", na barra lateral, do lado esquerdo. Será, então, redirecionado para o seu perfil pessoal. O ecrã de Perfil do médico é mostrado em Fig.25.

Deverá, então selecionar "Editar Perfil". O ecrã para Editar perfil é mostrado em Fig.26.

Fig. 25. Ecrã de Perfil

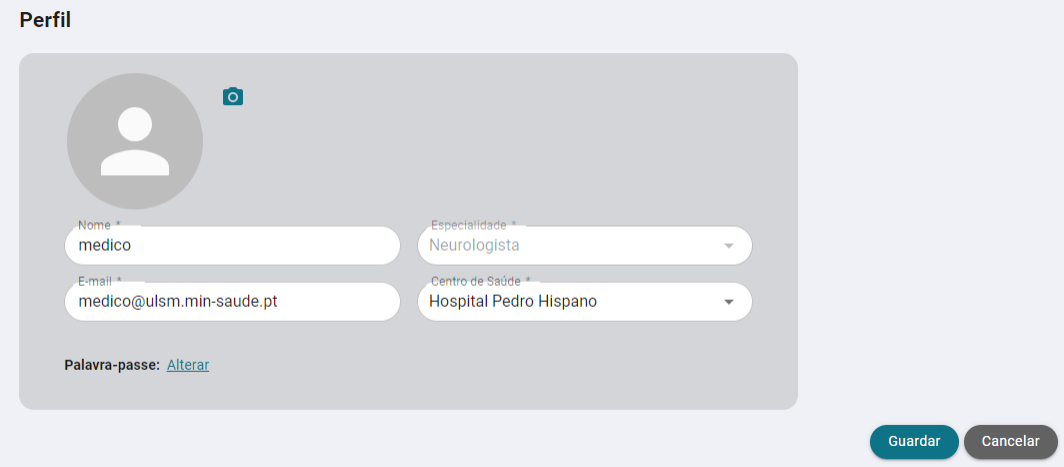


Fig. 26. Ecrã para editar perfil

Poderá, aqui, editar o seu nome, e-mail e local de trabalho, e ainda adicionar uma fotografia de perfil. Também pode editar a sua palavra-passe, ação que será explicada em 1.7.1.

Por fim, deverá carregar no botão "Guardar", no canto inferior direito, para guardar todas as alterações feitas.

1.7.1 Alterar a palavra-passe

Para alterar a sua palavra-passe, deverá clicar em Alterar, logo a seguir a "Palavra-passe:" - Fig.27.

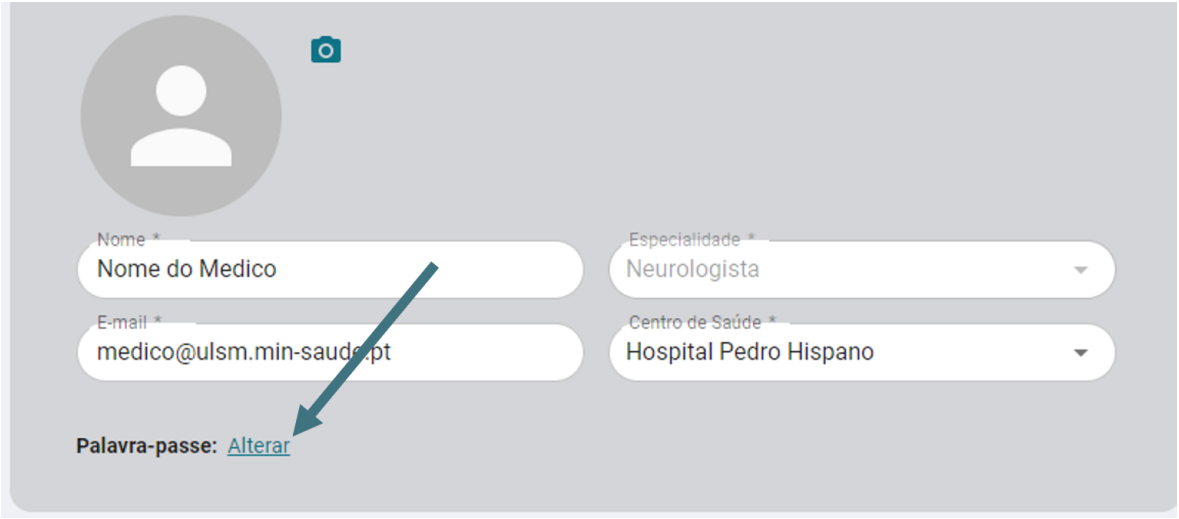


Fig. 27. Botão para alterar a Palavra-passe

Será, então, aberta uma caixa para proceder à mudança de palavra-passe, Fig.28.

Aqui, o médico deverá inserir a sua palavra-passe atual, a sua nova palavra-passe e confirmar esta última inserindo-a novamente. Para concluir o processo deverá carregar no botão "Alterar palavra-passe".

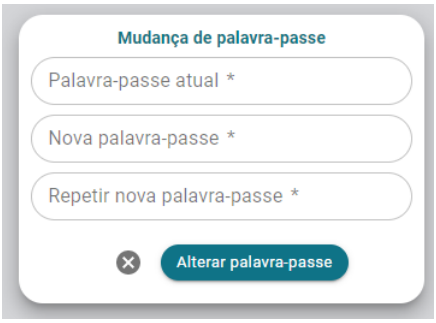


Fig. 28. Alterar Palavra-passe

1.7.2 Situações de erro

- Caso o médico tente guardar as alterações feitas no seu perfil, mas um dos campos por preencher, não conseguirá concluir a ação, e um aviso surgirá junto do campo vazio, solicitando para o seu preenchimento - Fig.29.

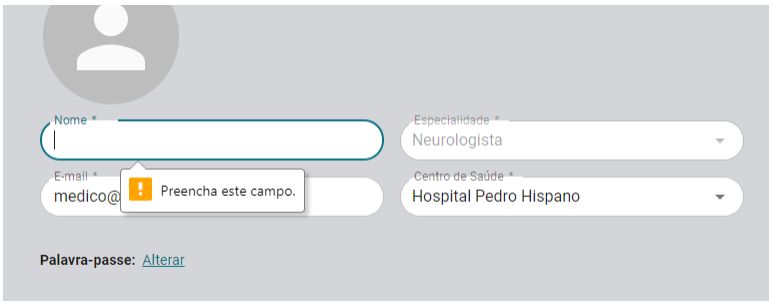


Fig. 29. Campos por preencher

- Caso o médico tente alterar a sua palavra-passe, inserindo como "palavra-passe atual" uma palavra-passe que não corresponde à correta, os campos ficarão todos a vermelho e uma mensagem surgirá abaixo informando que "a palavra-passe antiga está incorreta" - Fig.30.

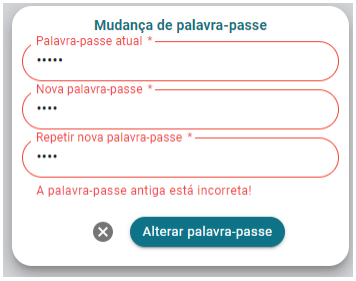


Fig. 30. Palavra-passe antiga está incorreta

- Caso o médico tente alterar a sua palavra-passe, inserindo palavras-passe diferentes nos campos "Nova palavra-passe" e "Repetir nova palavra-passe", os campos ficarão todos a vermelho e uma mensagem surgirá abaixo informando que "a nova palavra-passe e a repetida não correspondem" - Fig.31.

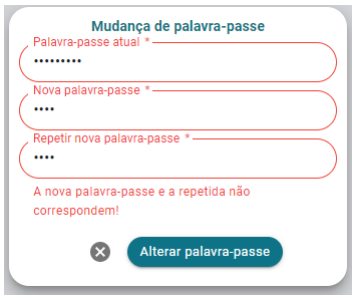


Fig. 31. Nova palavra-passe e repetida não correspondem

- Caso o médico tente alterar a sua palavra-passe, inserindo como "Nova palavra-passe" uma palavra-passe com menos de 4 caracteres, os campos ficarão todos a vermelho e uma mensagem surgirá abaixo informando que "a palavra-passe tem de ter no mínimo 4 caracteres" - Fig.32.

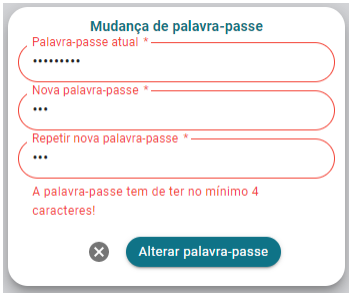


Fig. 32. Palavra-passe tem de ter no mínimo 4 caracteres

1.8 Terminar sessão

Para terminar sessão, o médico deverá aceder a "Perfil", na barra lateral, do lado esquerdo. Será, então, redirecionado para o seu perfil pessoal. Aqui deverá clicar no botão "Sair" no canto inferior direito da página - Fig.33.

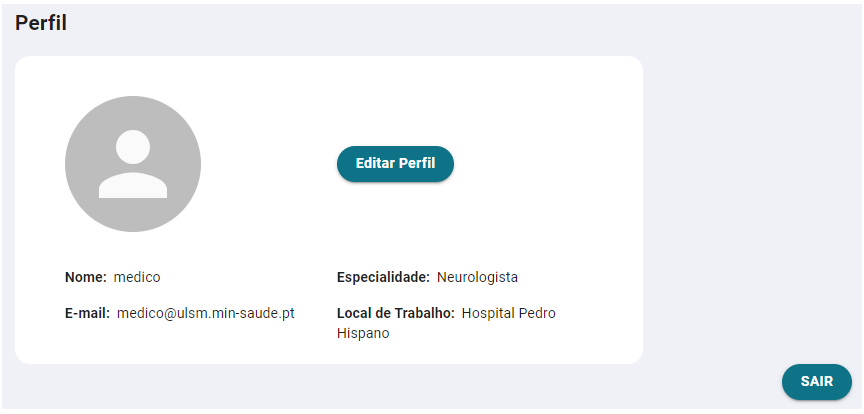


Fig. 33. Ecrã de perfil

2 Aplicação para Pacientes

A aplicação para pacientes está disponível para Smartphones Android. Para efetuar qualquer ação na aplicação é necessário ter acesso à internet. Todas as funcionalidades, dentro da aplicação, têm vídeos-tutoriais a explicar o procedimento. Estes vídeos são acessíveis sem que o paciente tenha de sair da aplicação.

2.1 Instalação da aplicação

Quando um médico adiciona um utilizador/paciente à plataforma, insere um endereço de email do paciente. O paciente receberá, então um email como o da Fig.34.

Fig. 34. E-mail com credenciais e link para download

Este email contem o link que o utilizador deverá usar para fazer o download da app, bem como as credenciais para conseguir aceder à sua conta.

Assim, a partir do telemóvel do paciente, este deverá aceder ao seu email e abrir a mensagem enviada, clicando de seguida no link que lá se encontra. Será, então, reencaminhado para uma página do browser com o conteúdo mostrado na Fig.35.

Nesta página, deverá carregar no botão "Download da App". Um ficheiro "myhealthdiary.apk" será transferido. Quando a transferência terminar, devrá selecionar

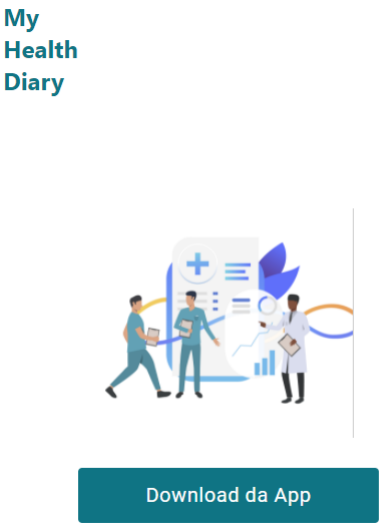
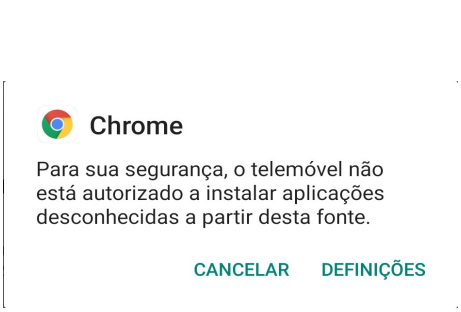


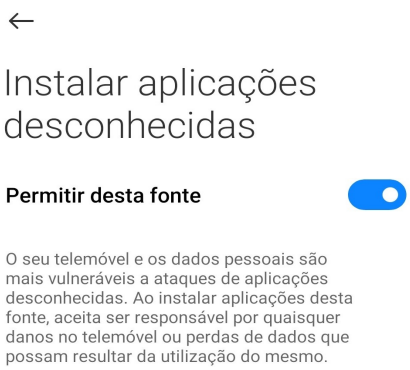
Fig. 35. Página para download da app

o ficheiro a partir do menu de notificações para proceder à instalção.

Para a instalação da app, como esta não será feita a partir do Play Store, é necessário dar permissão à aplicação do browser de forma a que se possa prosseguir. Apesar de variar de acordo com as marcas e modelos dos telemóveis, o processo passará por algo semelhante a Fig.36, sendo necessário aceder às Definições e dar permissão para instalar a aplicação a partir dessa fonte.



(a) Browser



(b) Definições

Fig. 36. Permissões para instalar a app

Com a app instalada no telemóvel o paciente pode então registar as suas cefaleias.

2.2 Guia de utilização

O guia de utilização corresponde a um conjunto de vídeos demonstrativos, criados especificamente para a aplicação My Health Diary, que pretendem mostrar ao utilizador como deve proceder de forma a usar as funcionalidades da app.

Os vídeos podem ser acedidos através da aplicação, estando ou não dentro da conta de utilizador. Também podem ser vistos a partir do Youtube, no canal My Health Diary.

Para assistir aos vídeos a partir da aplicação, deverá clicar no botão de menu, indicado na Fig.37. O menu mostrado na Fig.38 será aberto e, então deve carregar em "Guia de Utilização".

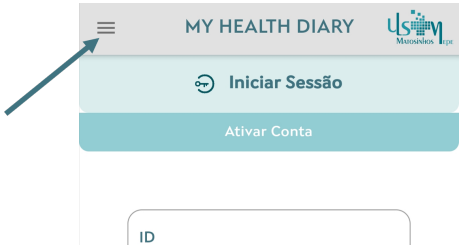


Fig. 37. Aceder ao menu

Fig. 38. Aceder ao Guia de utilização

O ecrã de Guia de utilização, mostrado na Fig.39 abrirá de seguida, e o primeiro vídeo começará a reproduzir automaticamente, seguindo a lista toda. O vídeo que está a ser reproduzido tem, à frente do seu título, na lista, o ícone de play, de forma a que o utilizador saiba qual o título a que está a assistir.

Poderá pausar a reprodução carregando no vídeo e depois no símbolo de pausa que surge por cima.

Neste ecrã, o utilizador tem a possibilidade de selecionar o vídeo que tem interesse em ver carregando num dos títulos da lista que se segue aos vídeos. Pode também passar a lista utilizando as setas, logo abaixo do vídeo. Se pretender ver os vídeos sem som, basta clicar no ícone de volume que se encontra entre as setas.

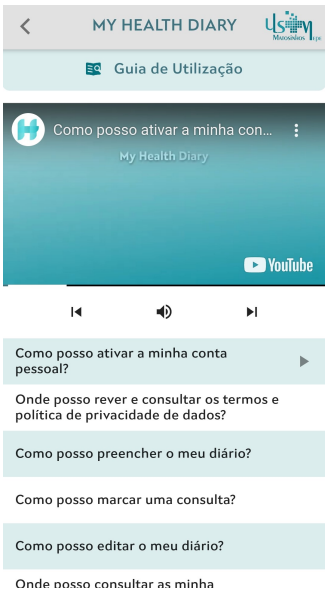


Fig. 39. Ecrã de Guia de utilização

2.3 Ativar a conta

Para que o paciente possa aceder à sua conta, a primeira ação necessária é Ativar a conta. Esta ação só é necessária na primeira vez que o paciente entra na sua conta. De forma a ativar a conta, o utilizador deve clicar em "Ativar conta" como mostra na Fig.37

Fig. 40. Botão para Ativar Conta

Será reencaminhado para a página de Ativação de conta - Fig.41.

Aqui deverá inserir as credenciais que lhe foram enviadas por email, bem como aceitar os termos de utilização e ter conhecimento e aceitar a política de privacidade. Em seguida deverá clicar no botão "Ativar Conta", sendo reencaminhado para o ecrã

seguinte onde deverá alterar a palavra-passe temporária, que lhe foi enviada por e-mail. Este ecrã é mostrado na Fig.42

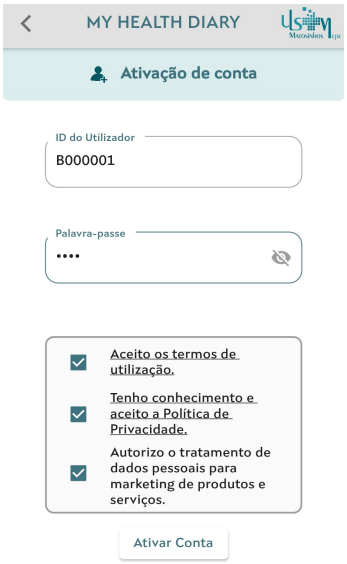


Fig. 41. Ecrã para ativar conta

Fig. 42. Ecrã para alterar palavra-passe temporária

Aqui, deverá inserir uma palavra-passe nova, que deve conter, pelo menos, 4 caracteres, e inseri-la novamente em Confirmar palavra-passe. Em seguida, deve carregar em "Continuar". O ecrã de "Conta ativada com sucesso" deverá, então, aparecer e passado alguns segundos retornar ao ecrã inicial, onde porderá iniciar sessão, com o seu ID e nova palavra-passe - Fig.43.

2.3.1 Situações de erro

- Caso o utilizador tente "Ativar conta" escrevendo credenciais erradas, diferentes das enviadas por e-mail, no Id de Utilizador e na Palavra-passe, uma mensagem de erro, aparecerá no fundo da página, dizendo "Credenciais incorretas"- Fig.44.
- Caso o utilizador tente "Ativar conta" sem ter marcado que "Aceito os termos de utilização" e "Tenho conhecimento e aceito a Política de Privacidade", a aplicação mostrará uma caixa de aviso, informando que a aceitação dos termos está em falta - Fig.45.
- Caso o utilizador, já dentro do ecrã para alterar a palavra-passe, inserir uma nova Palavra-passe que contenha menos de 4 carcteres, e emseguida "Con-

Fig. 43. Ecrã Conta ativada com sucesso

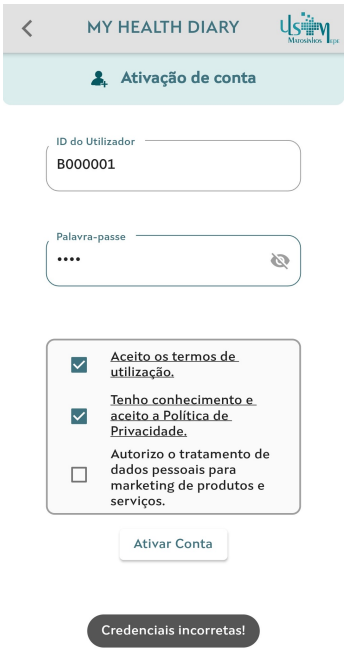


Fig. 44. Credenciais incorretas

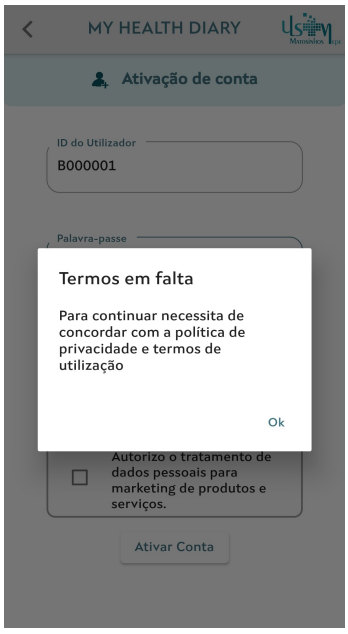


Fig. 45. Termos em falta

tinuar", uma mensagem de erro, aparecerá no fundo da página, dizendo "A palavra-passe tem de ter, no mínimo, 4 caracteres" - Fig.46.

- Caso o utilizador tente alterar a sua palavra-passe, inserindo palavras-passe diferentes nos campos "Nova palavra-passe" e "Confirmar palavra-passe", uma mensagem de erro surgirá no fundo da página, informando que "a nova palavra-passe e a repetida não correspondem" - Fig.47.

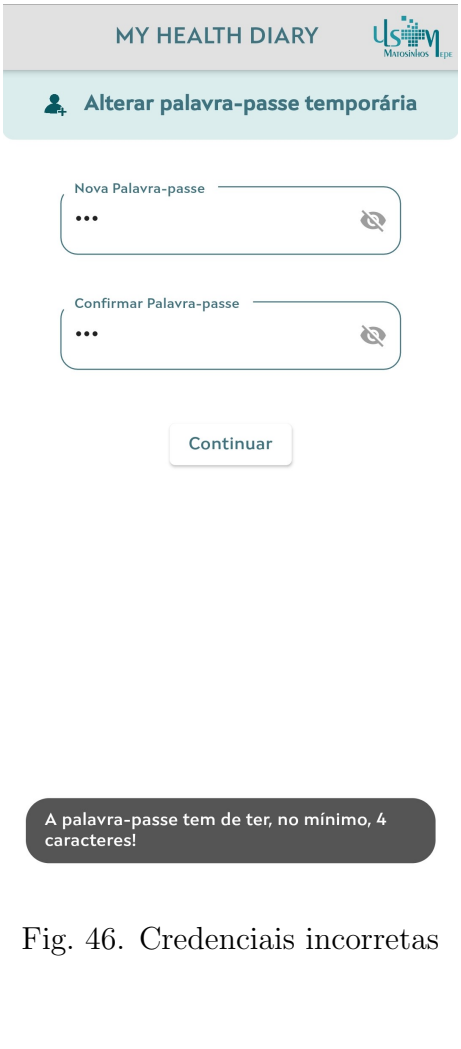


Fig. 46. Credenciais incorretas

Fig. 47. Nova palavra-passe e repetida não correspondem

2.4 Iniciar Sessão

O ecrã de iniciar sessão, é o ecrã inicial quando a app abre - Fig.48. Aqui, o utilizador poderá iniciar sessão com as suas credenciais escrevendo-as em ID e Palavra-passe e clicando em "Iniciar sessão".

Fig. 48. Ecrã Inicial

2.4.1 Situações de erro

- Caso o utilizador tente "Iniciar Sessão" sem anteriormente Ativar a sua conta, uma mensagem de erro, aparecerá no fundo da página, dizendo "Conta não ativada"- Fig.49. Deverá então proceder a Ativação da conta mostrada em 2.3.
- Caso o utilizador tente "Iniciar Sessão" escrevendo credenciais erradas no Id e Palavra-passe, uma mensagem de erro, aparecerá no fundo da página, dizendo "Credenciais incorretas"- Fig.50.

Fig. 49. Conta não ativada

Fig. 50. Credenciais incorretas

2.5 Recuperar a minha palavra-passe

No caso de o utilizador precisar de recuperar a palvra-passe, deverá clicar, na página principal, em "Recuperar Palavra-passe" como mostrado em Fig.51.

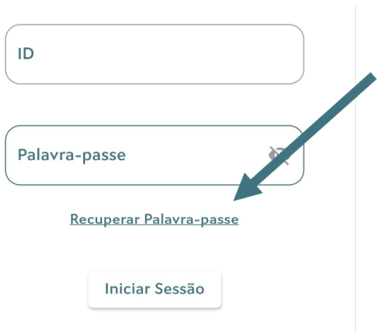


Fig. 51. Ecrã Inicial

O ecrã para recuperar palavra-passe, mostrado em Fig.52, será aberto, e aqui o utilizador deverá inserir o e-mail com o qual foi registado na aplicação, clicando em "Continuar", de seguida. O e-mail de reposição será então enviado com sucesso, mostrando o ecrã da Fig.53.

Fig. 52. Ecrã recuperar palavra-passe

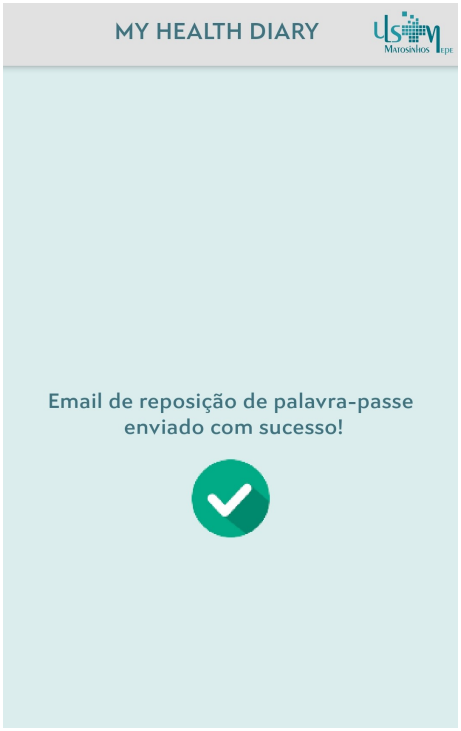


Fig. 53. Credenciais incorretas

O email que é enviado é mostrado na Fig.54.

Depois de ter recuperado a palvra-passe, poderá iniciar sessão normalmente utilizando a nova Palavra-passe que foi enviada no e-mail. Recomenda-se que o paciente troque esta palvra-passe para uma que seja mais facilmente lembrada por si - mostrado em 2.13.

2.5.1 Situação de erro

- Caso o utilizador tente "Recuperar Palavra-passe"com um e-mail diferente daquele com que foi registado, uma mensagem de erro, aparecerá no fundo da página, dizendo que o "Paciente com esse e-mail não existe"- Fig.55.

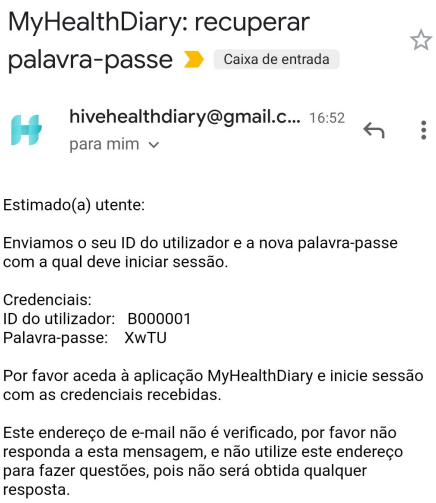


Fig. 54. E-mail para recuperar palavra-passe

Fig. 55. Paciente com email não existe

2.6 Criar registo de um diário

Para criar um diário o utilizador deverá estar no ecrã do calendário mostrado na Fig.56.

Um registo de diário só pode ser feito para o dia atual, ou para os 7 dias anteriores ao atual. Os dias que já passaram e para o qual não foi registado um diário encontram-se a vermelho. Os dias que têm um diário registado são marcados com um ponto por baixo do dia.

Na Fig.56, o dia marcado com um círculo, é o dia selecionado, o que significa que ao clicar em "+ Diário" estaremos a marcar um registo de diário para o dia 3 de fevereiro de 2021. Se o utilizador pretender registar um diário para o dia 2 de fevereiro, por exemplo, deverá carregar no dia 2, que ficará selecionado com o círculo, e depois clicar em "+ Diário".

Fig. 56. Calendário

Ao clicar em "+ Diário", o questionário para criação de diário é aberto e é composto por 7 questões divididas por 3 páginas.

Fig. 57. Pág1 questionário cefaleia

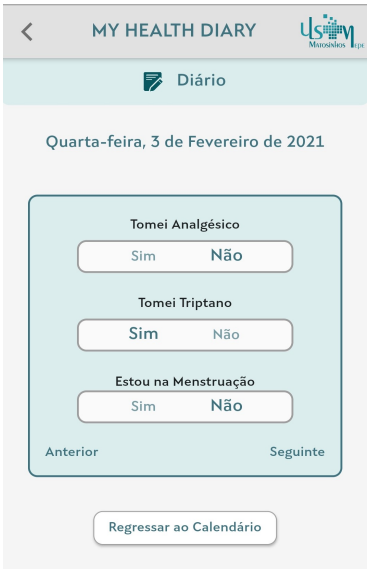


Fig. 58. Pág2 questionário cefaleia

A primeira página do questionário - Fig.57, diz respeito ao tipo de dor de cabeça que o utilizador sentiu nesse dia e a respetiva intensidade. A opção selecionada está num tom mais carregado e com um tamanho de letra maior. A intensidade deve ser selecionada, numa escala de 1 a 10, de acordo com as caras mostradas, sendo que a intensidade selecionada ficará com um tamanho maior relativamente às outras. Depois de selecionar a qualidade e intensidade da cefalei sentida, o utilizador deverá clicar em "Seguinte" para passar para a próxima página, mostrada em Fig.58.

Aqui, o utilizador deverá selecionar "Sim" ou "Não" para a toma de Analgésico, Triptano, e, caso seja uma mulher, se se encontra na menstruação. Em seguida, deverá clicar em "Seguinte" para passar para a próxima página, mostrada em Fig.59, na qual o utilizador deverá, também, selecionar "Sim" ou "Não" para ter faltado ao trabalho e ter ido às urgências. Depois de ter respondido, deverá clicar em "Finalizar" para concluir o registo. Será, então reencaminhado para a página do calendário, com uma mensagem de "Registo Adicionado com sucesso!" como mostrado na Fig.60.

No calendário, o dia ao qual foi adicionado um registo ficará marcado com um ponto por baixo.

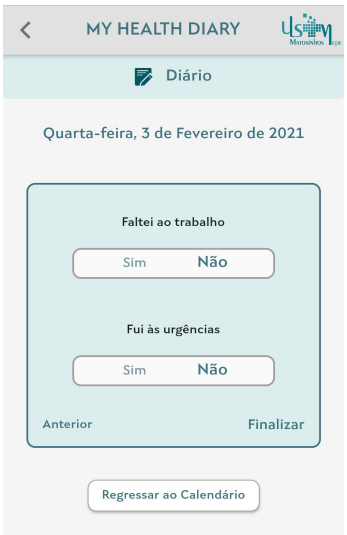


Fig. 59. Pág3 questionário cefaleia

Fig. 60. Registo adicionado com sucesso

2.7 Consultar diário

Para consultar uma entrada num diário, o utilizador deverá selecionar um dia que tenha um registo, isto é, que esteja assinalado com ponto, e em seguida deverá clicar em "Ver diário", por baixo do calendário - Fig.61. Então, passará para o ecrã de ver diário, mostrado na Fig.62.

Fig. 61. Calendário com registos

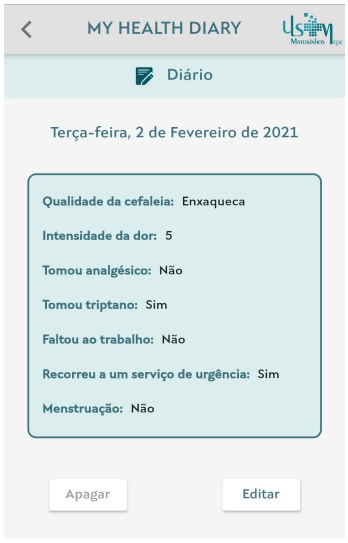


Fig. 62. Consultar um diário

2.7.1 Editar e apagar entrada no diário

A partir do ecrã Ver diário mostrado na Fig.62, duas opções estão disponíveis para o diário mostrado, editá-lo e apagá-lo.

Se o utilizador pretende editar o diário, deverá clicar no botão "Editar", por baixo da caixa que mostra o registo. Ao clicar será reencaminhado, novamente, para o questionário preenchido na criação do diário, devendo proceder da mesma forma.

Se o utilizador pretende apagar a entrada do diário, , deverá clicar no botão "Apagar", também, por baixo da caixa que mostra o registo. ao clicar, uma caixa surgirá para confirmar que pretende apagar o registo do diário - Fig.63.

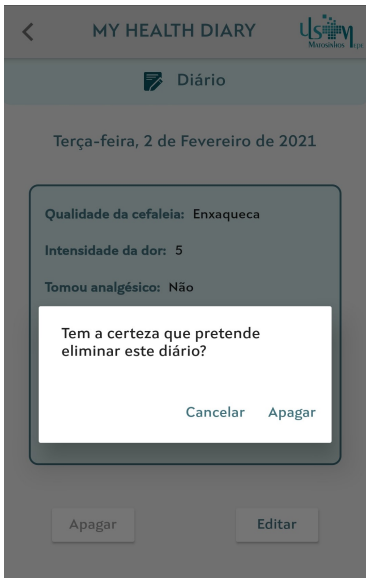


Fig. 63. Apagar diário

2.8 Criar registo de uma consulta

Para criar uma consulta, o utilizador deverá estar no ecrã do calendário mostrado na Fig.64.

Fig. 64. Calendário

Uma consulta só pode ser agendada para dias futuros.

Na Fig.64, o dia marcado com um círculo, dia 12, é o dia selecionado. Pode verificar-se que, onde antes dizia "+ Diário", diz agora "+ Consulta". Isto porque, o dia selecionado, é um dia futuro. Se o utilizador pretender agendar uma consulta para o dia 14 de fevereiro, por exemplo, deverá carregar no dia 14, que ficará selecionado com o círculo, e depois clicar em "+ Consulta".

Ao clicar em "+ Consulta", o questionário para criação de consulta é aberto. Este é composto por 5 questões, como mostrado na Fig.65.

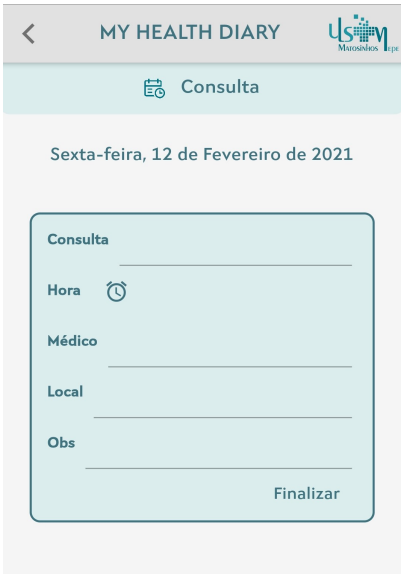


Fig. 65. Questionário consulta

Fig. 66. Hora da consulta

Aqui, o utilizador deverá preencher os campos de texto com os dados relativos à sua consulta. Para registar a hora da consulta, deverá clicar no ícone do relógio e um relógio como o da .66 surgirá na página. Quando tiver preenchido os campos, o paciente deverá clicar em "Finalizar" para concluir o registo. Será, então reencaminhado para a página do calendário, com uma mensagem de "Consulta adicionada com sucesso!" como mostrado na Fig.67.

No calendário, o dia ao qual foi adicionado um registo ficará marcado com um ponto por baixo.

Fig. 67. Consulta adicionada com sucesso

2.9 Consultar Consulta

Para consultar uma consulta, o utilizador deverá selecionar um dia do futuro que tenha um registo, isto é, que esteja assinalado com ponto, e em seguida deverá clicar em "Ver consulta", por baixo do calendário - Fig.68. Então, passará para o ecrã de ver consulta, mostrado na Fig.69.

2.9.1 Editar e apagar consulta

A partir do ecrã Ver consulta mostrado na Fig.69, duas opções estão disponíveis para a consulta mostrada, editar e apagar.

Se o utilizador pretende editar a consulta, deverá clicar no botão "Editar", por baixo da caixa com os dados da consulta. Ao clicar será reencaminhado, novamente, para o questionário preenchido na criação da consulta, devendo proceder da mesma forma.

Se o utilizador pretende apagar a consulta, , deverá clicar no botão "Apagar", também, por baixo da caixa com os dados da consulta. Ao clicar, uma caixa surgirá para confirmar que pretende apagar a consulta - Fig.70.

Fig. 68. Calendário com registos

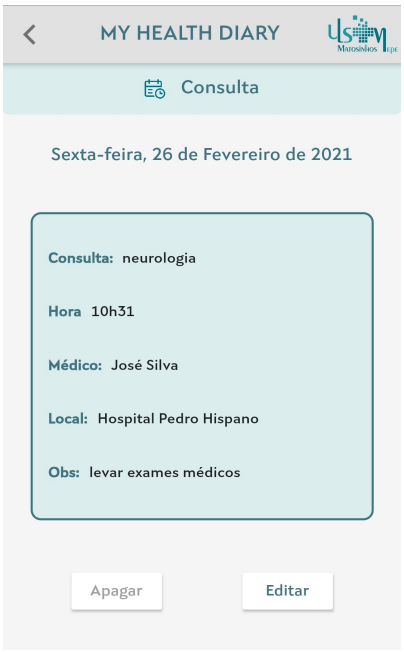


Fig. 69. Consultar uma consulta

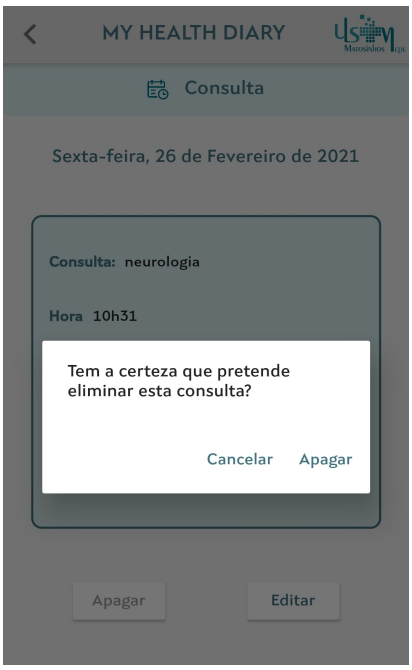


Fig. 70. Apagar consulta

2.10 Consultar notificações

Para consultar as suas notificações, o paciente deverá clicar no botão de menu, indicado na Fig.71. O menu mostrado na Fig.72 será aberto e, então deve carregar em "Notificações".

Fig. 71. Aceder ao menu

O ecrã mostrado na Fig.73 será então aberto. Aqui estão registadas todas as notificações que um utilizador recebeu durante o período de um mês. Estas notificações dizem respeito a não preenchimento de diários por mais de 3 dias, excesso de medicação, triptanos e analgésicos, e também agendamento de consultas.

Fig. 72. Aceder às notificações

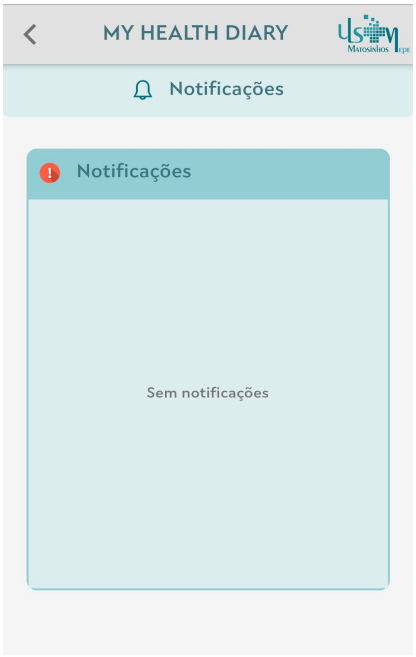


Fig. 73. Ecrã de notificações

2.11 Consultar o meu perfil

Para consultar o seu perfil, o paciente deverá clicar no botão de menu, Como mostrado em 2.10, o que abrirá o menu. Mas desta vez, o paciente deve carregar em "Perfil".

O ecrã do perfil divide-se em duas secções, "Dados pessoais" e "Dados de conta" - Fig.74 e Fig.75.

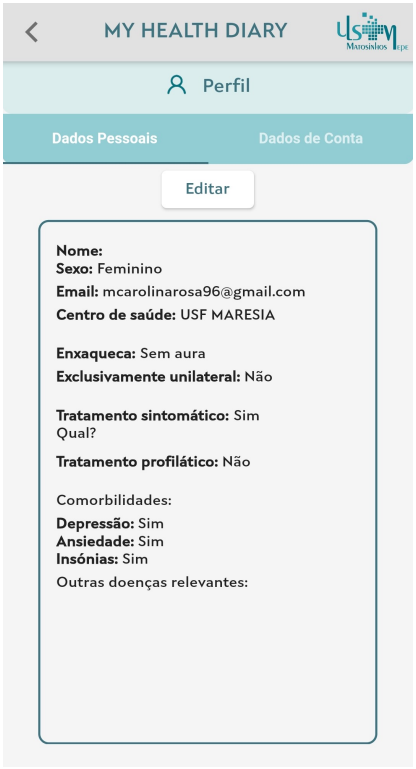


Fig. 74. Dados Pessoais

Fig. 75. Dados de Conta

2.12 Editar o meu perfil

Se o utilizador pretende editar o seu perfil, deve dirigir-se ao ecrã de perfil, secção de "Dados Pessoais". Aqui, o utilizador deve clicar no botão "Editar" que aparce no topo do ecrã.

Será, então, reencaminhado para o ecrã de editar perfil. Este divide-se em 3 separadores, "Pessoal" - Fig.76, "Tratamento" - Fig.77, e "Comorbilidades" - Fig.78.

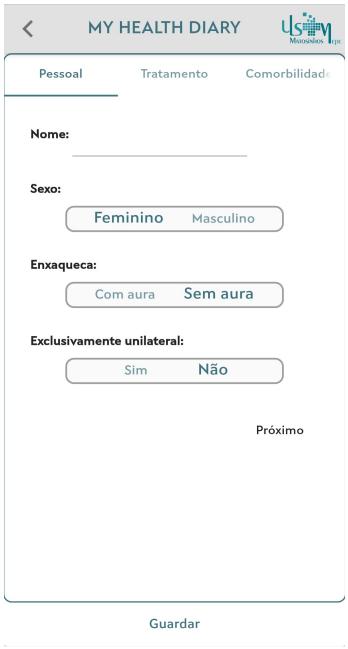


Fig. 76. Editar Pessoal

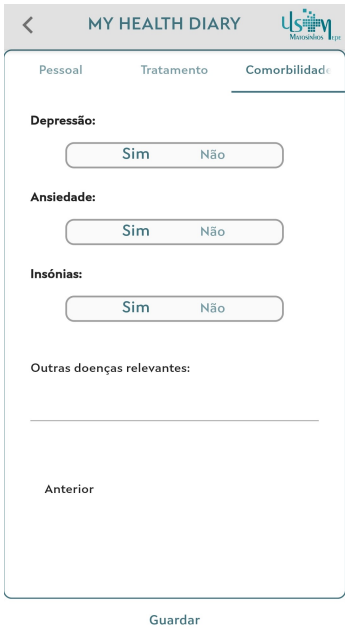


Fig. 78. Editar Comorbilidades

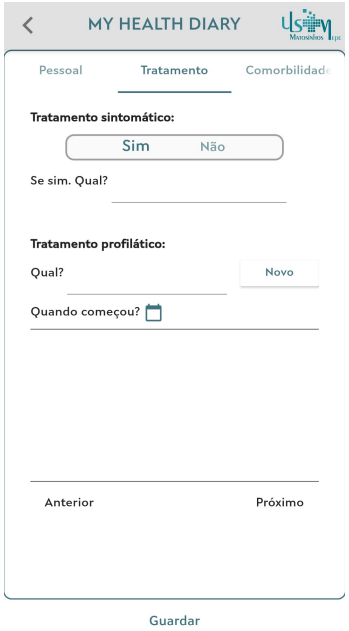


Fig. 77. Editar Tratamento

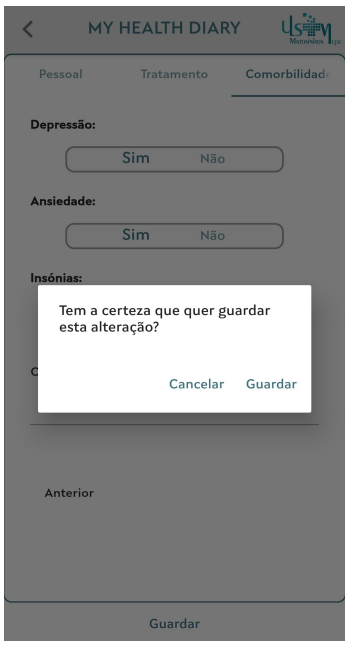


Fig. 79. Guardar alterações

Nestes ecrãs, o utilizador deve editar o seu perfil de acordo com a sua realidade. Quando terminar, deve carregar em "Guardar", no fundo da página. Uma caixa para confirmar que pretende guardar as alterações surgirá - 79, devendo o paciente clicar em "Guardar".

Se o utilizador entrou no ecrã de alterar perfil, fez alterações mas não pretende guardá-las, deverá retroceder no ecrã, clicando na seta que se encontra no topo esquerdo. Uma caixa com mensagem surgirá no ecrã informando que as alterações não serão guardadas - 80, ao que o utilizador deve carregar em "Continuar", regressando ao ecrã de Perfil, sem as alterações.

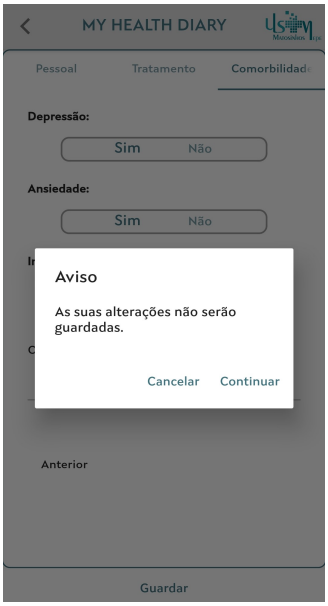


Fig. 80. Cancelar alterações

2.13 Alterar a minha palavra-passe

Se o utilizador pretende alterar a sua palavra-passe, deve dirigir-se ao ecrã de perfil, secção de "Dados de Conta" - Fig.75. Aqui, o utilizador deve clicar no botão "Alterar Password".

O ecrã para alterar a Palavra-passe será aberto - Fig.81.

Aqui, o paciente deverá inserir a sua palavra-passe atual, a sua nova palavra-passe e confirmar esta última inserindo-a novamente. Para concluir o processo deverá carregar no botão "Alterar password".

Fig. 81. Alterar Palavra-passe

2.13.1 Situações de erro

- Caso o paciente tente alterar a sua palavra-passe, inserindo como "palavra-passe atual" uma palavra-passe que não corresponde à correta, uma mensagem surgirá no fundo do ecrã informando que "a palavra-passe antiga está incorreta" - Fig.82.

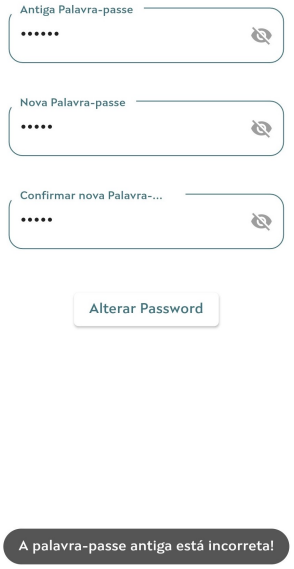


Fig. 82. Palavra-passe antiga está incorreta

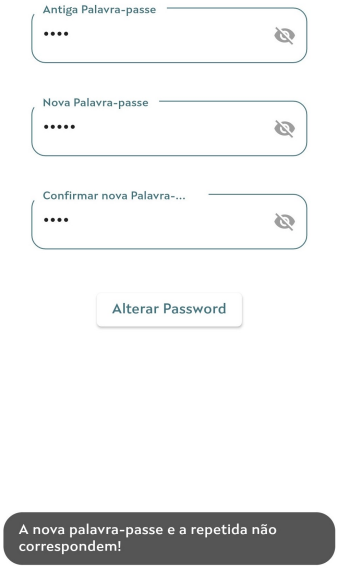


Fig. 83. as 2 palavra-passe não correspondem

- Caso o paciente tente alterar a sua palavra-passe, inserindo palavras-passe diferentes nos campos "Nova palavra-passe" e "Confirmar nova palavra-passe", uma mensagem surgirá no fundo da página informando que "a nova palavra-passe e a repetida não correspondem" - Fig.83.
- Caso o paciente tente alterar a sua palavra-passe, inserindo como "Nova palavra-passe" uma palavra-passe com menos de 4 caracteres, ouma mensagem surgirá no fundo da página informando que "a palavra-passe tem de ter no mínimo 4 caracteres" - Fig.84.

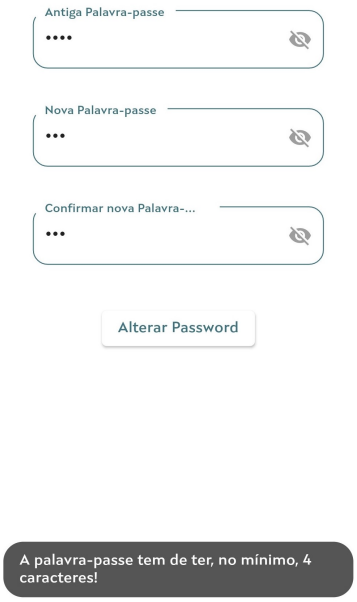


Fig. 84. Palavra-passe tem de ter no mínimo 4 caracteres

2.14 Apagar a minha conta

Para o utilizador apagar a sua conta deverá aceder ao Perfil, clicando de seguida em Dados de Conta - Fig.85 . Pode então carregar no botão "Apagar Conta", sendo reencaminhado para o ecrã da Fig.86. Aqui, poderá cancelar a operação, caso não pretenda realmente apagar a conta, ou pode apagar a conta clicando em "Apagar Conta", tendo em atenção que esta ação é irreversível e todos os dados relativos ao paciente serão apagados.

Fig. 85. Ecrã Dados de Conta

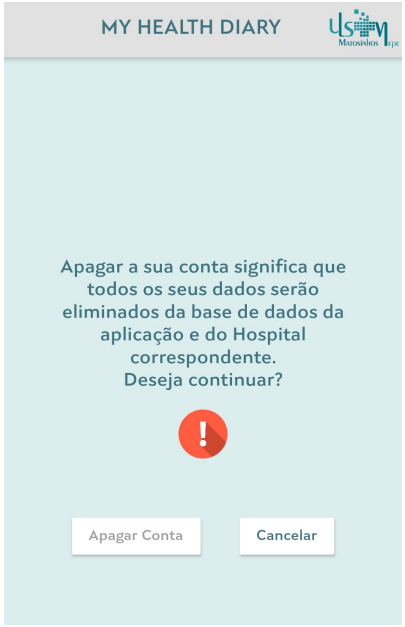


Fig. 86. Apagar Conta

2.15 Consultar a política de privacidade

Para consultar a política de privacidade deverá clicar no botão de menu, indicado na Fig.87. O menu mostrado na Fig.88 será aberto e, então deve carregar em "RGPD".

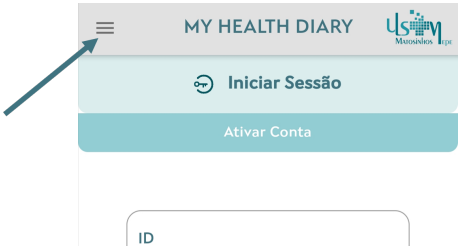


Fig. 87. Aceder ao menu

Fig. 88. Aceder a RGPD

O ecrã com a política de Privacidade e Termos de Utilização é então aberta, como

mostrado na Fig.89

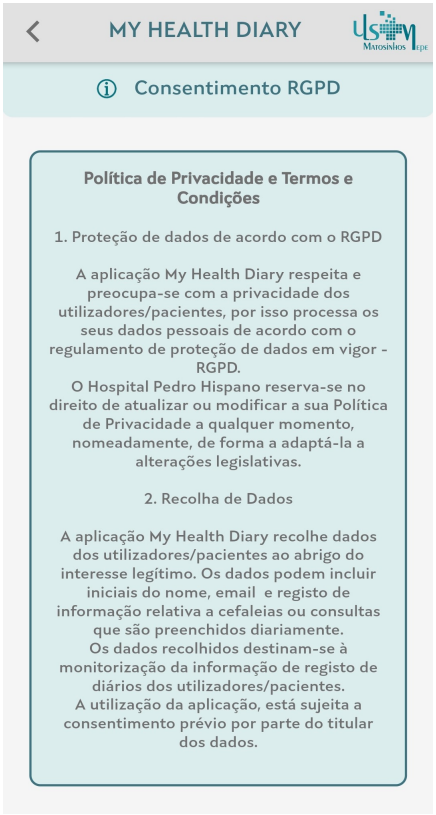


Fig. 89. Ecrã Política de Privacidade

2.16 Sem internet

A app necessita de ter acesso à internet para executar qualquer funcionalidade. Caso o utilizador tente concluir uma funcionalidade sem que tenha acesso à internet, a seguinte mensagem surgirá no fundo do ecrã - Fig.90

Fig. 90. Sem internet

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