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MIM

A prototype to promote patient empowerment using audit trails

Sandra Marisa Vieira Reis

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INFORMÁTICA MÉDICA
2º CICLO DE ESTUDOS

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“Without leaps of imagination, or dreaming, we lose the excitement of possibilities.

Dreaming, after all, is a form of planning.”

Gloria Steinem

Acknowledgments

First and foremost, thank you to my supervisor, PhD Ricardo Correia, for trusting and believing in me, for his guidance during the course of this work, for his criticism and advice and for his friendship.

I would specially like to acknowledge PhD Ana Margarida Ferreira, the co-supervisor of this work, whose availability and help whenever I requested, expertise and understanding were essential in accomplishing this work. As well as my co-supervisor, PhD Pedro Marques for the criticisms and advice, above all, by stimulating and helping to achieve this project.

I would also like to thank the help of my mentor in Healthy Systems Cátia Pereira for her motivation, advice and understanding that allowed me to do a better work. A special word of appreciation to all of my colleagues in Healthy Systems for their support and help, and the company for the theme and the support provided. A thank you to all of those who helped me in my dissertation by responding to the questionnaire sent and by participating in the evaluation of the prototype.

Finally, I would like to thank all my friends that supported me when I needed the most and who have always accompanied and encouraged me to fulfill my dreams and goals. And last but not least to my parents and all the family members for all the confidence, support and encouragement, because without them none of this would be possible.

Abstract

Personal Health Information (PHI) is collected and used by multiple health professionals and multiple information systems, and usually the patient does not know who accesses their information, when and for what purposes. According to United States of America (HIPAA) and European Union legislation (GDPR) a patient has the right to see his/her clinical information and to know who has access to it, however, the process of obtaining all this related information is still time consuming and complicated. Our aim is to allow the patient an easier access to the information that he/she is entitled to, providing patient empowerment.

In the first stage of the dissertation we conducted a study to the students of the University of Porto on the interest that they would have in having access to a tool that showed them which professionals of the health institutions acceded their PHI. The results of the study show that although the vast majority of participants did not have great knowledge about the current legislation (81%), half do not know about the use of their data (52%) nor which professionals access that data (53%), and more than 90% consider important the existence of a tool to view who accessed their health information.

Based on the result of the previous study, the motivation is to create a tool that aligns itself with the needs imposed by the legislation and the opinion and interest of the patients. We created personas, scenarios and use cases for a tool that allows patients the possibility to know who, when and where professionals had access to their information. The idealized tool is called MyRegister and is based on an audit trail, HS.Register, developed by Healthy Systems, which collects information from health information systems. We defined a set of requirements that we consider fundamental to the success of MyRegister and based on them we created a functional prototype focused on the usability of the interface to be pleasing and easy to use to all its users.

We consider important to evaluate the functional prototype with real users before starting the development of the tool to try to avoid, to the maximum, serious usability problems that require many modifications during the development phase. We created an evaluation instrument consisting of 4 tasks, a SUS questionnaire and a demographic information questionnaire that allowed us to evaluate the MyRegister interface of the prototype by the participants. The results of the evaluation of the prototype allowed us to identify some of the major usability problems of the interface. However, SUS score of 79.5 in 100 is a result that shows good usability. Regarding the tasks performed, all were completed by the participants but not all of them answered correctly to the questions asked. After correcting the problems found and implementing the suggestions of the participants that we consider permissible to include, we intend to continue this project with the development of the tool.

With the completeness of the dissertation we feel confident that the tool will be an asset for patients, health institutions and an advance for the compliance with GDPR in Portugal.

Key-words: Personal health information; Patient empowerment; Audit trail; GDPR; Usability.

Resumo

As informações de saúde pessoais são recolhidas e utilizadas por vários profissionais de saúde e múltiplos sistemas de informação, sendo que habitualmente o paciente não sabe quem acede às suas informações, quando e quais os fins do acesso. De acordo com a legislação em vigor nos Estados Unidos da América (HIPAA) e na União Europeia (GDPR), um paciente tem o direito de ver as suas informações clínicas e saber quem tem acesso a elas, no entanto, o processo para o paciente obter estas informações é geralmente demorado e complicado. Nós temos como objetivo permitir ao paciente o acesso mais fácil às informações que lhe são de direito, proporcionando o empoderamento ao paciente.

Numa primeira fase da dissertação realizamos um estudo aos estudantes da universidade do Porto sobre o interesse que estes teriam em ter acesso a uma ferramenta que lhes mostrasse que profissionais das instituições de saúde acedem às suas informações pessoais de saúde. Os resultados deste estudo mostraram que apesar da maioria dos participantes não terem mostrado conhecimento na existência da legislação em vigor (81%), nem terem conhecimento de como são usados os seus dados de saúde (52%), nem que profissionais os acedem (53%), 90% deles consideraram que seria importante a existência de uma ferramenta que lhes permitisse saber quem e quando acederam às suas informações de saúde nas instituições.

Partindo do resultado do estudo anterior ganhamos motivação para idealizar a criação de uma ferramenta que se aliasse às necessidades impostas pela legislação, e à opinião e interesse dos pacientes. Criámos personas, cenários e casos de uso para uma ferramenta que permitisse aos pacientes a possibilidade de saberem quem, quando e onde os profissionais tinham acedido às suas informações. A ferramenta idealizada chama-se MyRegister e tem por base um audit trail, o HS.Register, desenvolvido pela empresa Healthy Systems que recolhe a informação a partir dos sistemas de informação das instituições de saúde. Definimos um conjunto de requisitos que consideramos fundamentais para o sucesso do MyRegister e com base nos mesmos criamos um protótipo funcional com foco na usabilidade da interface para ser agradável e fácil de usar para todos os seus utilizadores.

Consideramos fundamental avaliar o protótipo funcional com utilizadores reais antes de começar o desenvolvimento da ferramenta para tentar evitar ao máximo graves problemas de usabilidade que exijam muitas modificações durante a fase de desenvolvimento. Criámos um instrumento de avaliação constituído por 4 tarefas, um questionário SUS e um questionário de informação demográfica que nos permitiu avaliar o interface do MyRegister através da utilização do protótipo por parte dos participantes. Os resultados da avaliação do protótipo permitiram identificar alguns dos maiores problemas de usabilidade da interface, embora no SUS os resultados tenham sido de 79.5 em 100 sendo considerado um resultado que revela boa usabilidade. Relativamente às tarefas executadas, todas foram completas pelos participantes no entanto nem todos responderam corretamente às questões feitas. Após as correções terminadas dos problemas

encontrados e da implementação das sugestões dos participantes que consideramos permitentes de incluir, pretendemos continuar este projeto com o desenvolvimento da ferramenta. Com a completude desta dissertação sentimo-nos confiantes que a ferramenta idealizada pode ser uma mais-valia para os pacientes e as instituições de saúde para além de contribuir para o avanço no cumprimento da legislação.

Palavras-chave: Informações de saúde pessoais; Empoderamento do paciente; Audit trail; GDPR; Usabilidade.

Preamble

My name is Sandra Reis, I'm 23 years old and I joined the Master's degree in Medical Informatics in 2016, which I'm concluding with this dissertation. My academic career began in 2013 with a degree in Bioengineering at the University of Beira Interior, which I concluded in July 2016. Throughout the degree I gained a particular interest for the area of informatics applied to health. In the final project of the degree I was able to put this interest into practice, and I published my first scientific paper entitled "Elderly mobility analysis during Timed Up and Go test using biosignals". When I graduated I felt the need to improve my knowledge in the area of health informatics and decided to join the Master's degree in Medical Informatics at the Faculty of Medicine of the University do Porto (FMUP).

In 2016, the possibility of working for Healthy Systems, a spin-off of the University of Porto with a focus on computer security in the hospital environment, appeared. Over the last 2 years I have been working as a Functional Consultant at Healthy Systems and I have been improving my knowledge through different projects. One of the most prominent projects in which I participated was the ODISSEIA project - Oncology Disease Information System [POCI-05-5762-FSE-039021] in which we had the opportunity to make an extensive survey of the functional processes of a large oncology hospital, systematization of processes based on the BPMN methodology, and the execution of requirements documents for numerous hospital information systems. Currently I collaborate in project management at the final phase of the project, in which I can follow the development of the information systems from which we elaborate the requirements. In other projects I surveyed the functional processes of hospital services and provided health institutions with recommendations based on their current situations and recommended international standards such as Integrating the Healthcare Enterprise (IHE). I have also been involved in the planning and design of company products having responsibilities such as: production of functional mockups, production of requirements documents, among others.

The last two years allying the MSc in Medical Informatics and the functions performed at Healthy Systems have given me more knowledge in the area of health informatics and even more interest in learning and contributing in the best way possible to patients' health care in Portugal.

Scientific Results

The outcomes of the work described in this thesis were published in the following article:

S. Reis, A. Ferreira, P. Vieira-Marques, C. Santos-Pereira and R. Cruz-Correia, "Do patients want to know who accesses their personal health information?: A questionnaire to university students," 2018 13th Iberian Conference on Information Systems and Technologies (CISTI), Caceres, 2018, pp. 1-6.

At the date of delivery of this dissertation, the article was accepted and presented at CISTI that took place between 13 to 16 June 2018. The full article is presented in annex 7.1.

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Acronyms

CRUD Create, Read, Update and Delete

CPR Cardiopulmonary resuscitation

DNR Do-Not-Resuscitate

DPO Data protection officers

EPF European Patients' Forum

EHR Electronic Health Record

FMUP Faculty of Medicine of the University do Porto

GDPR General Data Protection Regulation

HIPAA Health Insurance Portability and Accountability Act

HL7 Health Level 7

IAPP International Association of Privacy Professionals

NHS National Health Service

PHI Personal Health Information

PDS Plataforma de Dados de Saúde

PDS-PU Plataforma de Dados de Saúde - Portal do Utente

PDS-PP Plataforma de Dados de Saúde - Portal do Profissional

PDS-EPSOS Plataforma de Dados de Saúde - Portal Internacional

PDS-PI Plataforma de Dados de Saúde - Portal Institucional

PHR Personal Health Records

SMS Short Message Service

SUS System Usability Scale

UML Unified Modeling Language

W3C World Wide Web Consortium

WHO World Health Organization



Introduction

1. Introduction

Each patient who is treated at a health care facility has their health information stored. This information allows healthcare professionals to always give the best possible treatment to their patients. However, the patient has the right to have his/her Personal Health Information (PHI) kept private under local and international regulations and legislation and this is also an obligation of health professionals at least since the beginning of the Hippocrates Oath. Therefore, no one should have access to a patient's health information without his/her authorization (Annas and Others, 2003).

In order to protect patients and promote their right to privacy, healthcare data processors need to comply with available legislation. In the United States the legislation in force is HIPAA (Tovino, 2016). To be compliant with HIPAA is necessary that a system allows a patient to access his/her information and correct it if necessary, and that the patient also knows when his/her PHI is being accessed and for what purpose. When health information is not attached to personal identification HIPAA may allow disclosure to third parties (BMC, 2017). In Europe, the new GDPR has recently entered into force on 25th of May 2018 (Tovino, 2016). GDPR also states that automated devices need to be able to track the information to the user who made it (Castro, 2018). For this reason it is imperative that health institutions create safe and easy to use ways to fulfill the requirements of the legislation as well as patients' needs for control and privacy of their personal health related data (Reis et al., 2008).

1.1 Background

1.1.1 Personal Health Information

According to (Cavoukian, 2004), Personal Health Information PHI is the information that allows a person's identification when is about the person's:

- health (physical or mental);
- providing of health care;
- family medical history;
- payments for health care;
- eligibility for health care;
- donation of any part of the body or body's substance;
- examination of any part of the body or body's substance;

- health identifier number;
- legal decision-making representative.

This information can either be transmitted in writing (on paper or electronically) or orally. (Cavoukian, 2004).

Everyday PHI is collected and used by multiple users like physicians, researchers, pharmaceutical industry, statisticians etc. (Ruotsalainen et al., 2016) and it is important to notice that sharing PHI can increase quality of health care and reduce medical costs and errors (Abdelhamid et al., 2017). However different stakeholders have different opinions about how PHI should be disclosed and how much this information should be private for the patient. A patient, for example, may prefer that his/her PHI will not be disclosed or at least that no one could associate his/her information to him/her, apprehension of secondary uses of the information and lack of trust in health professionals are some of the reasons why (Abdelhamid et al., 2017; Ruotsalainen et al., 2016). However, a physician may think that disclosing PHI from one of his/her patients to other physicians can help with a diagnosis, and also a researcher may believe that the patient's PHI can help to understand and prevent diseases (Ruotsalainen et al., 2016).

For all these stakeholders there is a different level of privacy that suits them regarding the patient's health information. Privacy is strongly linked to the sensitivity of information, depending on the context in which it is used, with whom, what is the purpose of the information's use and also the trust that has been given. It is therefore a complicated and tricky concept that has to be adjusted to each specific situation (Ruotsalainen et al., 2016). In the health field, privacy of Health information is what allows controlling the dissemination of people's PHI (Jabeen et al., 2017). In order to satisfy all stakeholders, it is necessary to establish in each context the level of privacy to adopt for the correct and meaningful use of PHI. (Ruotsalainen et al., 2016).

It is only possible to share a patient's clinical information when he/she gives his/her consent. However according to literature, sharing patients' PHI is important to increase the technology investments in that will improve healthcare (Abdelhamid et al., 2017). To increase patients' willingness to share their PHI, it is necessary to address their concerns, one of these concerns is not knowing who will have access to the information and how that information will be used. Also patients who do not have the awareness of existing benefits in sharing information have less interest in sharing PHI. However patients with a good relationship with their doctors and with the perception of the benefits of sharing are more willing to do so. According to Abdelhamid et al (Abdelhamid et al., 2017), and their study about variables that influence patients' willingness to share their clinical information, concerns about the privacy of information and the relationship between patient and physician are two of the biggest reasons for patients who do not want to share their information. In this study the authors also concluded that one way to improve these results is to educate the patient, but also to educate the physician, resulting in a more informed patient and a physician with more attention to the relationship with the patient.

1.1.2 Patient Empowerment

According to the World Health Organization (WHO), the importance of patient empowerment has been increasing in the world, however the definition of patient empowerment is not internationally standardized (Barr et al., 2015; Risling et al., 2017).

First, to understand this concept, it is necessary to understand the concept of empowerment and then adapt it to the patient and the health care environment. Empowerment is the process where the individual increases his/her capacity for autonomy and to think critically when he/she is given an option for decision it also can be interpreted in two ways, such as "psychological empowerment" or "situational empowerment" (Anderson and Funnell, 2010). The first is based on the idea that the individual feels influential, important, and free to do his/her tasks as intended, the second aims to give tasks in which the individual has decision-making power and that responsibilities are delegated to him/her (Schulz and Nakamoto, 2013). Empowerment should be seen both as an individual and a group process (World Health Organization, 2009; Castro et al., 2016).

When empowerment is in the health environment, it focus on patient empowerment, and can be interpreted as the activity of including the patient as an autonomous and informed individual with certain responsibilities that allows him/her to participate in his/her health decisions (Schulz and Nakamoto, 2013).

The European Patients' Forum (EPF), an organization that provides support and represents patients with regard to policies and programs relating to patient-centered health care, defines patient empowerment as an activity that allows people the ability to control their own lives and increase their ability to solve issues they may consider important (Bravo et al., 2015; European Patients' Forum - Home, 2017).

There are still numerous and different definitions of the concept, and this can be explained by the existence of similar concepts such as patient-centered care, patient participation, patient engagement, patient activation, patient enablement etc. (Risling et al., 2017; Funnell, 2017; Fumagalli et al., 2015).

(Funnell, 2017) distinguished from patient empowerment two of these concepts, patient-centered care and patient participation. Patient-centered care is defined (Castro et al., 2016) as a process where there is an environment that allows patients to express their needs, such as communication between the patient and his/her health care professional. This communication should consist in having patients comfortably talking with health professionals, and having health professionals showing compassion, care and respect for their patients. This type of care is usually taken into consideration by health professionals when treating a patient (Funnell, 2017). Also in (Funnell, 2017), patient's participation is explained as the patient's right in having his/her opinion taken into consideration when discussing a treatment for example, but also his/her responsibility to take these decisions, indicating the importance of patients' health care literacy. To (Castro et al., 2016) blending patient's participation and patient-centered care provides the basis of patient empowerment.

(Fumagalli et al., 2015) reviewed several of these terms and concluded that the process of patient empowerment is a antecedent to patient participation while is considered a consequence of patient's engagement and enablement. In a simplified way the author described patient's enablement with patient acquisition of ability, patient engagement as the patient's acquisition of motivation for empowerment and considered that patient empowerment and patient activation are the acquisition of higher power by the patient. The distinction between activation and empowerment is that while patient's activation refers to a specific disease or program, empowerment is general (Fumagalli et al., 2015).

(Bravo et al., 2015) says that usually the method of empowerment evaluation is based on the improvement of the patients' health and the patients' adoption to their health self-management, also self-efficacy is usually used as a empowerment measure (Yin et al., 2012), because generally when empowered, patients develop more self-efficacy for example by asking questions about their illnesses and treatments. Some

of the behaviors expected by empowered patients are decision-making, communication and participation with supportive communities that allows patient's personal growth, self-management for informed decision making and patient dedication to comply with self-control proposals (Vitiello et al., 2017). These behaviors are related side by side with the capacities that patients gain from empowerment, such as: self efficacy (already mentioned), greater knowledge, skills, personal control and motivation, according to (Vitiello et al., 2017).

According to (Schulz and Nakamoto, 2013) when empowering a patient it is important also to take into account their health literacy, if empowerment is given to a patient with low health literacy their health management can be detrimental to him/her. However if this management is not given to the patient when he/she is an individual with high health literacy the result is a patient dependent on health professionals when he/she could participate in his/her clinical decisions.

As an example one of the most important and recognized measures of empowerment in the health environment is the Do-Not-Resuscitate (DNR) order. This measure allows a patient to choose to deny extraordinary life-saving measures. If a patient signs a DNR and their organs begin to fail, professionals are not allowed to do Cardiopulmonary resuscitation (CPR) or perform other resuscitation measures. This often occurs when patients are diagnosed with terminal illnesses or have suffered accidents/ injuries from which they will not be able to recover. This is one of the most empowering measures because it allows the patient to decide whether to die naturally or continue to live with the help of medicine (Ebell, 1994).

1.1.3 Legislation

HIPAA is the legislation in the United States that safeguards the safety and privacy of clinical information. Was created to protect PHI whether in paper, verbally or electronically (BMC, 2017; Annas and Others, 2003; Murphy-Abdouch, 2015). Since 1996 Hippa is present in United States law (Tovino, 2016). One of the principles of HIPAA is to bring information to patients by educating them about the importance of privacy and their rights (Annas and Others, 2003).

To be compliant with HIPAA a system must allow a patient to access his/her information and correct it if necessary, and that the patient also know when his/her PHI is being accessed and for what purpose (BMC, 2017). HIPAA is based on five rules (Edemekong and Haydel, 2018):

1. Privacy Rule
2. Transactions and Code Sets Rule
3. Security Rule
4. Unique Identifiers Rule
5. Enforcement Rule

The Privacy Rule is the rule that specifies who can access to PHI. This rule says that patients should have access to a copy of all their clinical information (Annas and Others, 2003; Murphy-Abdouch, 2015). This applies to all records, excluding the notes made by health professionals from mental health appointments and also excluding data collected for criminal, civil and administrative purposes (Annas and Others, 2003). A doctor is not obligated to accept the patient's request for access, he/she can deny

it: if they consider visualization of such information may endanger the patient or another person; if the health information refers to another person and access to that information may endanger that person; and if access of the information is requested by the patient's representative but this may put the patient or another person in danger. If a request for access is refused by a doctor the patient has the right to a second attempt. The second request should be answered by a doctor that was never involved in the patient's clinical records and should be chosen by the entity in question (Annas and Others, 2003).

The legislation considers that there are cases where the patient's right can not be exercised by him/her, for this reason the legislation provides that a legal representative can assume this right. Regarding children, parents (or legal guardians) have the right to access their medical records until they are of legal age (Annas and Others, 2003; HHS, 2018). Also if the patient assigned legally to other person the authority to make his/her decisions, he/she will also be entitled to the patient's right. Another case is when the patient is deceased for which a representative may also be entitled to the patient's right (HHS, 2018).

To share the information, a patient's signed consent is needed to allow the disclosure, except for situations such as disease outbreaks, terrorism, among others. This rule allows patients' privacy to be reserved but also to permits PHI to promote public health and health care quality (BMC, 2017; HHS.gov, 2017). When health information is not attach to personal identification HIPAA allows disclosure (BMC, 2017). If that is not possible the privacy rule includes a requirement that says that disclosed information that provides patient identification should be reduced to the lowest possible extent, unless authorized by the patient, required by law or sent to another health care facility for the patient (Annas and Others, 2003). For example, when information from clinical records is used for research, it may be used without the patient's consent, if the patient's identification is not easy to relate to those clinical records; if authorization is given by an institutional commission which has the authority to do so and in accordance with certain rules; and if the records are part of a data set with certain conditions (Annas and Others, 2003). Another controversial issue is when health students can see patient's health information for study and learning purposes. The legislation leaves this decision to be modeled by the internal policies of the institutions, always focusing on the purpose of disclosing as little information as possible (Annas and Others, 2003).

For patient authorizations/consents it is important to note that procedures in emergency situations will not be affected, giving priority to health and only afterwards will legal issues be addressed (Annas and Others, 2003).

In what concerns Europe, since 1995 that the European Data Protection Directive (Directive 95/46/EC) has come into force. This directive protected individuals in the processing and movement of their personal data (not only health-related data) by claiming the right of privacy and accuracy in their data when used by others (Shu and Jahankhani, 2017). With the changes in the paradigm of technologies and the fact that this directive was fragmented in different countries across Europe the need to create a new regulation emerged, and thus the new General Data Protection Regulation (GDPR) appeared (Lopes and Oliveira, 2018). The GDPR was adopted in April 2016 and became mandatory only on May 25 2018, after a period of two years of transition for the concerned entities to prepare. Compared to previous legislation, the GDPR introduces significant differences regarding the processing of data and obligations of citizens and entities. Some of the key differences to highlight are: the need to show compliance with the regulation, the clear need for consent by the data subject, the existence of Data protection officers (DPO), obligation

to be notified when breaches occur and new rights as the "right to be forgotten", the right to ask for data rectification and the right to "data portability" (Jornal Oficial da União Europeia, 2016; Crofts and Devlin, 2016; European Society of Radiology, 2017; Lopes and Oliveira, 2018).

Even though GDPR has not been created specifically for the health area, it is also applied when talking about health data. This regulation guarantees the right of patients to privacy, self-determination and wants patients to participate in their own health care. GDPR addresses health data in a special category, that is, with different limitations because it is considered sensitive data. The legislation considers health data as physical and mental data (Jornal Oficial da União Europeia, 2016).

According to (Castro, 2018) the GDPR (Jornal Oficial da União Europeia, 2016) claims that sensitive data, such as health data, should not be processed. However there are exceptions that allow the processing of this data:

- existing patient consent (following the legal rules of consent);
- patient's data were publicly disclosed by the patient;
- existing need to medical care;
- existing interest to public health;
- existing substantial public interest;
- existing need to comply with obligations (eg work, safety, social protection law);
- need to archive or perform scientific and statistical research.

Regarding the use of data for research (European Society of Radiology, 2017) states that GDPR (Jornal Oficial da União Europeia, 2016) allows the use of data for that purpose and proposes some techniques for data protection. Pseudo-anonymization is usually recommended, but data anonymization and encryption are also proposed.

HIPAA and GDPR are two legislations on two different continents that are applied to health data, with the goal to protect personal data and therefore, patients. Obvious similarities between both legislations relate to confidentiality and privacy of patient health data. Table 1.1 intends to make a brief comparison between both legislations on some of the most important concepts such as consent, use of data for marketing, rectification and erasure of data (Tovino, 2016).

Table 1.1: HIPAA and GDPR comparison (Tovino, 2016)

	HIPAA	GDPR
Consent	Consent (called authorization in HIPAA) is not define, is a default rule	Consent is defined as “freely given, specific, informed and unambiguous indication of the data subject’s (...) agreement to the processing of personal data relating to him or her.”
Consent Content	6 required components and 3 sentences	2 required components
Consent Format	Written; orally (only in specific situations)	Written; electronic check box; orally
Consent Conditioning	Prohibits the conditioning of treatments, payments among others if the patient does not give authorization (prohibition with 3 exceptions)	Has a requirement to validate whether the consent is freely given, which is based, among others, whether the performance of the contract is related to the consent of the data subject (element of the consent)
Consent Presentation	Prohibits authorization to be delivered to the patient with others documents (has exceptions)	Permits consent to be delivered to the patient with others documents if presented differently to be distinguished
Consent Revocation/ Withdrawal	Patients have the right to revoke authorization already given if it is in writing (has exceptions) – more difficult than give authorization	Patients have the right to withdrawal consent already given (has exceptions) – as easy as give consent
Marketing	Disclosure of marketing data, authorization is required	Disclosure of marketing data it is necessary to be clearly isolated from the remaining information
Amendment/ Rectification	Patient has the right to have their PHI or recorded amended	Patient has the right to rectify wrong personal information and to complete incomplete personal information
Erasure	Does not have the right to erasure	Have the right to erasure (has exceptions)

When a patients’ health information is accessed without their permission, this may negatively impact them. Privacy breaches can damage patients’ reputation, cause discrimination, abuse, impact on their freedom, autonomy and right for privacy, cause threats to their safety and lives, and may also cause patients’ mistrust in the health care system. It is critical to realize that unauthorized accesses to health data can have a huge impact on patient’s life and that existing European legislation aims to protect patients in this regard (Castro, 2018).

1.1.4 Anedoctal Cases

It is important to realize that a tool to allow patients to see who accesses their health information can be useful in real scenarios. Thus, we present three real cases where using a tool with these characteristics could help in protecting the privacy of the patient’s health data.

Celebrity Farrah Fawcett, diagnosed with cancer, publicly shared that throughout her illness she has suffered from leaks in her medical information. Fawcett was suspicious because whenever she was hospitalized the paparazzi quickly appeared in the hospital. The celebrity was convinced that this leakage of information came from the hospital where she was hospitalized: "I actually kept saying for months and months, this is coming from here". To prove it, in 2007, when she was diagnosed with a cancer's return, Fawcett did not tell anyone not even her closest friends and family. Four days after being diagnosed the news was scattered all over the tabloids, "I could not believe how fast it came out". Later a hospital administrative specialist was accused of selling medical information to the press from countless celebrities as well as politicians and non-famous patients. The administrative admitted in court what she had done, but passed away before being convicted (Charles Ornstein, 2015).

Besides celebrities also ordinary citizens can be affected by privacy breaches. Julie, a lawyer living in Boston was diagnosed with bipolar disorder and she found that her health information was easily accessed by any professional in the same health care system. When she went to a stomatology appointment she realized that the doctor knew of intimate issues that she had only shared with her psychiatrist and never even with her friends or family. In order to confirm this, she asked the institution for her clinical records and in these were all the conversations she had had with her psychiatrist, and any professional of the institution could access this information without asking permission to Julie (Avila and Marshall, 2012).

In North America there are many more cases of privacy data breaches (all types of breaches, not only unauthorized access), in 2017, 86% of the incidents of breaches occurring in the world were in North America while only 6% occurred in Europe. And of the total of 1765 incidents of data breaches worldwide 471 were in the health industry, being this the industry with more breaches in the year 2017 (Gemalto, 2018). Although with less incidence in Europe, health data breach incidents also occur, namely in Portugal. The Portuguese Medical Association presented a medical inquiry which indicated that false doctor profiles were being created in Centro Hospitalar Barreiro Montijo, to access the hospital's computer systems. Such unauthorized access may jeopardize the safety of patients' personal and clinical data and also of doctors, said a representative of the doctors. False doctor profiles were used by social workers in order to access patients' clinical processes and record information on them. Investigations into this incident remain open (Renascença, 2018).

It is important to realize that in these three cases the use of an access control tool could give the institution and patients greater power to protect themselves and to prevent these cases from recurring more easily.

1.2 State of the Art

Throughout the world, and more recently with an even greater focus on Europe because of the GDPR, tools have been developed to help to be compliant with the legislation in one way or another. The health sector, due to its complexity and the sensitive information it holds, requires tools that are appropriate to its needs. The annual International Association of Privacy Professionals (IAPP) privacy tech vendor report presents some products that may be useful to help comply with legislation (The International Association of Privacy Professionals, 2018). This report presents numerous products, oriented by different categories. Below are some examples of the products that monitor systems in the health area.

One of these products is HelioMetrics which is developed by an American company, which has different

solutions (The International Association of Privacy Professionals, 2018). HelioMetrics Healthcare Privacy Analytics monitors access to patient's Electronic Health Record (EHR) at health facilities to ensure data privacy. This product presents monitoring through dashboards and allows institutions to identify suspicious activity and behavior for further investigation. HelioMetrics also analyzes access to patient data by individual who accessed, individual profile (doctor, nurse etc.), department, floor and facility. The produced reports allow for data compliance officers to take a detailed look at the behavior of all employees and suppliers in general which means that random audits are not so often required. This tool reduces the effort for compliance in monitoring, ensures legitimate access to patients and provides the basis for organizations to be HIPAA compliant (HelioMetrics, 2018b; The International Association of Privacy Professionals, 2018). The Individual Patient Access Report (iPAR) is another HelioMetrics solution that provides the institutions with the possibility of having patients access their individual access reports. The report must include all accesses of the entity in question as well as all partners of the institution who need to have access to personal health information of the patient. The report includes names of the people or entities that accessed, the date and time of the accesses, the information accessed and the action done (creation, modification, access, deletion, printing etc.) HelioMetrics allows the entity to easily provide to the patient the requested information. HelioMetrics generates a report that can be sent by email, can be viewed securely online or printed and sent (HelioMetrics, 2018a; The International Association of Privacy Professionals, 2018).

Another EHR monitoring solution presented in The annual IAPP privacy tech vendor report is Protenus', patient monitoring platform created by an american company. It uses data mining and artificial intelligence to detect abnormal events (The International Association of Privacy Professionals, 2018). Collects information from multiple sources and presents the statistics through a dashboard. Because evaluates all the accesses made to the patients' records allows to alert the institution when an access can endanger the organization. Unlike HelioMetrics this does not have a component for the patients to use (Protenus, 2018).

The existing information on the tools presented in the The annual IAPP privacy tech vendor report, HelioMetrics and Protenus, is mostly for commercial purposes and therefore lacks relevant information for our study.

In order to comply with the requirements of the legislation in force, GDPR, institutions have to change some of their usual behavior, namely auditing requirements (Gonçalves-Ferreira et al., 2018). Knowing what health professionals have accessed the medical data of patients may be challenging, even when institutions' systems keep the access logs of health professionals. The records that show who accessed, what, when and what operations were made are called audit-trails (Cruz-Correia et al., 2013).

According to (Gonçalves-Ferreira et al., 2018) Portuguese hospitals rely on different systems, promoting a huge heterogeneity, and often the access logs are kept in each system and not in one single system, making it difficult for institutions to integrate and show this information (Cruz-Correia et al., 2013). For this reason Healthy Systems created an audit trail system to help institutions to be compliant with GDPR.

An audit trail is defined as a tool that records everything that is done in the user's session, with a set of features that allows the control of accesses and registration made by users of an information system (Paixão, 2008). In addition to being used to detect user's events when a problem occurs, audit trails also serve as a health service to improve information systems. (Cruz-Correia et al., 2013) pointed as an

example for improving information systems using audit trails the validation of clinical decision support systems. Another example is the use of audit trails to the integration of clinical trial in several health institutions for data management.

HS.Register is a software created by Healthy Systems and an audit trail system that was created to help health care institutions understand what is done in the portuguese institution's systems and who does it. With this product, it is possible to centralize in a single system the logs of the multiple systems of the institution facilitating this way systems' auditing. In addition to logs, the system stores Health Level 7 (HL7) messages and system events, everything that is stored must be traceable, auditable, non-removable, and non-refutable. The system provides institutions with an interface with dashboards where all data can be monitored through graphs and searches created by the user (Gonçalves-Ferreira et al., 2018). This product is already in operation in five Portuguese hospitals.

In Portugal patients are not very involved in their health care, and it is rare that they ask to see their medical records (Laranjo et al., 2017). However, when they do ask the process of obtaining all the information is still time consuming and complicated, requiring formal authorizations from health institutions (Zuniga, 2015). We tried to understand the process to obtain medical records in two public hospitals of two Portuguese metropolitan areas. When searching for information on the respective web pages of the hospitals we find that the process is to complete an access request form (provided by the institution) that can be delivered in person where the identity of the patient will be confirmed. If the delivery is not in person the form will have to be accompanied by a photocopy of the citizen's card (or other identity proof) (CHLN, 2018; CHSJ, 2018).

Patients tend to be reluctant to ask for access to their clinical information, and the same happens to using tools such as Personal Health Records (PHR). However the Portuguese National Health Service (NHS) created a PHR platform with EHR integration and access by health professionals (Laranjo et al., 2017). The "Plataforma de Dados de Saúde (PDS)" - Health Data Plataform - is a platform divided into several portals:

- "Plataforma de Dados de Saúde - Portal do Utente (PDS-PU)" - Patient's Portal;
- "Plataforma de Dados de Saúde - Portal do Profissional (PDS-PP)" - Professional's Portal;
- "Plataforma de Dados de Saúde - Portal Internacional (PDS-EPSOS)" - International Portal;
- "Plataforma de Dados de Saúde - Portal Institucional (PDS-PI)" - Institutional Portal.

PDS is a plataform that aims to exchange health information among patients and health professionals (Sá, 2013). One of the features of this platform is the possibility for any NHS professional to be able to view the patient's information that exists on the platform, regardless of the instituion where the information was recorded (Reis, 2013). The first portal to be release was the PDS-PU in May 2012, followed by the PDS-PP in July 2012 and the PDS-PI in November 2012 (Sá, 2013). The PDS-EPSOS was discontinued as it was an European project that ended in 2014 (European Commission, 2014).

The PDS-PU provides the patient with a list of authorizations to which he/she has access to control what health professionals have had access to his/her PDS's information and its content. Also on this portal, is an audit mechanism that allows patients to view the history of accesses that are made by health professionals through the PDS-PP to see their information in the PDS (Sá, 2013; Reis, 2013). The information presented to the patient concerns the professional that made the access (with profile

information), the date and time of access, the institution where the access was made and the type of episode (PDS, 2018).

To the best of our knowledge, and in Portugal, the only tool that allows an NHS patient to know who accessed their medical information through a web page is the PDS. However, this tool only provides access history for the accesses made in the platform, and not the accesses performed in the different databases of hospitals or primary care patient records (PDS, 2018).

1.3 Motivation

With the entry into force of the new GDPR on 25 May 2018, it became essential for healthcare institutions to ensure compliance with the regulation and to provide patients with easy and effective ways to enable them to see their legal rights possible. This MSc dissertation focuses research on developing and testing a prototype of a tool that meets the requirements of existing legislation in Portugal, promoting in this way patient empowerment. It is essential to create tools that allow patients to know who accesses their health information. Patients should be able to access this information easily and with the security it requires, considering the sensitive data it integrates. In addition to complying with legal requirements we consider essential to take into account patients' opinions and to know if a tool that allows them to control who accesses their information would be useful to them and how they would like to have access to it. We consider the importance that is prototyping a tool that is intuitive and provides the user with a pleasant experience. It is our intention to create a prototype with good usability that informs the user and allows him/her to easily access the information about who, when and where his/her health information is being accessed.

1.4 Research Questions

The main research questions that this study proposes to answer are:

1. Do patients want to know who accesses their Personal Health Information?
2. How should a tool that allows patients to know who accesses their health information be like?

1.5 Objectives

For the research questions that were formulated in the previous section, three main objectives were defined:

1. To analyze if Portuguese patients would be interested in having access to a tool that would show them which professionals see their health information and from which institutions;
2. Design a functional prototype of a user interface directed towards the common patient. The goal is to give a greater focus on the usability of the prototype and to consider all the specification of the tool that will be created, namely requirements and use cases.

3. Evaluate the created functional prototype and collect feedback from user tests to optimize the tool according to the obtained results. These tests comprise tasks that must be performed by users to assess the ease and speed with which they are made.



Study A - Questionnaire

2. Study A - Questionnaire

2.1 Introduction

This study aims to investigate the opinion of a determined population (e.g., university students) regarding a tool to verify whose healthcare providers have had access to patient's health information. We expect to understand people's awareness about this issue and which requirements a tool should have to fulfill the identified needs.

We decided to use for this study one of the most widely used data collection methods, the questionnaires. This method is a cheap, quick and convenient method for respondents because they can respond when they want. The fact that it can be sent over the Internet also allows for convenience and facilitates communication with study participants (Rowley, 2014; Bryman, 2016).

The university student population can be relevant as they are expected to be proficient in technologies, and more aware of their rights when compared to the overall population. They are also expected to shape social opinion for the next decades. For this reason and because it is an easily accessible population our questionnaire is intended for university students.

2.2 Methodology

2.2.1 Study Design and Data Collection

A web-based questionnaire was designed to examine the population's interest in having access to a tool that allows patients to know which healthcare providers access their health information in the institution's information systems. For the questions' development, it was taken into account the fact that the addressed population might not have knowledge about data protection or about how health information flows in health institutions. For this reason, the applied questions were simple, easy to understand and without concepts that need previous knowledge. To evaluate clarity of the information, as well as collect critiques and suggestions for the improvement of the questionnaire, a pre-test questionnaire was carried out. This test comprised 38 people and was available from the 9th of November 2017 until the 13th of December 2017. From this pre-test new questions emerged, which we considered pertinent to also integrate in the questionnaire, and corrected some existing ambiguities. After alterations, the final questionnaire was shared by email and applied online between the 2nd and the 12th of January 2018.

2.2.2 Study Participants

The sample we chose was a convenience sample, from the student's community at University of Porto. The questionnaire was sent to the target population via the institutional email, with a total of 33404 emails.

2.2.3 Questionnaire

The language of the questionnaire was Portuguese and included 30 questions divided into 8 parts. The questions are summarized in table 2.1. The complete questionnaire is presented in Annex 7.2.

Table 2.1: Questions cover in the questionnaire

Part	Question
Personal Information	Age Gender Academic Qualifications Health Professional or Student Caregiver
Technology Information	Usual use of email on the smartphone Usual use of the laptop at work Usual change of passwords
Knowledge on health information	Regular visits to health institutions Level of agreement with concern and knowledge of health information Knowledge of the existence of the user's portal of the National Health Service Knowledge of the existence of the access history functionality in the user's portal of the National Health Service Importance of that functionality
Legislation knowledge	Knowledge about GDPR Knowledge about patients' rights according to GDPR Informed consent
Tool	Tool's importance Tool's benefit Tool's importance to caregiver
Tool characteristics	Tool's visualization Tool's available information Tool's alarmistic Confirmation of tool usage Tool's frequency usage
Suggestion	Suggestions on the topic

2.2.4 Data Analysis

To perform data analysis, we used SPSS® in which statistical description measures were applied in order to evaluate the answers. Because most data were categorical variables, the results are shown as numbers and frequencies. To compare the results in different groups medians and quartiles were

calculated, also a Pearson's chi-square test was performed and a p value <0.05 was considered for a statistically significant value.

2.3 Results

589 participants answered the questionnaire (1.8% response rate), with all answered questionnaires being complete and usable. The submissions were recorded online, on the questionnaire form, and exported to a spreadsheet for analysis. Results from the questionnaire are shown on table I and II, the rows may not add to 100% due to rounding.

2.3.1 Personal and Technological Information

Information of 589 participants, 71% female and 29% male was analysed. The majority of answers were from participants aged between 18 and 30 and regarding academic qualifications, the most common was the Bachelor's degree, and most of the participants are not on a health related course nor are health professionals. Participants who are caregivers of either children, elderly or both were 8%. Most participants have a daily contact with technologies, 76% use a mobile phone daily to see their email and 84% use their computer to work/study. When asked about changing passwords 36% participants recognized that they never or rarely changed theirs. Personal and Technology information results are presented on table 2.2.

2.3.2 Health Information Access Knowledge

The results of the questionnaire reported that a majority of participants, 56%, went to a health institution 2 to 6 times in the last year, all the results can be seen in table 2.2. Regarding the statements evaluated with a Likert Scale, 39% of participants agree in part with the statement "I know which of my data health institutions have"; 27% agree in part with the statement "I know which health professionals have access to my health information"; also in the statement "I am concerned that a health professional, with whom I have never had contact, can see my health information", 24% of participants agree in part. About the statement "I am concerned that my health data is viewed and studied by students (medicine/nursing/ diagnostic technicians etc.)", 23% disagree in part; 24% disagreed in part with the statement "I am concerned that my health data will be used for studies in the pharmaceutical industry" and 48% of participants strongly agree with "I consider the protection of my health data important". All results are available in table 2.3

Regarding the Portuguese National Health Service user portal, 63% of participants never used it and of those who used it, only 24% were aware of the access history tool. However, 90% of participants consider this functionality useful, full results are presented in table 2.2.

2.3.3 Legislation Knowledge

Only 19% had heard about the new GDPR and only 16% had the knowledge that the GDPR indicates that patients have the right of accessing all their health information. When asked whether they ever give informed consent to a health institution, 61% of participants never did. Results concerning legislation knowledge are available in table 2.2.

Table 2.2: Questionnaire answers (1)

Age Group					
	<18	[18,30[[30,40[[40,60[[60,70[
n (%)	6 (1%)	503 (85%)	50 (9%)	27 (5%)	2(0.3%)
Academic Qualifications					
	3rd cycle	Secondary education	Bachelor's	Master	PhD
n (%)	2 (0.3%)	187 (32%)	249 (42%)	137 (23%)	14 (2%)
Profession					
	Health Student	Health Professional	Non Health		
n (%)	176 (30%)	46 (8%)	367 (62%)		
Caregiver					
	Non Caregiver	Children caregiver	Elderlies caregiver	Children & elderlies	
n (%)	545 (93%)	24 (4%)	7 (1%)	13 (2%)	
Email on Smartphone					
	Daily	1/ 2 week	1/ 2 month	1/ 2 year	Never
n (%)	449 (84%)	92 (16%)	29 (5%)	6 (1%)	5 (1%)
Laptop at work					
	Daily	1/ 2 week	1/ 2 month	1/ 2 year	Never
n (%)	493 (84%)	69 (12%)	16 (3%)	6 (1%)	5 (1%)
Password change					
	Once a month	Once a year	When others know	Never/Rarely	NA
n (%)	18 (3%)	106 (18%)	332 (56%)	67 (11%)	49 (8%)
Visits in the last year					
	0	1	[2,6[[6,12[>12
n (%)	35 (6%)	106 (18%)	332 (56%)	67 (11%)	49 (8%)
Knowledge of Plataforma de Dados de Saúde					
	Yes	No	Don't know/ Don't want to answer		
n (%)	200 (34%)	371 (63%)	18 (3%)		
Knowledge of Access History on Plataforma de Dados de Saúde					
	Yes	No	Don't know/ Don't want to answer		
n (%)	66 (11%)	520 (88%)	3 (0.5%)		
Importance of Access History					
	Yes	No	Don't know/ Don't want to answer		
n (%)	530 (90%)	24 (4%)	35 (6%)		

Knowledge of GDPR					
	Yes	No	Don't know/ Don't want to answer.		
n (%)	110 (19%)	476 (81%)	3 (0.5%)		
Patients data on GDPR					
	Yes	No	Don't know/ Don't want to answer		
n (%)	92 (16%)	490 (83%)	7 (1%)		
Informed Consent					
	Yes	No	Don't know/ Don't want to answer		
n (%)	137 (23%)	360 (61%)	92 (16%)		
Tool Importance					
	Yes	No	Don't know/ Don't want to answer		
n (%)	534 (91%)	28 (5%)	27 (4%)		
Tool can give more control over health information					
	Yes	Maybe	No	Don't know	
n (%)	351 (63%)	192 (34%)	10 (2%)	8 (1%)	
Alarms to notify accesses					
	Yes	No	Don't know/ Don't want to answer		
n (%)	391 (70%)	116 (21%)	53 (10%)		
Tool Frequent Use					
	Annually	Semi-annually	Monthly	Weekly	NA
n (%)	48 (9%)	127 (23%)	221 (40%)	112(20%)	53 (9%)

Table 2.3: Questionnaire answers (2)

	SA	AP	NAD	DP	SD
I know which of my information health institutions have	13%	39%	15%	22%	11%
I know which health professionals have access to my health information	26%	27%	8%	19%	19%
I am concerned that a health professional, with whom I have never had contact, can see my health information	20%	24%	18%	19%	18%
I am concerned that my health data is viewed and studied by students	12%	20%	19%	23%	26%
I am concerned that my health data will be used for studies in the pharmaceutical industry	19%	20%	15%	25%	21%
I consider the protection of my health data important	48%	28%	17%	5%	3%

SA- strongly agree; AP – agree in part; NAD – not agree or disagree; DP – disagree in part; SD – strongly disagree

2.3.4 Tool

When questioned about the importance of a tool that shows to patients all the health professionals that see and change their health information in different hospital systems, 91% of participants consider it important and 5% do not consider a tool with these characteristics important, and therefore finished the questionnaire in question 17. The remaining of the questionnaire was answered by 561 participants. About the benefit of the tool, 63% of participants consider that it can give the user a greater control over their health data. When asked to the participants who had someone in their care if the tool could be useful for greater control of the person they care, 83% think so.

2.3.5 Tool Characteristics

Concerning the tool characteristics, the first question was to select the two preferred modes to view the information, the answer chosen by most participants was the web page option (473 selections), as shown in figure 2.1. When asked about what information they would like to access on the tool (by selecting the four most preferred answers), the most preferred answer was “name and health professional’s profile” (505 selections), followed by “history of patient events (doctor’s appointments, medical exams, surgeries etc.)” (435 selections), then “reason for access” (406 selections), all results can be seen in figure 2.2.

As to alerts, most participants (69.7%) would like the tool to notify them when someone accesses their health information, results for this answer are presented in table 2.2. When faced with the question if they would use a tool with the characteristics previously mentioned 71.5% confirm that they would, 26.6% are not sure and only 1.2% would not use it. Considering that in a total of 589 participants, 401 confirmed they would use the tool. We can assume with a confidence level of 95% that if a tool with these functionalities was made available, between 64.1% and 72.1% of the representative population of our sample would use it. Those who answered that they would use the tool, 43.9% would use it monthly, 24.9% weekly, 21.9% semi-annually and 5.2% annually, as presented in table 2.2.

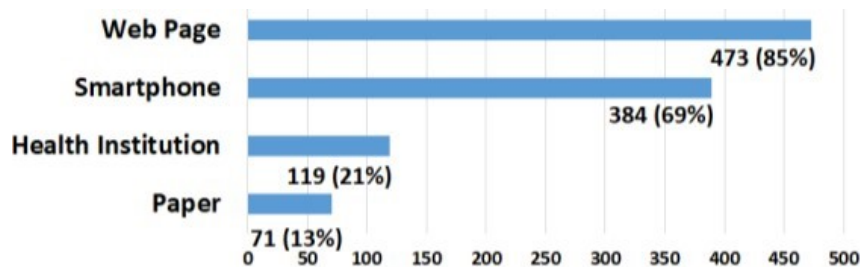


Figure 2.1: Modes to view the tool. Multiple choice allowed.

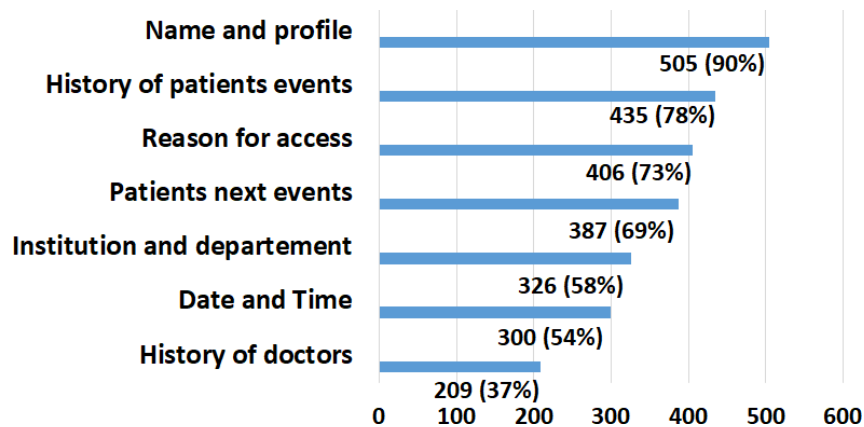


Figure 2.2: Information to view on the tool. Multiple choice allowed.

About 5% of participants who do not consider the tool important, reveal however relevant answers. In the statement "I am concerned that a health professional, with whom I have never had contact, can see my health information", 71% of them strongly disagree or disagree in part with the statement, the same results have been revealed in the other two statements about health students seeing their health information and about their health data being used in pharmaceutical studies. Although 50% of these participants did not believe in the importance of the history accesses tool of the NHS portal. Even that 57% of these participants strongly agree or agree in part that they give importance to the protection of their health data, they show that it is no problem for them to have their health information accessed wherever and by whoever wants to, so they are not interested in having a tool that shows them those records.

2.3.6 Suggestions

Of the 588 respondents, 22 answered the optional question for suggestions within the topic of the study. 2 of these responses were excluded because their content was not understood. The answers given were grouped into 3 different groups according to their content. In the group of suggestions to include in the tool the suggestions were: to consider carefully the need of security for the information; enable patients to update demographic data and disseminate this information to other systems; allow to request medication for the chronically ill, allow medication consultation; allow reminding the patient when vaccination is required; allow the patient to schedule, reschedule, and cancel doctor appointment; allow the patient to decide who can view their information (one information each time); inform patients about the use of their data for research purposes; allow the inclusion of prescription information to pharmacies; allow patients to see and manage all of their health information. In the group of opinions on the existence of the tool: negative opinions stated that although they understand the problem, they do not agree because it is based on controlling the health professionals, which would create more judicial processes that would occupy more health professionals and they would have less time to health care; also suggested that the tool be based only on changes in health information (eg change in medication) or reminders of upcoming appointments. Positive opinions referred to the need to take into account that there are people without internet access; take into account elderly who may not easily use a web application; take into account that caregivers and children should only have access to a part of the information because it is personal and sensitive; other opinions focused to the importance of the study and the recommendation that we

arry on this work.

In the group of suggestions that were based on access to information, the participants suggested: access to health information by the patient should be mediated by a physician to avoid self-diagnosis; access by health professionals should be made available according to their profile (doctor, nurse, technician, etc.); access to patient information should be by "opt-in" and patient consent should be required; the use of data for teaching and research should always require patient's consent.

These suggestions will be considered for the next steps of the study.

2.3.7 Analysing Groups

In order to understand if the groups of people we came across, had different knowledge and different perspectives in this issue we calculated the medians of the answers to some questions and compared them in the different groups. The selected questions were the statements to agree or disagree on and the question about the importance of the tool. We present the results in table 2.4, they are shown as median values [first quartile value; third quartile value]. The statements and questions analysed were: "I know which of my information health institutions have", "I know which health professionals have access to my health information", "I am concerned that a health professional, with whom I have never had contact, can see my health information", "I am concerned that my health data is viewed and studied by students (medicine/ nursing/ diagnostic technicians etc.)", "I am concerned that my health data will be used for studies in the pharmaceutical industry", "I consider the protection of my health data important" and "Do you consider important the existence of a platform for patients to know all the health professionals who see and/or change their health information in different hospital systems?". Also, the answers were transform in ordinal numbers to calculate the median, for the 6 statements the correspondent answer is: 1-Strongly agree; 2 - Agree in part; 3 - Does not agree or disagree; 4- Disagree in part; 5 - Strongly disagree. To the question "Do you consider important the existence of a platform for patients to know all the health professionals who see and/or change their health information in different hospital systems" the answer correspondent is: 1- Yes; 2 - Do not know or do not want to answer; 3 - No.

Comparing the health group with the non-health group, these groups were created considering the answers from the question "Are you a health professional, a student in health area, or neither?" given in the questionnaire, most of the medians between the groups were not significant. However, the median of the answers to "I know which of my information health institutions have" and "I know which health professionals have access to my health information" were shown to be significant. The health group agrees more with those statements than the non-health group, so participants in the health area seem to be better informed about what information is kept by the healthcare institutions and what types of health information do health professionals have access to. Regarding the remaining questions, no statistically significant differences were found between the medians in both groups, as described in table 2.4.

Another defined group was based on the data obtained from the question about whether participants had ever heard of GDPR. Participants with positive responses were allocated to one group, and those with negative responses to another. For the purpose of this analysis participants who did not know or did not want to answer were not taken into account. When the medians were analysed considering these defined groups, two of the questions were significantly different. One of those is the statement concerning health information being used for pharmaceutical industry studies, the median of those who know about

GDPR is greatly concern than those who do not know about the legislation. Also, the statement that emphasizes the concern of participants in the protection of their health data, presented a median that shows more concern in participants who are aware of the legislation, as presented in table 2.4.

The next two comparison groups were based on the participants' habit of changing passwords, for these groups the answers to the question "Do you usually change the passwords of your email and/or facebook?" were used. One group comprises respondents with the habit of changing passwords "at least once a month" and "at least once a year". The other group is composed of participants who answered they change passwords "only when others have access to the password" and "never or rarely". Participants who did not know or did not want to answer were not taken into account.

Considering the results available in table 2.4, the group that changes passwords regularly shows greater concern in having health professionals with whom they have never had contact with to see their health information. Also in the statement "I am concerned that my health data is viewed and studied by students" the median is significantly different in the analysed groups. The participants of the group that do not change passwords regularly are not as concerned about their health data being seen by health students as the group that changes passwords regularly. Also, the statement about the concern of participants in the protection of their health data, presented a median that shows more concern in participants who change regularly their passwords, as presented in table 2.4.

Table 2.4: Median comparison between groups (health participants vs non-health participants; GDPR knowledge vs non-GDPR Knowledge; regular change in passwords vs non regular change in passwords)

	Health (n=222)	Non- health (n=367)	P value	GDPR (n=110)	Non- GDPR (n=476)	P value	Passwords (n=179)	Non- passwords (n=380)	P value
I know which of my information health institutions have.	2 [2;4]	3 [2;4]	0.000	2 [2;4]	2 [2;4]	0.731	2 [2;4]	3 [2;4]	0.103
I know which health professionals have access to my health information.	2 [1;4]	3 [2;4]	0.002	2 [1;4]	2 [1;4]	0.609	2 [1;4]	2 [1;4]	0.144
I am concerned that a health professional, with whom I have never had contact, can see my health information.	3 [2;4]	3 [2;4]	0.658	3 [2;4]	3 [2;4]	0.359	2 [2;4]	3 [2;4]	0.046
I am concerned that my health data is viewed and studied by students.	4 [2;5]	3 [2;4]	0.200	3 [2;4]	4 [2;5]	0.602	3 [2;4]	4 [2;5]	0.025
I am concerned that my health data will be used for studies in the pharmaceutical industry.	4 [2;4]	3 [2;4]	0.391	2 [1;4]	3 [2;4]	0.044	3 [2;4]	3 [2;4]	0.115
I consider the protection of my health data important.	1 [1;2]	2 [1;3]	0.229	1 [1;2]	2 [1;3]	0.001	1 [1;2]	2 [1;3]	0.005
Tools Importance.	1 [1;1]	1 [1;1]	0.069	1 [1;1]	1 [1;1]	0.054	1 [1;1]	1 [1;1]	0.084

Median [Q1;Q3]

2.4 Discussion

In general, we can consider that although the vast majority of participants did not show great knowledge about the legislation (81%), about half do not know about the use of their data (52%) nor which professionals access that data (53%), more than 90% consider important the existence of a tool to view who accessed their health information.

2.4.1 Legislation awareness

Even when the new regulation comes into force in May 2018 the lack of knowledge regarding that legislation is evident, possibly justified by the lack of information from mass and social media. This can also justify the lack of interest that some people have in protecting their health data. Nevertheless, questionnaire results show that although participants have little knowledge on privacy and data protection (19%) they realize the importance of a tool to search for who accesses and uses their health data. A study by Tierney et al. to health professionals revealed that 46% of participants strongly agreed or agreed in part that the information present in an EHR is owned by the patient, this indicates that the rest are not aware of the legislation (Tierney et al., 2015). Comparing with our study these results are higher, however this difference in results can be justified by the difference in population and also the fact that the question is considerably different. Nevertheless, in both studies is recognizable that legislation is not yet widely known by ordinary citizens. Being more informed and more concerned about the use of their data, those who know GDPR, consider the pharmaceutical studies possibly something secondary to their health care and therefore are more concerned with the use of their data for this specific purpose.

2.4.2 Health Information Access Awareness

Health professionals and non-health participants are more concerned (46% e 33% respectively) when compared to health students (26%), about students in health areas viewing their health information. This is an expected result since students are in fact those who use and need the data to study. Considering the 93% of health professionals who believe that an access control tool would be important for the patient, we can say there was a great adherence on the part of health professionals in our study. Slightly different from Tierney et al. study in which 54% of health professionals strongly agree or agree in part that it is ok for patients to have control of who saw their EHR (electronic health record) but only 42% strongly agree or agree in part on this being a good thing for patients (Tierney et al., 2015). Since the Tierney study was conducted a few years ago (3 years), this difference in results can be justified by the increase in the disclosure of data protection information. Another justification may be the difference in population. The need to keep the patient to rely and trust on health professionals and their work, more than ever, may be a factor for the health professional to accept this transparency of information. The fact that health group participants are more familiar with health systems that keep patient's information and all the dynamic of health institutions, can justify the greater knowledge that they consider to have about which are and who sees their health information. Those who change passwords regularly show more concern about data security and privacy and they do not want "strangers" to see their most personal information. For this reason, they are more worried that health students and health professionals, who they have never had contact with, see their health information.

2.4.3 Tool Characteristics

From the questions about the characteristics of the tool it was found that the preferred way to use the tool was through a web page. Considering the frequency that the user would use the tool, it makes sense that that is an easier way to access data without being intrusive into the user's life. Also considering that our sample had a very technological background it was expected that this option would be preferable to them. The questionnaire also allows us to realize that the most important information in the tool for a user would be the name and profile of the healthcare professional who accessed the information, followed by the patient's own events (like doctor appointments, exams, etc.) and the reason for seeing the information. When these three pieces of information are combined the user can more easily understand whether the access to his/her information was made in the context of a health episode or not. Therefore, this is a mandatory requirement for the development of a new tool in order to promote patient's empowerment.

2.5 Limitations

One limitation of study A is the number of responses to the questionnaire which manifested a very low response rate (1.8%), only 589 out of 33404. This value can be justified by the fact that the questionnaire was sent through an institutional email that is often recipient of questionnaires for the same purpose, which leads to students' disinterest to answer and also the existence of emails that are not used by the students. Our population was students of higher education in a metropolitan area, and although this can be one of the target audiences for the tool, we would need to test with the general public. This will be approached in future work. Because our sample is very homogeneous and has mostly the same personal characteristics, like age, academic qualifications and technological habits, it is not possible to aggregate and compare responses of participants with those attributes. In addition, although the results are positive regarding the participants' intention to use the tool, more research is needed to confirm this assertion.



Study B - Tool Specification

3. Study B - Tool Specification

3.1 Introduction

Considering the results obtained in the questionnaire presented in chapter 2 and the need that is expected for the institutions to be compliant with the new legislation in force presented in chapter 1, we propose the creation of a tool that complies with both. This tool will be based on the information gathered by the HS.Register audit trail, described in the section 1.2 of chapter 1. As presented, HS.Register is an audit trail that collects events, logs and HL7 messages from hospital information systems. We intend to collect in our tool the information from the repository of HS.Register (where all the information is stored) and present clearly and structurally useful information to the patient through a web page. We will only collect information from the patients who did the enrollment in our tool. This will be an extension of the HS.Register that will allow to give information directly to the patient and this tool in the course of this document will be called MyRegister.

In order to create a successful tool, it is necessary to take into account all the parties involved, the stakeholders. Stakeholders can be people or organizations that are involved in some direct or indirect way in the process of creating and using a system (Rogers et al., 2011). The stakeholders of our tool comprise:

- the patients;
- the health institutions;
- the professionals working in the health institutions;
- the parties responsible for managing patient information within health institutions;
- the institution's DPO;
- the development team.

MyRegister has a main focus on its users, in this way we intend to understand as best as possible who would use the tool and in what situations. In this chapter, we intend to present the tool's personas, scenarios, use cases and requirements' list. Defining requirements for a system is not an individual process and must be on par with the design and collection of evidence, which is an iterative and constant improvement process. Although done in parallel, each of these, collection and systematization of evidences, definition of requirements and design, is executable differently and presents different results (Rogers et al., 2011). For this reason, we present each of the results in the next sections, starting with

the systematization of evidence through the personas, scenarios and use cases, followed by the definition of requirements and finally the presentation of the tool desing through the creation of a functional prototype. This prototype has a focus on the usability of the tool considering that it should be accessible to anyone regardless of their age, schooling and/or technological knowledge. To conclude this chapter we will present an architecture proposal for MyRegister.

Assumptions for MyRegister:

Considering the sensitive and personal information that the system allows to access, and knowing that the information should only be disclosed to the patient, we propose that for the enrollment process it is necessary to confirm the identity of the patient, in person, at a health institution. If the patient has a legal representative, he/she may be able to access the MyRegister information, starting from the same assumptions as if it were the patient himself/herself. For this, it is necessary the collaboration of the health institutions to define a person to be responsible for the confirmation of the patient's identification and to give the patient a code of access for the creation of the account in MyRegister. For the creation of a code for the patient we propose that there is a module of the MyRegister in which the employee of the institution enters the SNS number of the patient and MyRegister returns a code, this code will be associated with the number of SNS of the patient and stored in the MyRegister's database to allow account creation. This code creation and association module does not fall under the scope of this dissertation. The collection of information from HS.Register to MyRegister is periodically made in order to keep the information updated for the user and to allow sending alarms when asked. We suggest that the query should be done every 10 minutes, depending on the weight that this collection has on the system servers and the user expectation the value should be adjustable to allow a better performance. MyRegister will only be made available to patients from healthcare institutions who have HS.Register and will only provide information from health information systems that are integrated with HS.Register. For the use of MyRegister we consider to the best of our knowledge, that when it is made available to patients, their mental state must be taken into account. If they have any associated mental illness, a health professional should evaluate whether they should have access to the tool.

3.2 Personas

A persona is a fictional individual who intends to represent a group of people with the same interests and characteristics (Miaskiewicz and Kozar, 2011). Initially the concept of personas was exclusively used for marketing, however later it was proposed to be a design technique in software development (Almaliki et al., 2015). Although a persona is not a real person, giving it real features like a name and a look, makes it easy for both developers and consumers to understand how the product can help a particular person (Miaskiewicz and Kozar, 2011). A persona should be constructed and characterized through its physical, psychological state, background and emotional state. Therefore, the persona should be created as a fictional individual with an age, a gender, a visual aspect (represented for example through a photograph), with motivations, likes and dislikes, a professional occupation, a level of education, a social and cultural position, family, locality, etc.. The persona should also present her goals and ambitions, these should meet the problem that is intended to solve/mitigate in the creation of the persona (Almaliki

et al., 2015; Nielsen, 2003; Miaskiewicz and Kozar, 2011).

Over the years personas have been facilitating the process of software development, some of the benefits found with the use of personas are (Almaliki et al., 2015; Miaskiewicz and Kozar, 2011; Courage and Baxter, 2005):

- instead of using abstract data from a consumer, developers relate the product to a human face and to a name creating empathy with the user;
- defines the set of features that are expected for the product;
- help to unify the communication between developers and designers enhancing collaboration between teams;
- limit the possibility of stakeholders changing the product according to their preferences;
- helps individuals working on the product to realize how different they are from the persona and therefore to move away from the desire to change characteristics in the product that they would prefer;
- helps focus only on target users and their characteristics, and all team members can realize who are the target users;
- allows the validation of the product considering the needs of the personas;
- can measure the effectiveness of the product;
- reduces the need to change characteristics at the end of the development process because they were not previously planned;
- can give more inspiration to the design team and help with a more friendly product design;
- can help with product marketing.

In order to present the personas that we consider relevant to our tool, we validate the aspects that characterize a persona, and select those that we consider most relevant to MyRegister. For this reason we present three personas, Persona 1 a young woman with curiosity to know who accesses her health information, Persona 2 a caregiver of an elderly person who needs to keep up to date on the health information and doctors of his father, and the Persona 3, is an elderly person who has every interest in maintaining her privacy and getting the best health care at the same time. These three personas were created considering that they are three types of users that can greatly benefit from the tool, however this tool can be used by any type of person and therefore this should be taken into account in the idealization of the tool.

Persona 1

Name: Anna Smith

Age: 31

Gender: Female

Job: Shopkeeper

Interests: Read through long hours of the night, go to the movies, hang out with friends

Profile: Curious

Statement: "I want to know which health professionals have accessed to my medical information."

Anna is used to technologies (computer and smartphone). Curious about the use of her personal data and interest in staying involved in her health, Anna wants to know what health professionals have seen her information and what kind of changes they made in her medical records (such as deleting or changing information). She understands that her health information is a sensitive data and that not all people should have the right to see it. Anna likes to have access to information of her interest without great effort to obtain it and wants to feel that she has power in her clinical decisions and is involved in her health.

Persona 2

Name: Phillip Sloan

Age: 47

Job: Nurse

Interests: Spend time with family, travel, read.

Profile: Worried

Statement: "Which are the health care providers who look after my father?"

Phillip is the informal caregiver and legal representative of his father, Joseph with 85 years old, with a fragile health and who frequently goes to health institutions. Even with his health more fragile, Joseph

likes to maintain his independence and go alone, whenever possible, to his doctor's appointments. Phillip wants always to be informed about his father's health, when he can not accompany his father he wants to be sure that his father attended the appointment and wants to know which health professionals were with him, and when his next appointment or medical exam are. It is very important for Phillip to be involved in his father's health in order to prolong and improve his quality of life.

Persona 3



Name: Susan King

Age: 67

Job: Former teacher; retired.

Interests: Spend time with her family, specially her grandsons, travel with her husband, read, see movies and play cards with her friends.

Profile: Private

Statement: "I want the best health care keeping my privacy and enjoying life."

Susan has finally time to be with her family and doing all the things she did not have time when she worked. However she began to feel more tired and with less strength as is normal with her aging process. So her health is very important to her and she always try to be as healthy as possible so she is always present at all appointments and scheduled exams. However, she does not like to worry her family and friends and therefore considers important to maintain her privacy and for this reason she wants to be sure that only the health professionals who treat her have access to her clinical information.

3.3 Scenarios

A scenario is a narrative description of a human activity along with a given set of events, described informally (Rogers et al., 2011). As a partial description, it can be a way to show sequences of interactions between users and the system. The descriptions are only partial because they only reveal characteristics that are relevant to the situation, not describing in full everything that involves the situation. (Benner et al., 2014).

When creating scenarios it is possible to use as characters of the scenario the personas of the tool. A persona is a static element in the software engineering process, however when aligned with scenarios it becomes dynamic. In a scenario the persona has a goal to meet their needs (already described in the persona characterization), this goal is the starting point of the scenario that involves all steps to achieve it (Nielsen, 2003). The scenarios add more details to the existing personas, this allows the individuals

developing the product to understand more about the system requirements (Almaliki et al., 2015).

According to Nielsen a scenario is a story that includes a persona, with a purpose, in a certain place to act in a situation with a system. During the scenario there is a narrative of events that leads the persona to reach their goal through a solution. To achieve this goal the persona may have to overcome obstacles, these can be overcome in the story or carry the story on. For the scenario to be interpreted correctly by the reader, the scenario should present a solution and always maintain coherence. The solution of the whole scenario or of small events in the scenario should exist because it allows the reader to finish the story and have closure. When the scenario is coherent the reader can see that the story may be real, making coherent the persona, its characteristics and the situation that involves it (Nielsen, 2003). An explanatory scheme of the interaction between persona and scenarios, as described before, is presented in Figure 3.1.

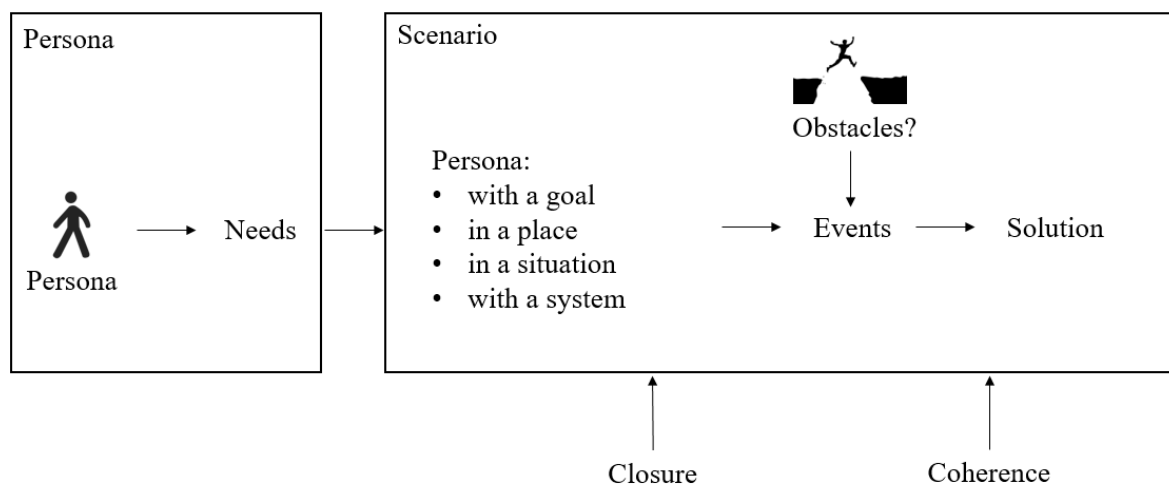


Figure 3.1: Interaction between personas and scenarios. Adapted from (Nielsen, 2003)

As MyRegister can be used by any patient of a health institution, without a strong reason for its use, we chose to identify possible scenarios that would motivate even more and more frequently the use of the tool. Below, we present the scenarios based on the personas that were created (because more scenarios were created than personas we used a persona more than once in different scenarios).

Scenario 1

Anna recently read an article that talked about the relevance of the GDPR in the health industry and she became more curious if and which health professionals would be accessing her health data. So she decided she wanted to know which healthcare professionals have seen and/or changed her health information in the hospital where she usually has her doctor appointments. As she knows that this information is difficult to obtain when addressing an health institution with this request, as it requires filling forms and waiting for a response and possibly paying for it, she decides to access a web page that allows her to obtain that information. After registration, all the information she wanted to know about whom and when professionals saw her health information was available to her.

Scenario 2

Phillip a 47 years old nurse, son and caregiver of Joseph, 85 years old, has no chance to accompany his father in all his medical appointments. Phillip is the legal representative of his father, besides that he is also a very concerned son. Joseph likes his independence, and for that reason he likes to go to his appointments. This morning Joseph had an appointment and he, as usually, went alone. When Phillip asked Joseph about his next appointment, his father was not able to remember for when it was scheduled. Also Joseph can not tell his son who was the doctor who attended him, since his usual doctor was not present. An easy-to-access, online solution allows Joseph's son to access all of his father's information without additional effort.

Scenario 3

Phillip works at Hospital A and is 47 years old and he was recently diagnosed with cancer. To keep his disease private he decided not telling anyone. However, some of his co-workers have heard of his cancer diagnosis. When he noticed that his colleagues knew of his health information without him ever disclosing it, he wondered how they would have known this information. Everyone could have access to information through information systems, but it would break Phillip's right to privacy without a medical purpose. If someone has accessed Phillip's health information without authorization, an access control tool would allow Phillip to know who broke his privacy.

Scenario 4

Susan has been diagnosed with a rare disease many years ago. This disease has an associated treatment that if followed as suggested by the doctor allows Susan to maintain her quality of life. However the treatment has very high costs associated, as usual in rare diseases, which are mostly paid by the NHS. Susan prefers to keep her illness and her treatment private since she has been accused of spending money from the NHS that could be used to treat more people with lower-value treatments. It is very important for Susan to maintain the maximum privacy of her health information and it would be important to have access to a tool that would let her know who accesses her health information and for what purpose.

Scenario 5

Fifteen years ago Anna has had an unwanted pregnancy, and for personal reasons decided that the best thing for her and her family was to have an abortion. Often people who know this deal with Anna differently and so she prefers that no one knows about it. It is very important for Anna to maintain the maximum privacy of her health information and it would be important to have access to a tool that would let her know who accesses it.

Scenario 6

Anna, 31 years old, was recently diagnosed with a digestive disease for which she was prescribed with a very aggressive treatment. Anna wants to request a second opinion to review her treatment. For the second opinion appointment the doctor needs to see all the medical exams done by Anna. She has already done numerous medical exams and in different institutions and no longer remembers which medical exams were done in which health institutions. It would be very useful for Anna to have access to a tool that allows her to access her medical exam history in different institutions so that she can go directly to the institution to request a copy for each of the medical exams correctly.

3.4 Use cases

Use cases are commonly used to help understand the functional requirements of a software tool. Also, use cases focus on users' goals by showing the interaction between the user and the software. This is widely used by developers to initially promote the design of the product and also for verification and validation of the final product, helping in functional tests of the tool. The use case consists in the information of who is the actor, the system, and the purpose of use through the system (Anda et al., 2001; Rogers et al., 2011). For each use case there is the main use case or normal course that predicts the use of the system to achieve the goal of the actor through a sequence of actions. When actions considered habitual are not feasible for some reason, there may be the alternative course which is a sequence of alternative actions (Rogers et al., 2011).

For creating and modeling the functional requirements of a system, textual use cases together with visual demonstrations are used essentially to allow better communication between developers and product stakeholders (Sinha et al., 2008). A use case may be described in Unified Modeling Language (UML), allowing to define the actors, the systems and the connection between actors, systems and use cases (Gutiérrez et al., 2008).

UML can be used in several types of diagrams, some of the most known diagrams are the Activity Diagram, Use Case Diagram and Sequence Diagram. An activity diagram allows you to document the process flow. They allow to show the activities that occur sequentially or in parallel, to show the objects of the activities, the responsible of the activities and the relation between the activities (Virzi, 1992).

For the specification of MyRegister we consider that it would be better to combine the use cases with the activity diagrams in order to show the interaction between the components of MyRegister and allow to understand the activities' flow. We chose to use the 2.1.4 UML version based on (GEAMBASU, 2012) and we created the diagrams using the online tool VisualParadigm. We then present 10 use cases and their Activity diagrams.

Use case 1

The patient wants to create an account in MyRegister. He/she knows that a code has to be given, in person, by the health institution for this purpose, so he/she goes to the institution, confirms his/her identity with an health institution's employee responsible for MyRegister. The employee gives him/her an access code. When he/she accesses the web page he/she registers with his/her SNS number and the code that was made available to him/her.

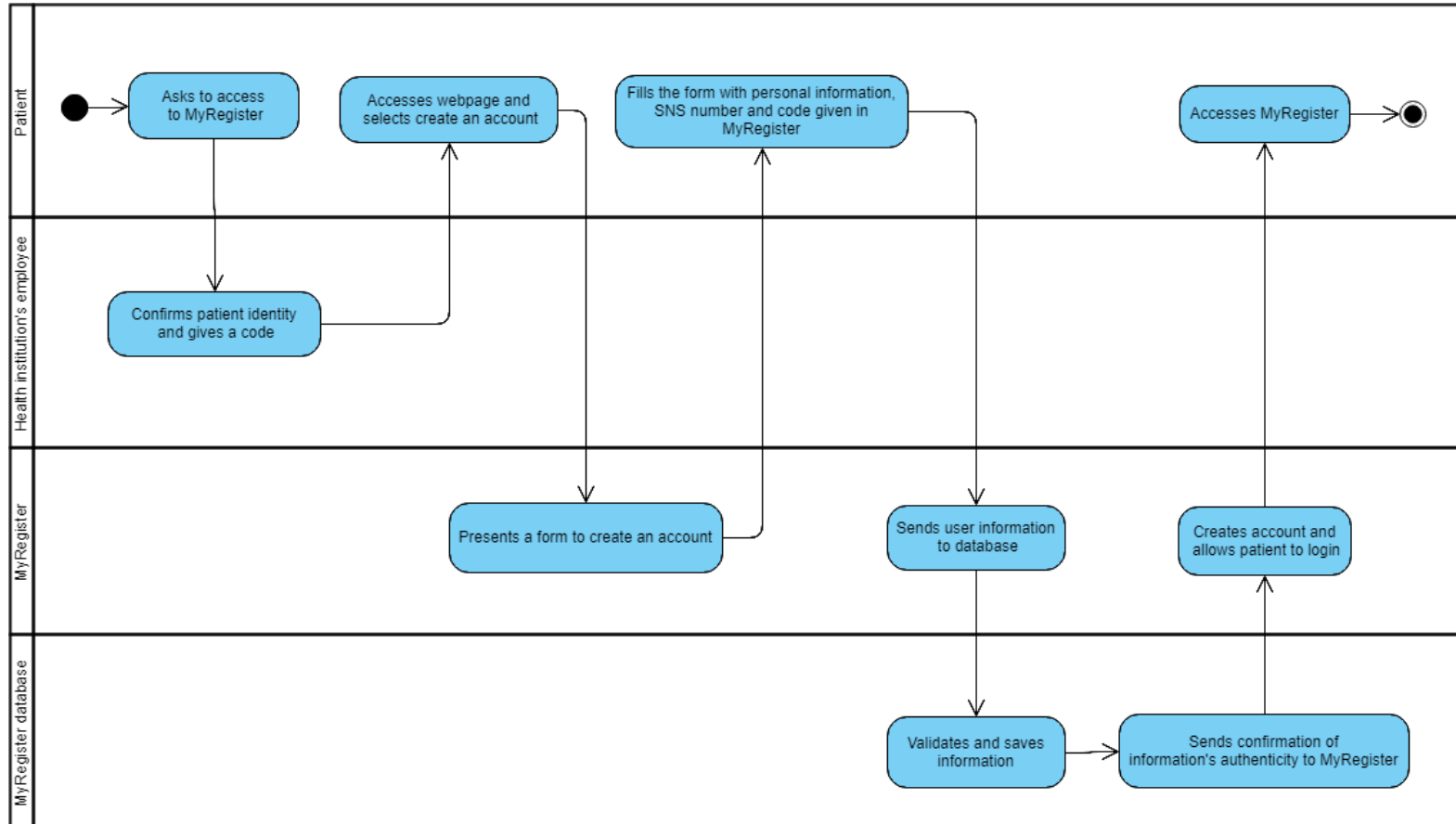


Figure 3.2: Activity diagram for use case 1

Use case 2

The patient wants to login to his/her MyRegister account. He/she puts his/her credentials, logs into MyRegister to have access to all his/her updated information.

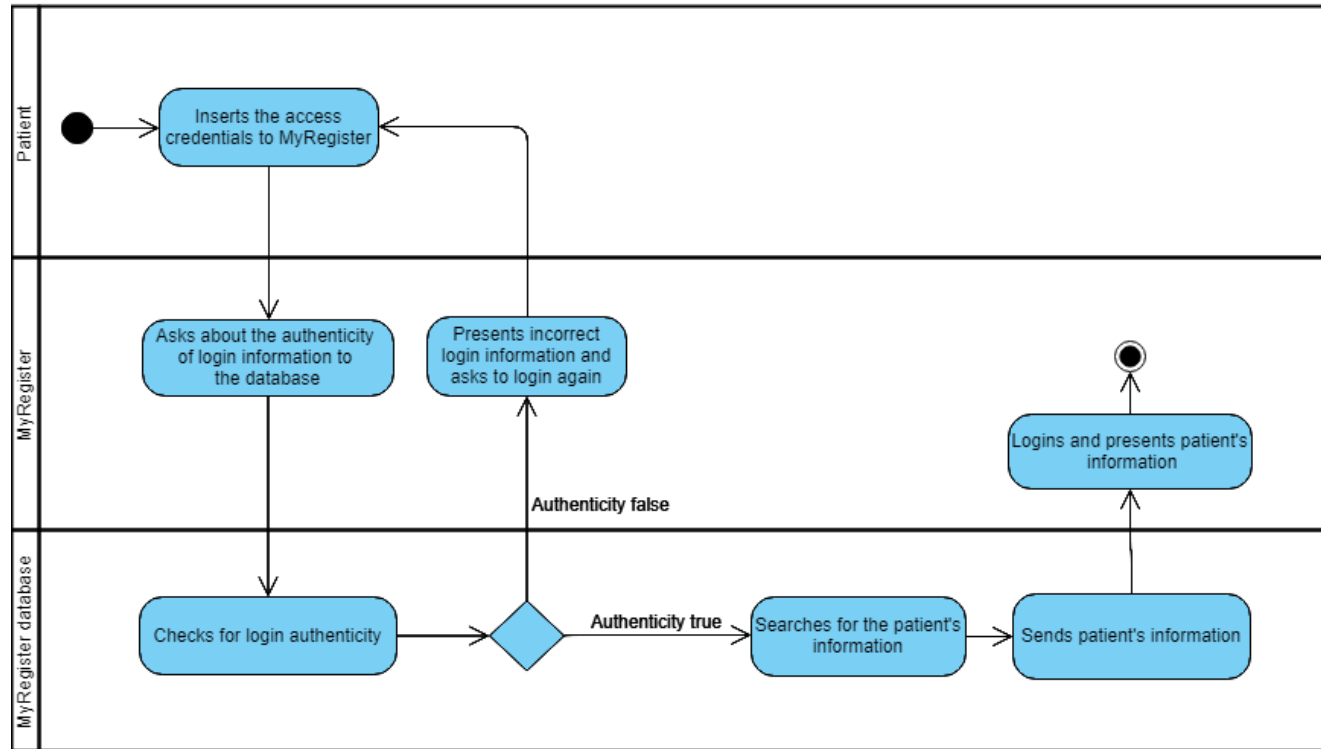


Figure 3.3: Activity diagram for use case 2

Use case 3

The patient wants to know which healthcare professionals had access to his/her information in the last 2 months. The patient logs into MyRegister and accesses the Access History page, on this page he/she filters the results for the last 2 months and sees the information that he/she needs.

*Assume that for this use case the login has already been made

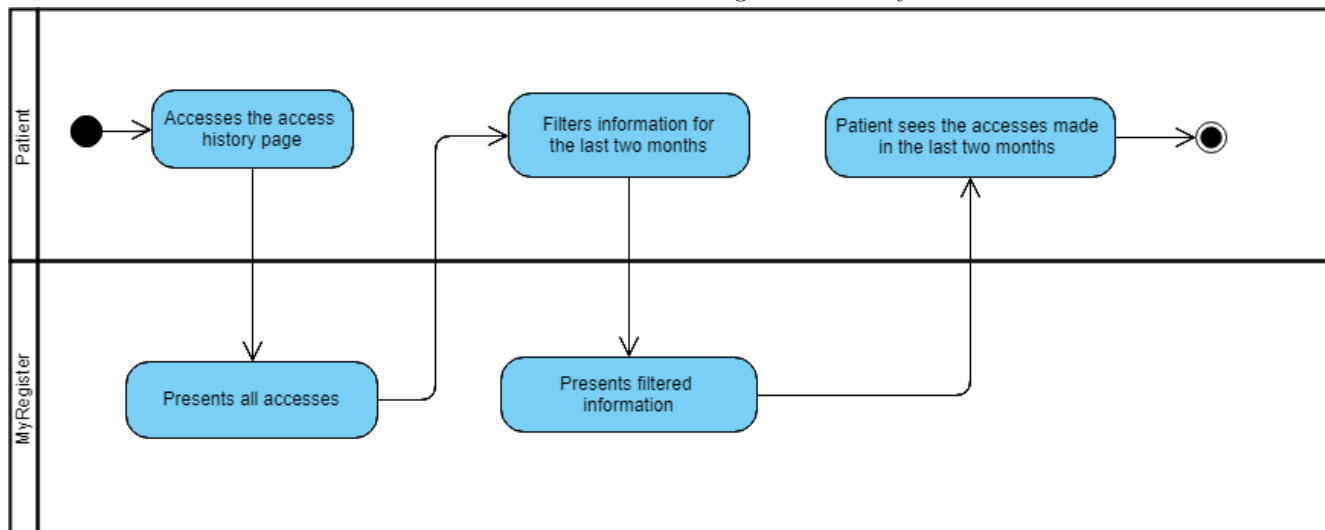


Figure 3.4: Activity diagram for use case 3

Use case 4

The patient wants to know when is the next doctor appointment that was already been scheduled. He/she logs into MyRegister and accesses the Future Episodes page. This page shows all health episodes that have been scheduled but not yet performed, allowing the patient to know what he/she needs.

*Suppose that for the use case the login action has already been made

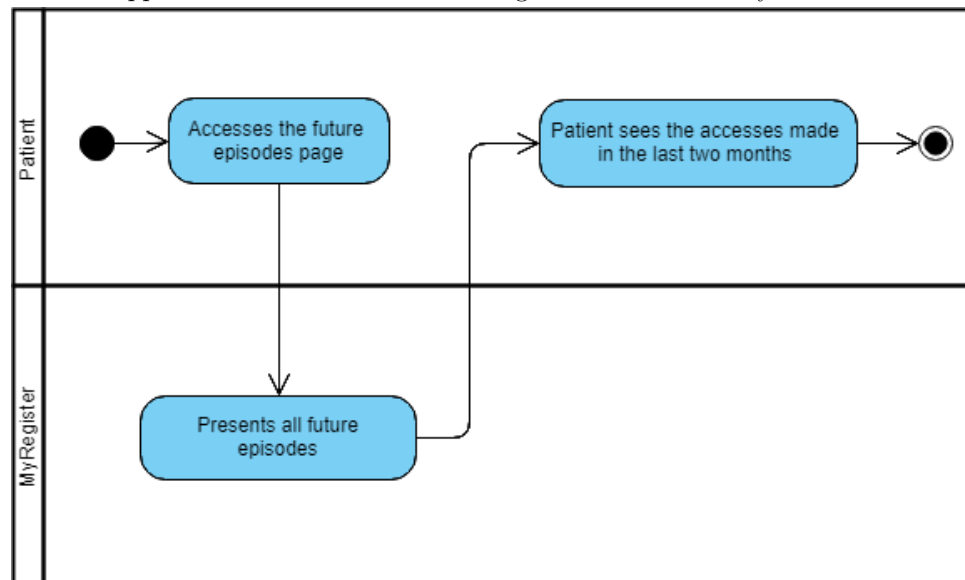


Figure 3.5: Activity diagram for use case 4

Use case 5

By accessing MyRegister, a patient sees an access of a doctor, which he/she does not know if occurred during a health episode that could justify it. To confirm if there was a health episode on that date the patient visits the page of the patients past episodes at MyRegister and confirms this information.

*Assume that for this use case the login has already been made

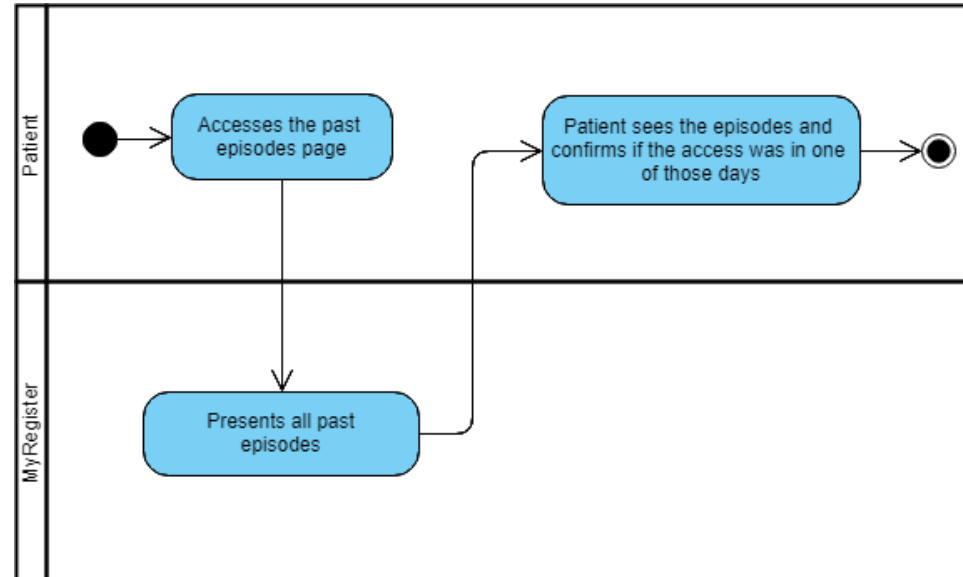


Figure 3.6: Activity diagram for use case 5

Use case 6

The patient has found an access that he/she considers suspicious, a doctor he/she never knew accessed his/her information without his/her authorization, so he/she intends to report this situation to his/her health institution. In MyRegister he/she accesses the list of accesses where the suspicious access is and makes the report.

*Assume that for this use case the login has already been made

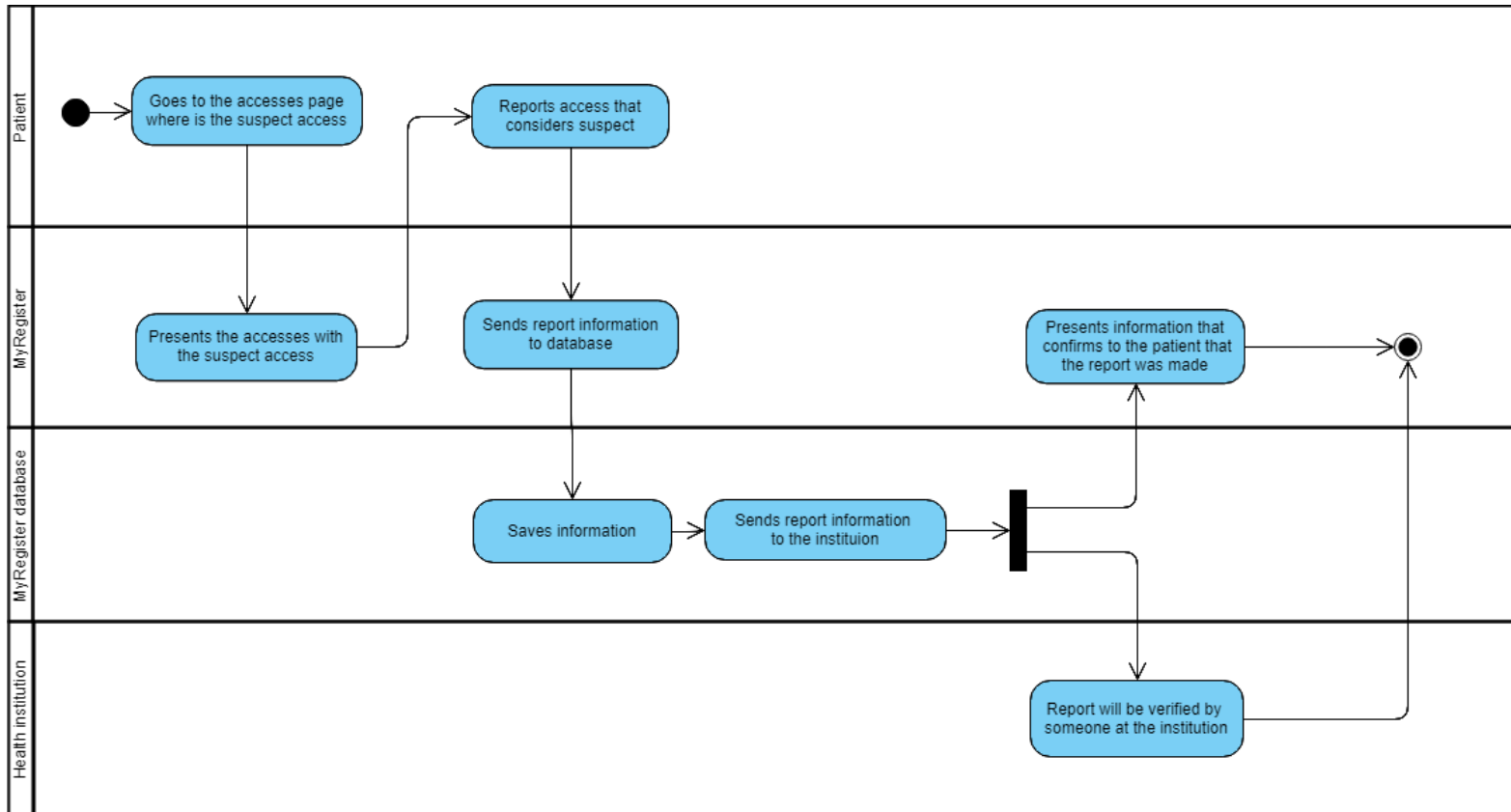


Figure 3.7: Activity diagram for use case 6

Use case 7

The patient has a doctor's appointment in a private clinic that is not registered in MyRegister. The patient uses MyRegister as a health agenda and therefore wants to add the doctor's appointment that is not automatically integrated into his/her account. The patient logs into MyRegister, accesses the future episodes page and adds a new episode, from that moment on the patient has his/her health agenda updated.

*Assume that for this use case the login has already been made

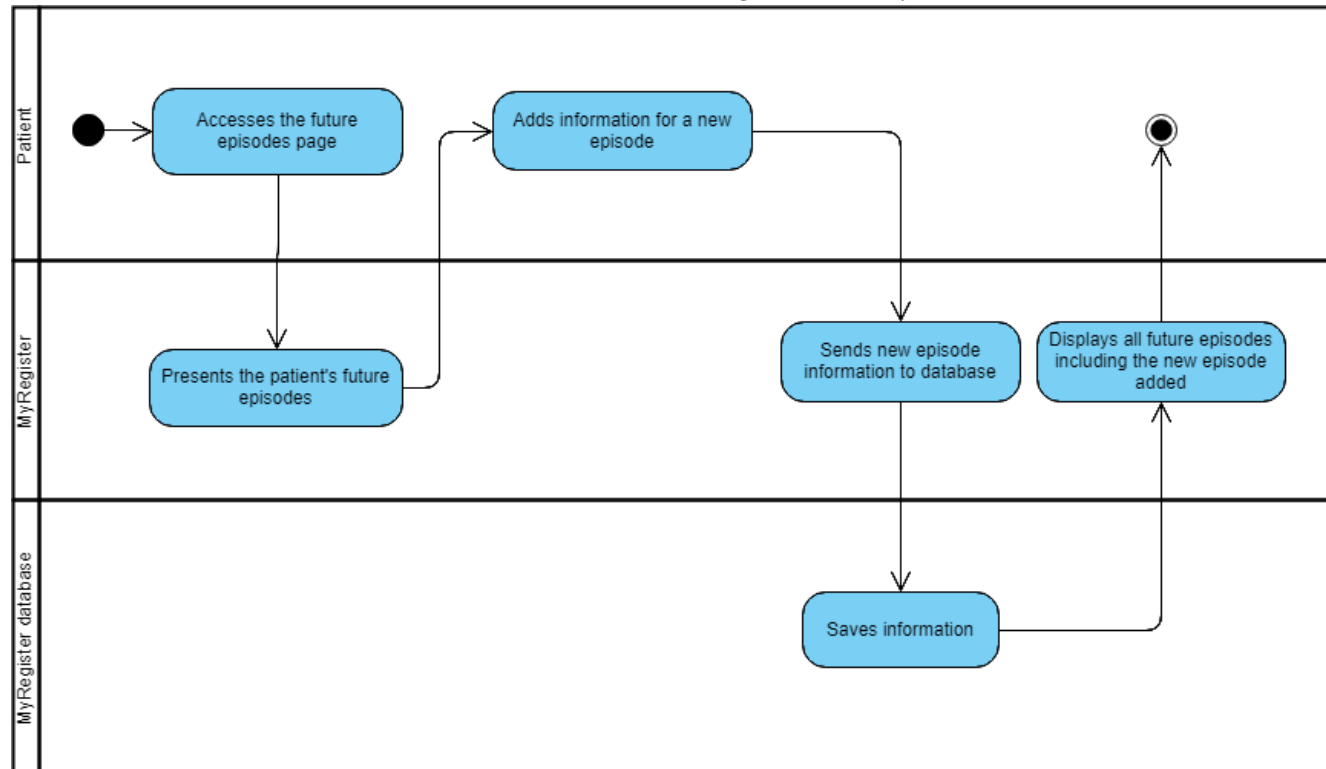


Figure 3.8: Activity diagram for use case 7

Use case 8

The patient wants to receive alerts, via email, whenever a professional accesses his/her information. He/she logs into MyRegister and accesses the settings, on this page he/she has the possibility to add the alert he/she wants. (This use case is similar when sending SMS)

*Assume that for this use case the login has already been made

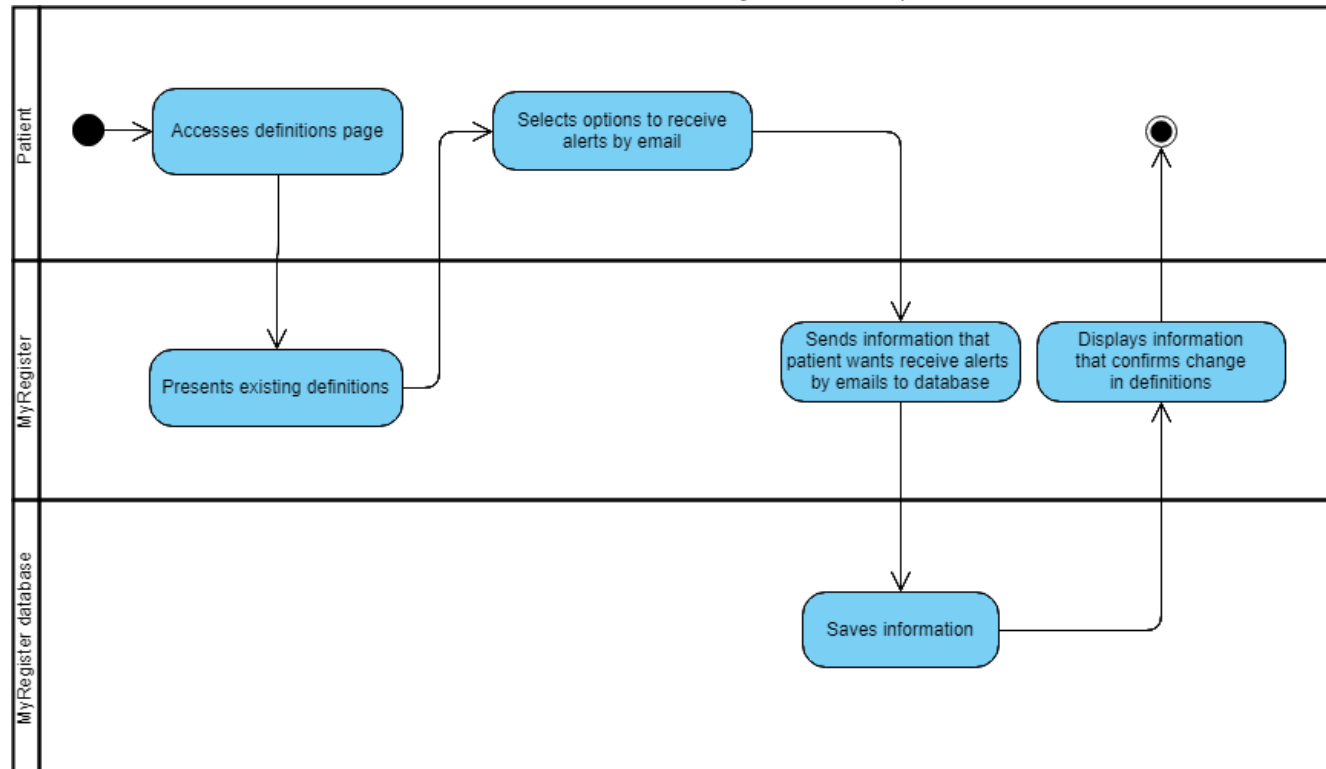


Figure 3.9: Activity diagram for use case 8

Use case 9

Someone accessed the patient's clinical information, this patient has a MyRegister account and wants to be alerted when someone access his/her information. He/she receives an email alerting him/her of that access. (This use case is similar when sending SMS)

*Assume that for this use case the login has already been made

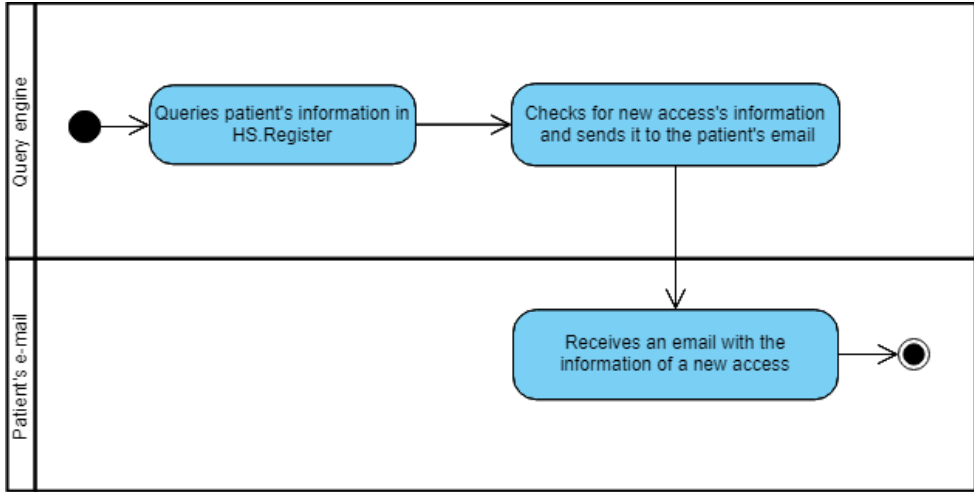


Figure 3.10: Activity diagram for use case 9

Use case 10

The patient wants to add another health institution to his/her MyRegister account in order to see the accesses and episodes of that institution. To do this, he/she goes to the health institution and confirms his/her identity to receive the institution's access code to MyRegister. Then he/she accesses MyRegister and through the settings page adds that institution and inserts the given code. From there he/she will also see the information of that new added institution.

*Assume that for this use case the login has already been made

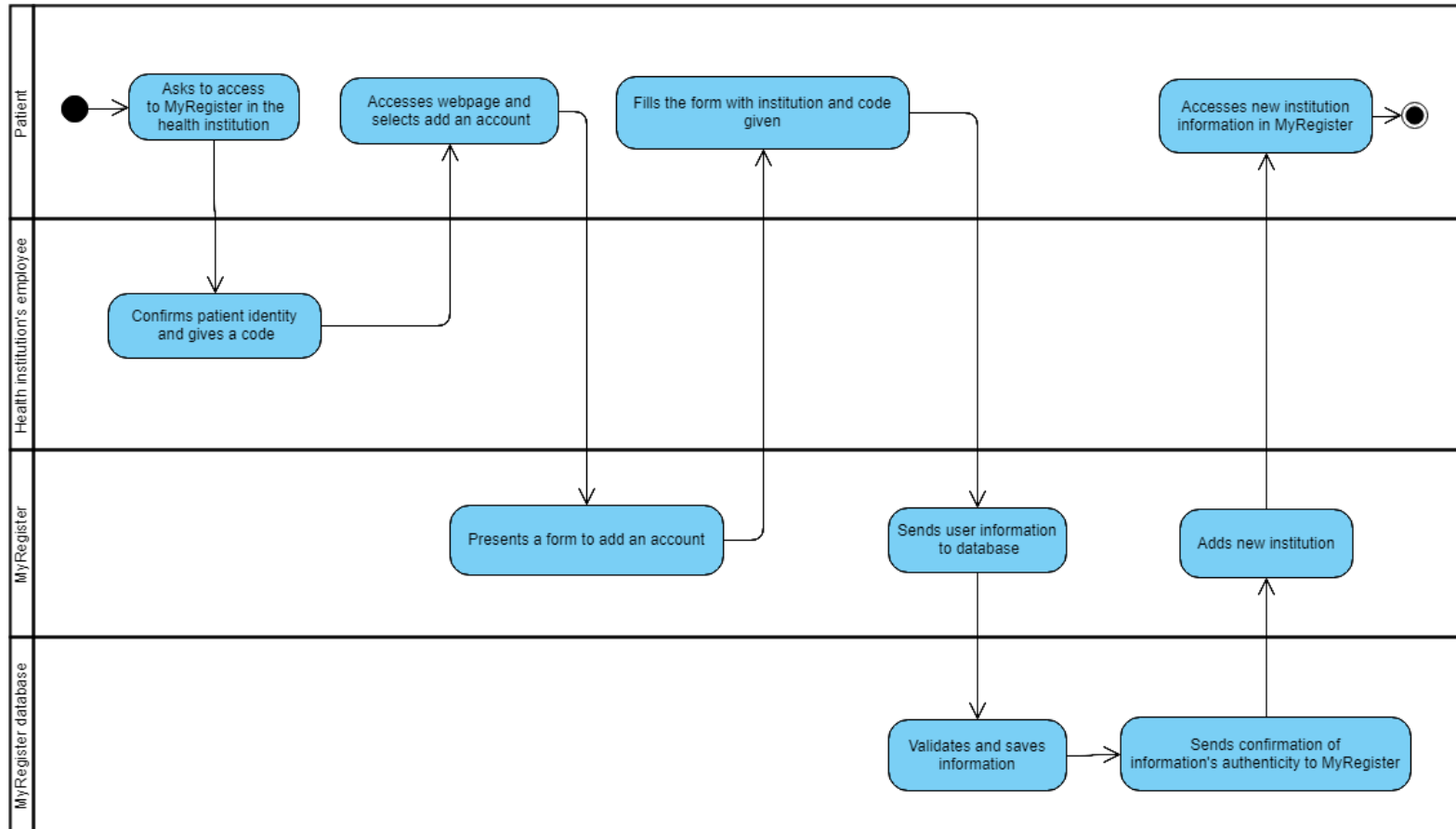


Figure 3.11: Activity diagram for use case 10

3.5 Requirements

Requirements are statements that explain how a system or product should work, that is, what are the functions and how those functions should be delivered. The requirements are divided into two types: functional requirements and non-functional requirements. The functional are the requirements that allow to describe the functions of a system, that is, what the system does. The non-functional requirements allow to describe how are the system functions, that is, how the system is. The requirements can be divided into several sub-types, according to Suzanne Robertson (Rogers et al., 2011) the non-functional requirements can be divided into:

- Usability Requirements
- Security Requirements
- Look and Feel Requirements
- Cultural and Political Requirements
- Legal Requirements
- Performance Requirements
- Operational Requirements
- Maintainability and Portability

The requirements should be specific, clear, unambiguous, complete and possible. This is important because everyone should understand the requirements and be able to implement them in the system. The definition of requirements is an iterative process and requires the collaboration of all stakeholders of the system. Users are fundamental at this stage because it is through their identified needs that most requirements are created. The final system should allow users to achieve their goals. Therefore, this phase provides for two goals, the first goal is to understand the needs of users and the second is to effectively define the requirements to meet the needs identified in order to proceed to the design phase (Dick et al., 2017; University of Alberta, 2015; Rogers et al., 2011).

The main functional requirements of MyRegister are presented in table 3.1. All of the requirements identified for the implementation of MyRegister, functional and non-functional (security and usability) requirements are available in Annex 7.3.

As mentioned previously, the process of defining requirements involves the stakeholders and mainly the users and their needs. The requirements presented are the result of the identification of user's needs, the identification of personas, the scenarios and use cases defined for the tool. Identification of user's needs was based on the survey questionnaire presented in chapter 2 as well as expert opinions.

Table 3.1: Functional Requirements

ID	Requirement description	Use case related
FR1	The tool should allow to create a new account on the web page.	Use case 1
FR2	The tool should allow to login into the webpage using the user's SNS number and the chosen password (considering that the user has already been registered).	Use case 2
FR3	The tool should be able to present the institution's information as updated as possible depending on user's SNS number registered.	Use case 2
FR4	The tool should be able to present to the user the following areas: - Profile area; - Access history; - Past health episodes; - Future health episodes; - Contacts and support; - Definitions; - About the tool; - Privacy policy; - Legislation information.	-
FR5	The tool should calculate whether an access occurred outside the context of the episodes and show it in the timeline.	-
FR6	The tool should be able to present all accesses made to the user information and each access should present: - Date (when it was performed); - Professional (who performed it); - System (system where was performed); - Institution (where was performed); - Action (which action was performed).	Use case 3
FR7	The tool should allow to filter the accesses by: - Institution; - Time; - Professional who accessed the information; - Action done in the access (Create, Read, Update and Delete (CRUD)).	Use case 3
FR8	The tool should allow the user to report any access that he/she believes is suspicious.	Use case 6
FR9	The tool should allow to view all future user's health episodes and present for each of the episode: - Date (when it was performed); - Professional (who performed it); - Institution (where was performed); - Episode (what is going to be performed); - Description of the episode if it exists (for example in a surgery "knee surgery").	Use case 4

ID	Requirement description	Use case related
FR10	The tool should allow to view all user's health episodes already performed (past episodes) and present for each of the episodes: - Date (when it was performed); - Professional (who performed it); - Institution (where was performed); - Episode (what is going to be performed); - Description of the episode if it exists (for example in a surgery "knee surgery").	Use case 5
FR11	The tool should allow the user to add a new health episode to the future episodes' list.	Use case 7
FR12	The tool should allow to filter the episodes (past and future) by: - Institutions; - Time; - Professional.	-
FR13	The tool should allow the user to authorize to receive emails when new accesses to his/her clinical information are done and/or when a new health episode is scheduled.	Use case 8
FR14	The tool should allow the user to authorize to receive Short Message Service (SMS)'s when new accesses to his/her clinical information are done and/or when a new health episode is scheduled.	Use case 8
FR15	The tool should alert the user by email when new accesses to his/her clinical information are made and/or when a new episode is scheduled.	Use case 9
FR16	The tool should alert the user via SMS when new accesses to his/her clinical information are made and/or when a new episode is scheduled.	Use case 9
FR17	The tool should allow the user to add more institutions to his/her account.	Use case 10
FR18	The tool should allow the user to log out in all tool's pages.	-

3.6 Functional Prototype

A prototype is something that allows stakeholders to understand what the system or product will actually look like and allow them to experience what their use will be. A prototype can be one-screen drawings on a sheet or even a mockup of a product. The main goals of prototypes are to be the communication devices to use with the stakeholders and to allow easy testing of the team's ideas. There are different ways of presenting prototypes, they may be low-fidelity or high-fidelity. The low-fidelity are simple, fast and inexpensive prototypes that allow to exchange ideas, although they are not very similar to the final product. They are easy to change and therefore are more commonly used in the early stages of ideas. Examples of these are paper drawings. High-fidelity prototypes are very similar to the final product and should be used when the ideas for the product are more defined. These should allow the user

to interact with the product and simulate a real situation. For software prototypes there are online tools that can help in the prototyping phase and make the prototype as close to the final product as possible (Rogers et al., 2011).

For the prototype of MyRegister we chose to present a prototype of high-fidelity that later allows the users to evaluate and realize the potentiality of the tool. We used the Justinmind Prototyping tool to build the prototype. The mockups created are presented in Annex 7.4.

For the creation of the tool design, we took into account the defined requirements (Section 3.5 and annex 7.3 as well as good usability practices (Usabilidade.gov.pt, 2018; Elastic, 2018).

Considering that we aim to use this tool for any adult person in the country, we have to predict that innumerable people with different pathologies and/or interests will be able to use the tool. We consider necessary to have a special focus on the way which the content of the tool is visualized, namely with regard to colors, letter sizes among others.

According to the specifications of the W3C (international organization that establishes World Wide Web usage patterns), color contrast checking is a factor of importance when users have low visual difficulties. According to W3C the contrast ratio between background and text color should be bigger than 4.5:1 and for bold text contracts should be bigger than 3:1. This does not apply to logos or decorative images (W3C, 2018).

To verify that the colors chosen for MyRegister are correct considering the previous explanation, we use an online tool that allows us to evaluate the contrast. We have inserted in the web page <https://webaim.org/resources/contrastchecker/> the colors defined for the tool:

- #FFFFFF - color background
- #008080 - background color and text color
- #000000 - text color
- #FF0000 - text color

The existing combinations and their results were:

Background color: #FFFFFF and text color: #008080

*Image from <https://webaim.org/resources/contrastchecker/>

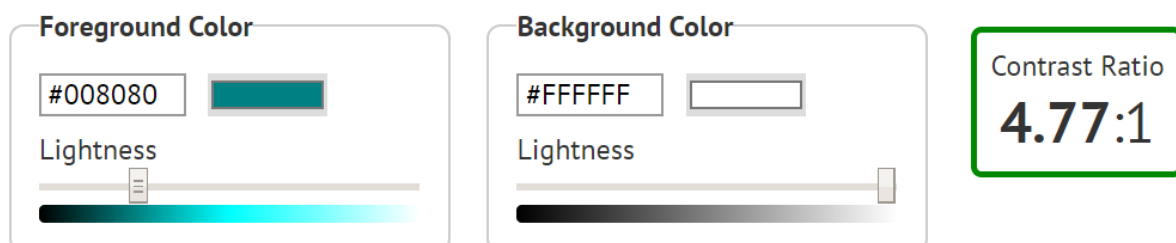


Figure 3.12: Contrast Result one

Background color: #FFFFFF and text color: #000000

*Image from <https://webaim.org/resources/contrastchecker/>

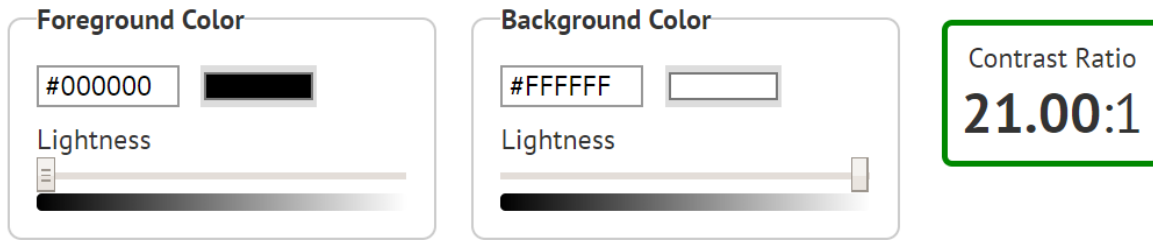


Figure 3.13: Contrast Result two

Background color: #FFFFFF and text color: #FF0000

*Image from <https://webaim.org/resources/contrastchecker/>

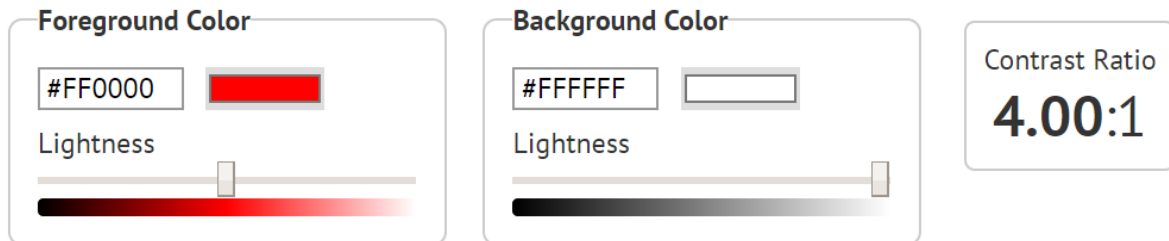


Figure 3.14: Contrast Result tree

Background color: #008080 and text color: #FFFFFF

*Image from <https://webaim.org/resources/contrastchecker/>

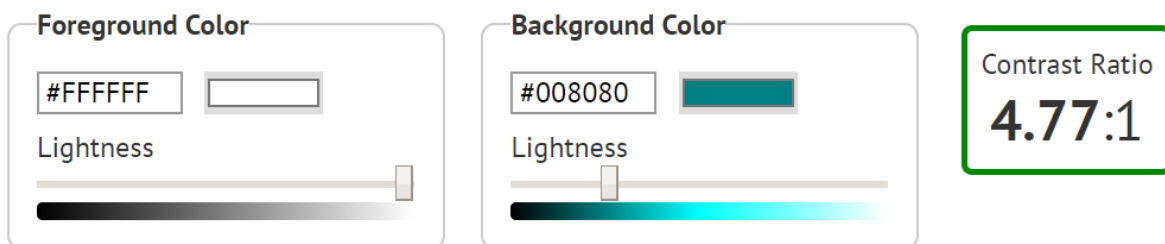


Figure 3.15: Contrast Result four

As we can see in the figures presented previously, 3.12, 3.13, 3.14 and 3.15 only one of the combinations tested did not present a contrast superior to 4.5:1. Considering that this combination is only used punctually we chose to change the text of this combination to bold, passing in the contrast ratio to positive because bold should be bigger than 3:1.

3.7 Architecture proposal

Here we present an architecture proposal for the implementation of MyRegister. Figure 3.16 shows a possible installation diagram, followed by the description of the information circuit in the diagram.

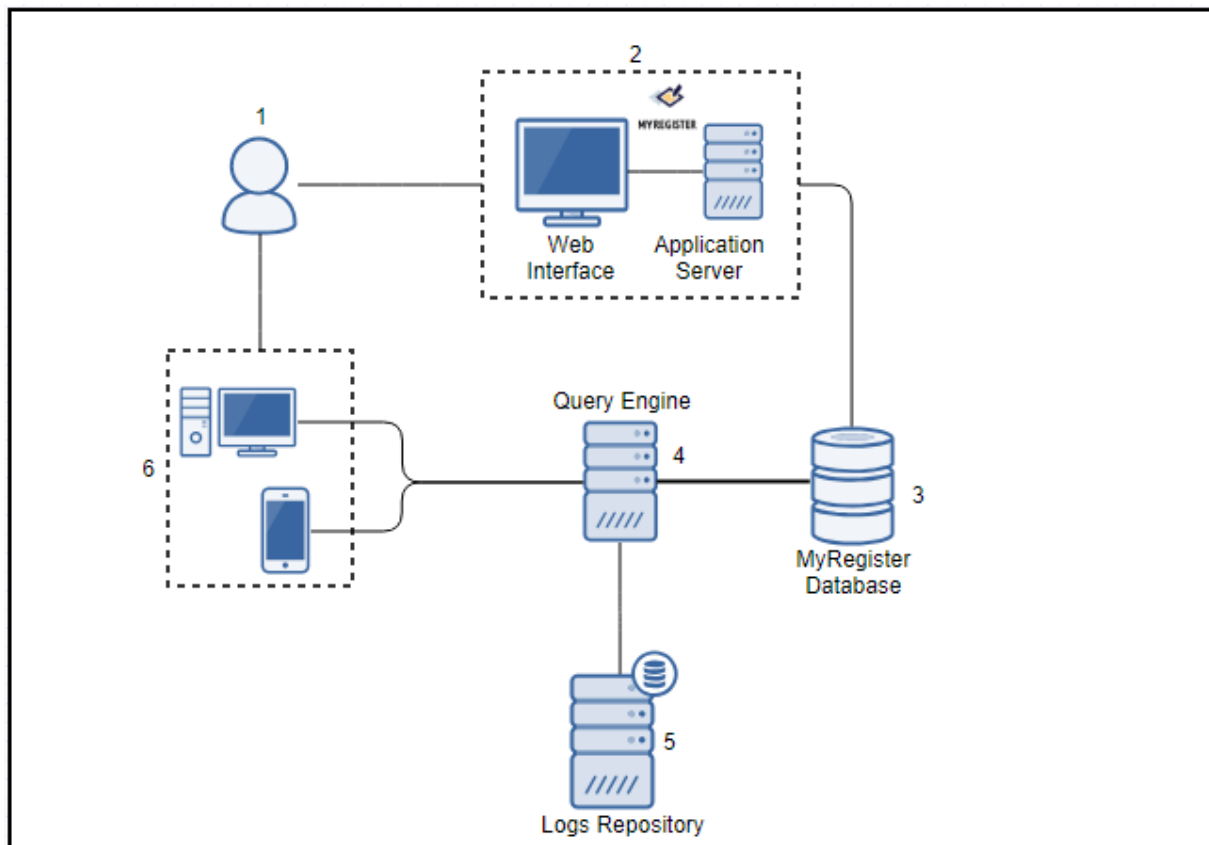


Figure 3.16: Architecture Proposal

Description:

1. The user has access to the information through MyRegister web page. It is also possible through his e-mail and/or SMS to receive the alerts.
2. MyRegister is composed of a web interface and an application server and connects to the database;
3. MyRegister's own database stores all user information. It connects to MyRegister and the query engine.
4. The query engine allows you to collect information from the Repository of HS.Register, communicate with the user via email and/or sms and with the MyRegister database.
5. The repository of HS.Register is where all the information of the HS.Register is stored. The query engine is the only element of MyRegister that will communicate with the repository.
6. The user devices allow the user to receive the MyRegister alerts.

3.8 Discussion

The first sections of this chapter allow us to understand which users may use the tool, how these users are, what are their capabilities, their goals, under what conditions the tool can be used, and so on. From the systematized information was created a requirements' list and a functional prototype based on the defined requirements.

The specification phase is of great importance for the success of the tool. The definition of requirements was considered in (Taylor, 2000) as one of the phases that causes more failure in a project. The cause of

this failure is the definition of unclear objectives and requirements. Regarding the criteria for success were pointed out the requirements that are defined in a clear and detailed way. In order for the set of defined requirements to be detailed and clear it becomes imperative a good knowledge of the users and the goals of the tool for them. We believe that this chapter is essential for the success of MyRegister because it shows all the necessary information from the personas, the scenarios and the use cases of the tool that originated a set of requirements with enough detail that will allow the development team to create the tool as close to the end user as possible. The functional prototype will also allow the development team to follow the design that we consider most appropriate and that will already have been evaluated by the users (chapter 4).

When users' voices are heard and taken into account it is possible to create a tool that will be useful, enjoyable and responsive to their needs (Rogers et al., 2011), as presented in chapter 4.

3.9 Limitations

The major limitations of study B is the difficulty in defining the target audience of the tool. Although we have chosen the personas that we consider would benefit most from the use of the tool, this information was not possible to validate so we can not say with certainty that this are the personas of the tool. The same happens with the scenarios that have come out of situations for which we consider the use of MyRegister to be useful. Since the tool is intended to be used by any adult patient, focusing on a specific type of person and a situation can be challenging and difficult.



Study C - Prototype Evaluation

4. Study C - Prototype Evaluation

4.1 Introduction

Usability aims to guarantee the quality of the interface, allowing the user an easy, pleasant and transparent interaction, and transmitting the sensation of the user having control over the use of the system. In addition, usability can influence the use of the tool and make users more interested in using it and using it more frequently. We can not assume that following good design practices is enough to please users, evaluation is necessary to ensure that the system can be used and users like it (Rogers et al., 2011).

In order to take into account the needs of the users during the design and development phases, it is important to evaluate the application at various stages to correct the problems encountered, as soon as possible. Deficiencies detected can and should be solved during system development. If those are discovered at the end of the development process it can be problematic as correcting a problem identified at an advanced stage can result in high costs due to the need to make changes to the entire system. Such changes may lead to delaying the final development deadlines. Therefore it is essential to start evaluating as soon as possible, preferably in the system's design phase (Santos, 2015).

Efficiency, efficacy and satisfaction are three important points to consider in the usability of a system. Usability tests need to measure the performance of usual users to perform usual tasks. Through questionnaires and interviews it is also possible to measure user's satisfaction (Rogers et al., 2011).

After the construction of the functional prototype presented in chapter 3, we consider the importance of evaluating it with the users. This evaluation will allow us to validate our work, improve it and move on to a development phase with greater certainty of what the user wants and needs in MyRegister.

4.2 Methodology

4.2.1 Study Design and Data Collection

In order to evaluate the functional prototype we decided to present the study participants with four tasks to accomplish, these were triggered by four questions. Participants had the functional prototype created presented through the Justinmind software, this allows interactions of the pages through clicks simulating a real web page. At the beginning of the activity it was given a brief explanation of what MyRegister is and what they could expect from this tool, namely that it allows to know which health professional saw the patient's health information as well as access their health episodes. For this usability test we asked the participants to use the prototype in order to answer the four questions presented, we

asked them to speak out loud and explain their difficulties of what they were encountering while we were taking notes of the use of the prototype and the timing of each task completion. No instructions were given to the participants on how to carry out the tasks nor was there a time limit for doing them. After completing the tasks we provided the user with the System Usability Scale (SUS) questionnaire to respond according to the use of the functional prototype. We also gave the participants the possibility of continuing to explore the prototype to respond more accurately to the questionnaire. We added a question for suggestions, this was for the user to leave recommendations or improvements in any part of the prototype, including design and/or content. At the end of the SUS we ask the participants to fill out a questionnaire with sociodemographic information. This information allows us to understand the type of population that was evaluating our prototype (age, academic qualifications, technical habits, use of similar webpages etc.). The three documents presented to the participant are available in annex 7.5.

4.2.2 Study Participants

We used a non-probabilistic method of convenience, because we selected the most easily accessible people that met the inclusion and exclusion criteria.

Inclusion criteria:

- Older than 18 years;
- Fluent in Portuguese.

Exclusion criteria:

- Can not read and/or write;
- Have any motor deficiencies that prevent the use of the computer.

According to (Virzi, 1992) only 5 participants will be enough to find 80% of usability problems. Being that more serious problems will be found more easily initially and that additional participants reveal less and less problems. Because we decided to divide the participants into four different groups according to their expertise and ages we decided that each group would have between 2 and 3 participants. Groups are presented in table 4.1.

Table 4.1: Evaluation Groups

Group	Description	n participants
A	Expert participants (in software development, medical informatics and data protection)	3
B	Young participants ([18, 30[years)	3
C	Adult participants ([30, 50[years)	2
D	Older participants (>50 years)	2

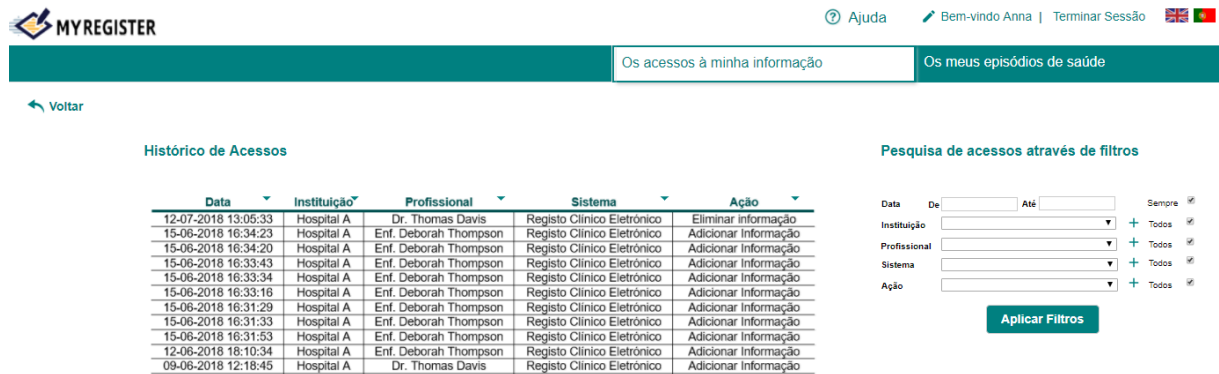
4.3 Results

4.3.1 Results of the tasks performed

During the accomplishment of tasks notes were taken regarding the behavior of the participants with the prototype. These are presented in annex 7.6 in chronological order of the evaluation. After the evaluation of the prototype with the first 4 participants, we immediately identified 3 major problems:

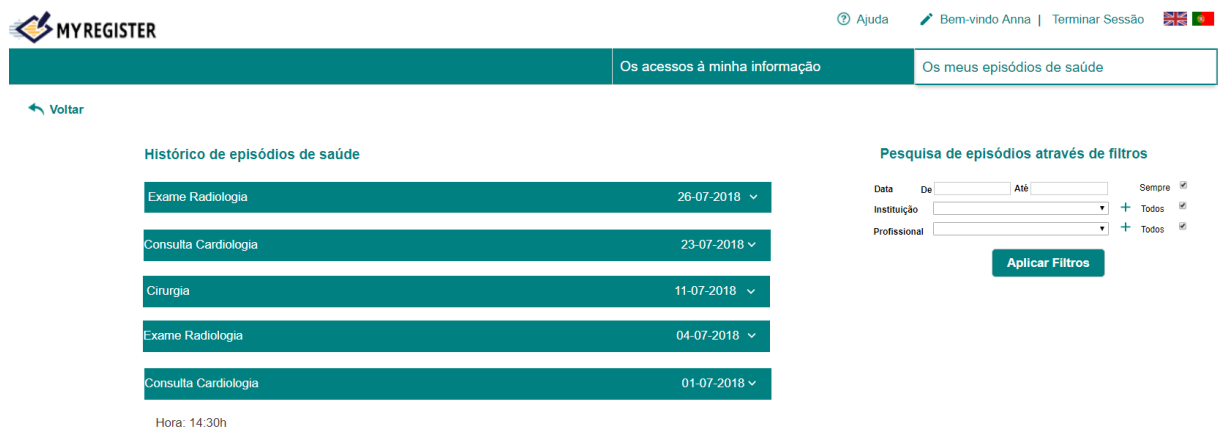
- difficulty in returning to the home page;
- lack of use of filters;
- difficulty in understanding the difference between access and health episode.

From the previous three problems we consider that the first two are easily solved unlike the last one that would require a reconstruction of the prototype. In order to avoid that the remaining participants were affected by the problems already identified we chose to solve the first two. We introduce a back button on every page of the prototype as shown in figures 4.1 and 4.2 and also decided to remove the symbol before the title of the pages because it misled the participants thinking they could return to the homepage by clicking there. To solve the second problem we chose to include a title for the filters in order to draw attention and explain their existence, as shown also in figures 4.1 and 4.2. The prototype with the changes was presented to the remaining of participants.



Data	Instituição	Profissional	Sistema	Ação
12-07-2018 13:05:33	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Eliminar informação
15-06-2018 16:34:23	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Adicionar Informação
15-06-2018 16:34:20	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Adicionar Informação
15-06-2018 16:33:43	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Adicionar Informação
15-06-2018 16:33:34	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Adicionar Informação
15-06-2018 16:33:16	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Adicionar Informação
15-06-2018 16:31:29	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Adicionar Informação
15-06-2018 16:31:33	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Adicionar Informação
15-06-2018 16:31:53	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Adicionar Informação
12-06-2018 18:10:34	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Adicionar Informação
09-06-2018 12:18:45	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Adicionar Informação

Figure 4.1: All accesses mockup updated



Exame Radiologia	26-07-2018
Consulta Cardiologia	23-07-2018
Cirurgia	11-07-2018
Exame Radiologia	04-07-2018
Consulta Cardiologia	01-07-2018

Figure 4.2: Past health episodes mockup updated

The major problems found in the remaining of participants' evaluation were:

- difficulty in understanding the difference between access and health episode;
- difficulty in interpreting the dates in the timeline;
- difficulty finding the report access button.

From the previously identified problems we verified that the difficulty in understanding the difference between accesses and health episodes occurred in several participants in addition to the first 4 participants. The two problems identified and changed in the prototype in the first 4 participants' evaluation were solved and allowed users to show two new problems.

Each of the questions asked had an associated solution, some of the questions would have different ways of achieving the result but all the participants should be able to give the correct answer. All participants in all questions asked were able to complete the task required to give the answer, however the answers given were not always correct. In table 4.2 we present the results of each of the participants, the percentage of correct answers of each group and the percentage of all groups.

We can verify by table 4.2 that questions 2 and 3 were answered correctly by all participants. Question 1 was answered correctly by all participants in group A and question 4 by all participants in group C. 4 of the participants answered all of the questions correctly, 2 of whom were in group A, 1 in group C and one in group D. We can assume that question 4 was the one that created more difficulties in the participants (with 60% of correct answers) followed by the first question (with 70% of correct answers). The changes made in the prototype after evaluation of 4 of the participants did not show evidence of having interfered with the answers given by the participants.

Table 4.2: Results: task answers

	Question 1	Question 2	Question 3	Question 4
Participant 1.A	Correct	Correct	Correct	Incorrect
Participant 2.A	Correct	Correct	Correct	Correct
Participant 3.A	Correct	Correct	Correct	Correct
Answers correct Group A	100%	100%	100%	66%
Participant 1.B	Correct	Correct	Correct	Incorrect
Participant 2.B	Incorrect	Correct	Correct	Correct
Participant 3.B	Correct	Correct	Correct	Incorrect
Answers correct Group B	66%	100%	100%	33%
Participant 1.C	Correct	Correct	Correct	Correct
Participant 2.C	Incorrect	Correct	Correct	Correct
Answers correct Group C	50%	100%	100%	100%
Participant 1.D	Incorrect	Correct	Correct	Incorrect
Participant 2.D	Correct	Correct	Correct	Correct
Answers correct Group D	50%	100%	100%	50%
Total Answers correct	70%	100%	100%	60%

In table 4.3 we present the time each participant took to complete the tasks to answer the questions.

It is important to note that the times presented are counted from the moment the participant starts reading the question until a final answer to the question is given. Considering that all questions were answered by the participants, even if they were answered wrongly we chose to count all response times. As shown in table 4.3, we can verify that in all the questions, Group A (experts) obtained a mean time of resolution of the tasks much lower than the other groups. With special focus on the last question that was resolved much faster by Group A than the other groups. Comparing groups B, C and D, we realized that the results are not so distant from each other. Although it is possible to verify that group D, older than 50 years, has a mean time superior to the remaining groups, between group B and C the values are lower in one or the other depending on the questions. Contrary to the task answers, the task execution time may have been influenced by the changes made in the prototype after the evaluation of the first 4 participants (participants 1.B; 2.B; 3.B; 1.C). The first 4 participants showed that they had a longer response time, essentially in questions 2 and 3, which, considering the notes taken during the evaluation, allows us to say that these results were based on the difficulties inherent in returning to the home page and the use of the filters, problems solved for the remaining participants.

Table 4.3: Results: task time (seconds)

	Question 1	Question 2	Question 3	Question 4
Participant 1.A	78	47	29	83
Participant 2.A	48	63	41	73
Participant 3.A	45	46	50	92
Mean Group A	57	52	40	83
Participant 1.B	99	95	97	200
Participant 2.B	59	128	48	199
Participant 3.B	35	133	128	175
Mean Group B	64	119	91	191
Participant 1.C	61	86	102	204
Participant 2.C	99	94	69	189
Mean Group C	80	90	86	197
Participant 1.D	167	84	154	203
Participant 2.D	78	73	65	129
Mean Group D	123	79	110	166
Mean all groups	77 [35,167]	85 [46,133]	78 [29,154]	155[73,204]

Mean all groups: median[min,max]

4.3.2 Results of the SUS

For the evaluation of usability we chose to present to the user a questionnaire already validated and used all over the world. The questionnaire applied was the SUS translated into Portuguese and validated by (Martins et al., 2015).

The SUS is composed by 10 statements to which a level of agreement, based on a likert scale, should be associated by the participant. For the answers of "strongly disagree " is assigned the value 1, to

"disagree in part" the value 2, for the "not agree or disagree" is assigned the value 3, for the "agree in part" the value 4 and for the "strongly agree" the value 5. For each participant the calculated score will allow us to measure the level of usability of the product. The score ranges from 0 to 100 and is calculated by summing the results of each statement multiplied by 2,5 (Brooke et al., 1996; Martins et al., 2015). The result of each statement is calculated by:

- For the statements 1, 3, 5, 7, and 9: assigned value (1 to 5 according o the answer) minus 1;
- For the statements 2, 4, 6, 8 and 10: 5 minus value assigned (1 to 5 according o the answer).

According to (Martins et al., 2015) a product is considered above average, and therefore with good usability, if it obtains a SUS score above 68.

In table 4.4 we present the values of the likert scale of each participant in each question/statement and in the last column the participant's SUS score. We can verify that only 2 participants obtained a result inferior to 68, one of Group A and one of Group B. The mean scores of the groups were all higher than 68, with the highest mean in group C and lowest in group B. The changes made in the prototype after the evaluation of the first 4 participants showed no evidence of interfering with the results of the SUS score. The median of the SUS score of all the participants is 79.5, that is above the average and reveals a good usability of the prototype MyRegister.

Table 4.4: Results: SUS

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	SCORE	SUS
Participant 1.A	5	1	4	1	5	1	5	1	5	5	87,5	
Participant 2.A	2	3	4	2	3	4	5	2	4	1	65	
Participant 3.A	5	2	4	1	5	1	3	2	5	2	85	
Group A Score											79,17	
Participant 1.B	4	4	4	4	5	1	3	4	2	3	55	
Participant 2.B	5	4	3	1	3	1	5	1	3	2	75	
Participant 3.B	5	4	4	1	4	1	5	2	4	2	80	
Group B Score											70	
Participant 1.C	4	2	4	1	5	1	5	1	5	1	92,5	
Participant 2.C	4	1	5	1	5	1	5	1	4	1	95	
Group C Score											93,75	
Participant 1.D	4	3	4	4	4	1	5	1	2	3	70	
Participant 2.D	4	2	5	1	5	2	4	1	5	1	90	
Group D Score											80	
Total Score											79,5	

1 – strongly disagree; 2 – disagree in part; 3 – not agree or disagree; 4 – agree in part; 5 – strongly agree

Below we present the suggestions left by the participants at the end of the questionnaire:

- Add "Back" button (suggestion before prototype changes);
- Add title to filters (suggestion before prototype changes);

- Add information on the timeline for the month in question and add indication of the days on the line;
- Add a filter to access only out-of-context accesses;
- Add a signalization in the total access history for the accesses that are out of context;
- Add information explaining the action that is triggered when a button is clicked (hover the button to see more information);
- Add information in the timeline about the accesses, namely the institution where they were made (hover the button);
- Change the "Report" and "Access History" buttons to give more prominence;
- Add checkboxes in each access to be able to report more easily;
- When a health episode of the timeline is selected, only the episode in question should be presented or be marked with a different color to give more prominence;
- Add an area with the description of the most technical/specific vocabulary of the tool giving context and examples.

4.3.3 Results of the demographic questionnaire

To understand the results of the evaluation it is necessary to also understand our population under study. Group A consisted of 3 individuals under 50 years of age, with masters or PhD degrees, who always use the computer and who have in common the use habits of similar web pages. Group B is composed entirely of students who frequently use the computer but not as frequently use similar webpages to our prototype. Group C consists of participants with a higher academic degree with a high frequency in the use of computers and webpages similar to the prototype. Finally, the last group, the Group D is composed by 2 participants with secondary education who use the computer but never used similar webpages as the ones presented. The characterization of each participant is presented in Table 4.5.

Table 4.5: Results: Demographic Information

	Gender	Age	Academic Qualifications	Occupation	Personal computer	Use the computer	Use bank webpage	Use finance webpage	Use PDS webpage
Participant 1.A	F	18-30	Master/PhD	Worker	Yes	Always	Frequently	Never	Sometimes
Participant 2.A	M	30-50	Master/PhD	Worker	Yes	Always	Sometimes	Frequently	Never
Participant 3.A	M	18-30	Master/PhD	Worker	Yes	Always	Always	Frequently	Rarely
Participant 1.B	F	18-30	Secondary	Student	Yes	Frequently	Never	Never	Rarely
Participant 2.B	F	18-30	Secondary	Student	Yes	Always	Rarely	Never	Never
Participant 3.B	F	18-30	Secondary	Student	Yes	Always	Rarely	Never	Sometimes
Participant 1.C	F	30-50	Post-graduation	Worker	Yes	Frequently	Always	Always	Sometimes
Participant 2.C	F	30-50	Bachelor's	Worker	Yes	Always	Always	Always	Sometimes
Participant 1.D	F	50-60	Secondary	Worker	Yes	Rarely	Never	Never	Never
Participant 2.D	M	50-60	Secondary	Worker	Yes	Frequently	Never	Never	Never

4.4 Discussion

The study C aimed to evaluate the created functional prototype of MyRegister and collect feedback from user tests to optimize the tool according to the obtained results. From the results presented previously we can verify that the prototype had in general positive results when used by the study participants.

Regarding the answers to the questions presented, the answers were mostly correct. Those that were not correct were due to difficulties in interpreting the question or the topic that is addressed in MyRegister and not because of difficulties in the usability of the prototype. We can then ensure that the study population was able to use the prototype to answer the questions. The answers to the only questions that obtained incorrect answers (Question 1 and Question 4) can be justified. Question 1 was the first question and therefore the first contact the participant had with the prototype. In this first phase the participant was trying to understand what was presented in the prototype and could not be able to easily interpret the information presented leading to incorrect answers. Question 4 was a question with an associated difficulty. It was expected that the participant would have knowledge about what an abnormal access by a health professional would be and required knowledge of the legislation and interpretation of the text provided as context for the question. In this question the incorrect answers were always referring to the access where the deleted information was. We understand that there is a perception of the participants that no information should be eliminated independently of the healthcare professional who does it. The intent of this question was to see if the participants understood what an abnormal access was and that it should be reported. Although 4 of the 10 answers were wrong, we did not consider that these participants would report in a real situation only all accesses with information deleted. We believe that the problem in this question was the difficulty that existed in interpreting the context and therefore understanding what would be a suspicious access or not. We believe that if the participants saw real information from their health professionals, actions taken etc. would have been easier to report correctly.

About the time the participants took to complete the tasks we can say that for a first use of the prototype, in our opinion, we have had positive results. The execution time of all tasks was between 29 seconds and 204 seconds (3 min 24 sec). Being that the question with superior times was the question 4 that as referred it demanded a greater knowledge on the part of the user. We can verify that the smaller average times were observed in Group A, which is expected considering that the population in question would dominate both the technological environment and MyRegister topic. In Groups B and C the average times are similar and show that there were no difficulties that delay the execution of tasks. Group D obtained the highest mean values on some questions. Considering the age of the participants in this group and the technological habits presented in the socio demographic results it is expected that, in comparison with the other groups, they have higher values of time to perform the tasks.

In the usability evaluation, the SUS results were positive, showing that the prototype provided users with good usability. Comparing with the results of the SUS applied in other studies we consider that our result was very good. In (Konstantinidis et al., 2016), the SUS score for a platform to assist in the physical practice of the elderly was 76.3 and in (Triantafyllidis et al., 2014) the SUS score was 73 for a mobile health platform. The score that our study obtained was 79,5 showing that users had a pleasant experience in using the prototype.

Two of the problems found in the first 4 participants were the need for a back button and a need to

give greater focus to the filters. After being solved for the remaining participants it was possible for us to identify other problems. One of the biggest problems found in most of the participants was the difficulty they had in distinguishing what are accesses and what are health episodes. One solution to this problem would be to restructure the entire prototype in order to group each type of information to allow the user to more easily understand and separate it. Considering that this requires a considerable reformulation, another hypothesis that was also suggested by the participants would be to create an area of clarification of the terms used in MyRegister, with associated examples to facilitate the user's understanding. Another problem found was the difficulty that the user had in finding the secondary buttons, namely the button to report the accesses. As a solution to this problem the button colors can be changed to draw more attention to the user. Other suggestions from the participants were given, they did not interfere with the ability to perform the tasks but would provide the user with a more enjoyable experience. In this way, we intend to reformulate the mockups to apply them and promote the greatest usability possible.

4.5 Limitations

The major limitation of study C was that we did not have the opportunity and time to validate the usability assessment task script presented to the participants. The validation of the questions and the answers given would be essential to ensure that it would be easy for users to interpret the given questions, as well as to be sure that the answers considered by us as correct did not raise any doubts that those would be the correct ones. Some of the answers given by the users were not considered for us initially as being possible correct answers, but we equate the hypothesis of these answers being considered as correct. Another limitation of this study is the chosen population that besides being constituted by a low number of participants those were chosen for convenience. A recognized limitation was that changes were made to the prototype during the course of the evaluation. Although we consider it important to solve the problems found to not affect all the participants, these changes have prevented us from making a comparison between the different groups with certainties. We consider it necessary to make an evaluation with more participants and with a random sample of the Portuguese population. Another limitation is the evaluation method chosen, SUS and the interviews (through the accomplishment of tasks) although used successfully are not detailed enough to say with certainty that the prototype has a good usability. Besides that the SUS test is most often applied after frequent use of the tool by the user, which did not happen in our study since we used a prototype for evaluation. To evaluate the usability of the tool other methods such as a First Click Testing or Eye Tracking can be added.



Final Discussion

5. Final Discussion

5.1 Discussion of main results

GDPR forces that healthcare institutions must maintain records of all processing activities and be able to easily report on personal data use and processing compliance. The implementation of software tools that provide detailed audit logs including changes and usage are essential to automate this process and guarantee logs integrity.

The results of this dissertation constitute the starting point for creating a tool that shows patients which professionals access their health information. As a first step we did a study, presented in chapter 2, that allowed us to understand that the respondents (students of the University of Porto) had interest in having access to a tool that would show them who accesses to their health information since 90% consider important the existence of such tool and 71.5% confirm that they would use it. This study also allowed us to understand the awareness that this population has of the health information present in the health institutions and about the existing legislation, that only 19% had heard about. With the result of this study we were more motivated to continue with this work and create a tool for the use of all adult patients in the country.

The second phase was the specification of the tool and creation of the functional prototype. This prototype was created based on the needs and opinions gathered in chapter 2 and the requirements created and presented in chapter 3 and annex 7.3. This prototype was created for any patient to use the tool, focusing on the usability of the interface. In order to verify that the created prototype met the needs of its users in an effective, efficient and satisfactory way, we performed the study presented in chapter 4. In this study we present the results of the prototype's evaluation done with real users. The results obtained were, in our opinion, positive since the prototype created was tested to evaluate the usability of the interface and results show that has good usability with a score of 79,5 in 100 for the SUS test. Also results show that the users were able to complete all the tasks and in a maximum time of 3 minutes 24 seconds. We believe that it would be interesting to make a comparison of the results of the time taken to perform the tasks initially with the time after a period of experimentation by the user. In this way the time difference between group A (experts), who obtained inferior times, and the remaining groups could be reevaluated. If the time difference between the groups diminished in the second evaluation (assuming that the time of group A would be maintained) would allow us to verify that the difficulties found referred to the lack of habituation to the tool and not due to usability problems. Although 17.5% of the total of questions was wrongly answered we do not consider that these were wrong due to a problem in our interface but rather difficulties in interpreting the question and/or lack of knowledge of the legislation.

After the evaluation of the first 4 participants and identification of the problems, an improvement in the use of the prototype was evident in the other participants. We believe that although it may have somehow influenced the results of the evaluation, it has enabled us to more easily find minor problems that could not be discovered if the major problems that the first 4 participants pointed out had not been corrected. The problems that have not yet been corrected will be corrected shortly. We also intend to consider the suggestions made by users in order to contribute to the improvement of the prototype.

With the conclusion of this study prior to the development of the tool we consider it essential, we now have more certainties of the course that we must follow in the development of the tool, we have confirmation of the necessity of the tool's existence and we present a proposal for the presentation of the tool already validated by real users. This initial study will allow the development team to avoid mistakes that could be made without this study and speed product development.

With the completeness of the dissertation we feel confident that the tool will be an asset for patients, health institutions and an advance for the compliance with GDPR in Portugal.

5.2 Limitations of MyRegister

Considering that the limitations of the three studies presented in the dissertation were described in each study, we now point out the limitations that we consider to exist in MyRegister. To use this tool it is essential that health institutions want to collaborate with the project and allow their patients to consult the information that is available in MyRegister. It is also important that institutions make themselves available to have resources for patient's registration to ensure that information is only provided to those entitled to it. Another limitation pointed to the use of MyRegister is that it is dependent on the HS.Register which means that it is obligatory that the health institutions have HS.Register integrated within their information systems. Regarding limitations that directly affect the patient, it should be referred that the lack of knowledge regarding legislation, patients' rights and interest in these matters can influence the patient's interest in using the tool as well as the ability to use correctly and interpret the information presented.

5.3 Future work

Future work includes the revision of the functional prototype based on the results of the evaluation presented in chapter 4. After correction and improvement of the prototype it would be important to make a new evaluation with a larger number of participants and randomly chosen in order to sustain our goal of making MyRegister usable for all patients in the country. Another important addition would be to apply to these participants the questionnaire of the study of chapter 2 before the evaluation of the prototype and try to understand if there is a relation between both results. The next step will be the development and implementation of MyRegister for use in real context.

5.4 Main Contributions

The main contributions of this dissertation are:

- The results of chapter 2, published in (Reis et al., 2018), that allow us to confirm the interest of the population interviewed in the existence of a tool that shows them the accesses to their health information;
- The requirements list for the development of the tool;
- The functional prototype of the tool that was evaluated by real users in chapter 4;
- The methods and instruments used for the evaluation of the functional prototype, chapter 4, that can be reproduced and used for similar studies.



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6. References

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Annexes

7. Annexes

7.1 Published article in the proceedings of the CISTI2018 conference.

Do patients want to know who accesses their Personal Health Information?

A questionnaire to university students

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Abstract — Personal Health Information (PHI) is collected and used by multiple health professionals and multiple information systems, and usually the patient does not know who accesses their information, when and for what purposes. According to USA (HIPAA) and EU legislation (GDPR) a patient has the right to see his/her clinical information and to know who has access to it, however, the process of obtaining all this related information is still time consuming and complicated. We aim to investigate the opinion of university students regarding the existence of a tool to verify whose healthcare providers access their health information. A web-based questionnaire was designed, 33404 university students were contacted and 589 answered it (1.8% response rate). 90.7% of participants recognize that a tool with those characteristics is important, and 71.5% of them agree to use that tool. In general, we can consider that although the vast majority of participants did not show great knowledge about available healthcare legislation (81%) and that about half of respondents do not know about the use of their data by other parties (52%), more than 90% consider important the existence of a tool to view who accesses their health information. We intend to continue research on this topic and design an access control tool that can empower patients to better control their privacy and rights so to address the gaps existing in the area.

Keywords - Personal health information, access control, patient access to records, patient empowerment, GDPR, HIPAA.

I. INTRODUCTION

Every day Personal Health Information (PHI) is collected and used by multiple users like physicians, researchers, pharmaceutical industry, statisticians, etc. [1], who recognize that sharing PHI increases quality of health care and reduces medical costs and errors [2]. However, there is no consensus about how and what PHI should be disclosed to the patient. A patient may prefer that his/her PHI remain private but from a healthcare professional's perspective the disclosure of this information may assist with a diagnosis, and help to understand

and prevent diseases [1,2]. Health care should promote the acceptance of patient's needs, and therefore allow the patient to access his/her clinical information as well as promote the power to choose. According to HIPAA (Health Insurance Portability and Accountability), the legislation in the United States that safeguards the safety and privacy of clinical information, a health system must allow a patient to access his/her clinical information and to know who has access to his/her PHI [3]. In Europe, with the new GDPR (General Data Protection Regulation) in force in May 2018, the right of patients to access their clinical information [4] and to know who accessed it, becomes even more evident and required [5]. According to legislation a patient has the right to see his/her clinical information and to know who has access to it however, the process of obtaining all this related information is still time consuming and complicated, requiring formal authorizations from health institutions [5,6]. Following these requirements, healthcare Institutions need to create secure and usable means to fulfill this legislation as well as patients' requirements [7]. Knowing what health professionals have accessed the clinical data of patients may be challenging, even when institutions' systems keep the access logs of health professionals. Often these access logs are kept in each system and not in one single system, making it difficult for institutions to integrate and show this information [8]. In Portugal, there is a public tool created by the National Health Service that allows the patient to view which health professionals accessed their national patient clinical summary (named PDS - Plataforma de Dados de Saúde - Health Data Platform). However, this tool only provides access history for that national platform, and not the accesses performed in the different databases of hospitals or primary care patient records [9].

Following the identification of this gap, this study aims to investigate the opinion of a determined population (e.g., university students) regarding a tool to verify whose healthcare

providers have had access to student's health information. We expect to understand people's awareness about this issue and which requirements a tool should have to fulfill the identified needs. The university student population can be relevant as they are expected to be proficient in technologies, and more aware of their rights when compared to the overall population. They are also expected to shape social opinion for the next decades.

II. METHODOLOGY

A. Study Design and Data Collection

A web-based questionnaire was designed to examine the population's interest in having access to a tool that allows patients to know which healthcare providers access their health information in the institution's information systems. For the questions' development, it was taken into account the fact that the addressed population might not have knowledge about data protection or about how health information flows in health institutions. For this reason, the applied questions were simple, easy to understand and without concepts that needed previous knowledge. To evaluate the clarity of the information, as well as collect critiques and suggestions for the improvement of the questionnaire, a pre-test questionnaire was carried out. This test comprised 38 people and was available from the 9th of November 2017 until the 13th of December 2017. From this pre-test new questions emerged, which we considered pertinent to also integrate in the questionnaire, and corrected some existing ambiguities. After alterations, the final questionnaire was shared by email and applied online between the 2nd and the 12th of January 2018.

B. Study Participants

The sample we chose was a convenience sample, from the student's community at University of Porto. The questionnaire was sent to the target population via the institutional email, with a total of 33404 emails.

C. Questionnaire

The language of the questionnaire was Portuguese and included 29 questions divided into 6 parts: a) personal information (5 questions); b) questions to understand if the person was accustomed to the use of technologies (3 questions); c) questions to understand the level of knowledge and concern about health data and the frequency with which they use hospital institutions (10 questions – 6 of them using the Likert Scale); d) data protection questions, namely knowledge on the new GDPR (3 questions); e) a question about the importance of a tool that shows to patients all the health professionals that see and/or change their health information in different hospital systems (1 question - if this answer was negative the questionnaire ended here; and 2 more questions about the tools benefits); and f) questions about characteristics that may add interest to the tool (5 questions).

D. Data Analysis

To perform data analysis, we used SPSS® in which statistical description measures were applied in order to evaluate the answers. Because most data were categorical variables, the results are shown as numbers and frequencies. To compare the results in different groups medians and quartiles were calculated.

Also a Pearson's chi-square test was performed and a $p < 0.05$ was considered for a statistically significant value.

III. RESULTS

589 participants answered the questionnaire (1.8% response rate), with all answered questionnaires being completed and usable. The submissions were recorded online, on the questionnaire form, and exported to a spreadsheet for analysis. Results from the questionnaire are shown on table I and II, the rows may not add to 100% due to rounding.

A. Personal and Technological Information

Information of 589 participants, 71% female and 29% male was analysed. The majority of answers were from participants aged between 18 and 30 and regarding academic qualifications, the most common was the Bachelor's degree, and most of the participants are not on a health related course nor are health professionals. Participants who are caregivers of children, elderly or both were 8%. Most participants have a daily contact with technologies, 76% use a mobile phone daily to see their email and 84% use their computer to work/study. When asked about changing passwords 36% of participants recognized that they never or rarely changed theirs.

Personal and Technology information results are presented in table I.

B. Health Information Access Knowledge

The results of the questionnaire reported that a majority of participants, 56%, went to a health institution 2 to 6 times in the last year, all the results can be seen in table I.

Regarding the statements evaluated with a Likert Scale, 39% of participants agree in part with the statement "I know which of my data health institutions have"; 27% agree in part with the statement "I know which health professionals have access to my health information"; also in the statement "I am concerned that a health professional, with whom I have never had contact, can see my health information", 24% of participants agree in part. About the statement "I am concerned that my health data is viewed and studied by students (medicine/ nursing/ diagnostic technicians etc.)", 23% disagree in part; 24% disagreed in part with the statement "I am concerned that my health data will be used for studies in the pharmaceutical industry" and 48% of participants strongly agree with "I consider the protection of my health data important". All results are available in table II.

Regarding the Portuguese National Health Service user portal, 63% of participants never used it and of those who used it, only 24% were aware of the access history tool. However, 90% of participants consider this functionality useful, full results are presented in table I.

C. Legislation Knowledge

Only 19% had heard about the new GDPR and only 16% had the knowledge that the GDPR indicates that patients have the right of accessing all their health information. When asked whether they ever give informed consent to a health institution, 61% of participants never did. Results concerning legislation knowledge are available in table I.

TABLE I. QUESTIONNAIRE ANSWERS (1)

Age Group					
n (%)	<18	[18,30[[30,40[[40,60[[60,70[
	6 (1%)	503 (85%)	50 (9%)	27 (5%)	2 (0.3%)
Academic Qualifications					
n (%)	3rd cycle	Secondary education	Bachelor's	Master	PhD
	2 (0.3%)	187 (32%)	249 (42%)	137 (23%)	14 (2%)
Profession					
n (%)	Health Student	Health Professional	Non Health		
	176 (30%)	46 (8%)	367 (62%)		
Caregiver					
n (%)	Non Caregiver	Children caregiver	Elderlies caregiver	Children & elderlies	
	545 (93%)	24 (4%)	7 (1%)	13 (2%)	
Email on Smartphone					
n (%)	Daily	1/2 week	1/2 month	1/2 year	Never
	449 (84%)	92 (16%)	29 (5%)	6 (1%)	5 (1%)
Laptop at work					
n (%)	Daily	1/2 week	1/2 month	1/2 year	Never
	493 (84%)	69 (12%)	16 (3%)	6 (1%)	5 (1%)
Password change					
n (%)	Once a month	Once a year	When other know	Never/Rarely	NA
	18 (3%)	106 (18%)	332 (56%)	67 (11%)	49 (8%)
Visits in the last year					
n (%)	0	1	[2,6[[6,12[>12
	35 (6%)	106 (18%)	332 (56%)	67 (11%)	49 (8%)
Knowledge of the Plataforma de Dados de Saúde					
n (%)	Yes	No	Don't know/ Don't want to answer		
	200 (34%)	371 (63%)	18 (3%)		
Knowledge of Access History on the Plataforma de Dados de Saúde					
n (%)	Yes	No	Don't know/ Don't want to answer		
	66 (11%)	520 (88%)	3 (0.5%)		
Importance of Access History					
n (%)	Yes	No	Don't know/ Don't want to answer		
	530 (90%)	24 (4%)	35 (6%)		
Knowledge of GDPR					
n (%)	Yes	No	Don't know/ Don't want to answer		
	110 (19%)	476 (81%)	3 (0.5%)		
Patients data on GDPR					
n (%)	Yes	No	Don't know/ Don't want to answer		
	92 (16%)	490 (83%)	7 (1%)		
Informed Consent					
n (%)	Yes	No	Don't know/ Don't want to answer		
	137 (23%)	360 (61%)	92 (16%)		
Tool Importance					
n (%)	Yes	No	Don't know/ Don't want to answer		
	534 (91%)	28 (5%)	27 (4%)		
Tool can give more control over health information					
n (%)	Yes	Maybe	No	Don't know	
	351 (63%)	192 (34%)	10 (2%)	8 (1%)	
Alarms to notify accesses					
n (%)	Yes	No	Don't know/ Don't want to answer		
	391 (70%)	116 (21%)	53 (10%)		
Tool's Frequent Use					
n (%)	Annually	Semi-annually	Monthly	Weekly	NA
	48 (9%)	127 (23%)	221 (40%)	112 (20%)	53 (9%)

TABLE II. QUESTIONNAIRE ANSWERS (2)

	SA	AP	NAD	DP	SD
I know which of my information health institutions have	13%	39%	15%	22%	11%
I know which health professionals have access to my health information	26%	27%	8%	19%	19%
I am concerned that a health professional, with whom I have never had contact, can see my health information	20%	24%	18%	19%	18%
I am concerned that my health data is viewed and studied by students	12%	20%	19%	23%	26%
I am concerned that my health data will be used for studies in the pharmaceutical industry	19%	20%	15%	25%	21%
I consider the protection of my health data important	48%	28%	17%	5%	3%

SA- strongly agree; AP - agree in part; NAD - not agree or disagree; DP - disagree in part; SD - strongly disagree

D. Tool

When questioned about the importance of a tool that shows to patients all the health professionals that see and change their health information in different hospital systems, 91% of participants consider it important and 5% do not consider a tool with these characteristics important, and therefore finished the questionnaire in question 17. The remaining of the questionnaire was answered by 561 participants. About the benefit of the tool, 63% of participants consider that it can give the user a greater control over their health data. When asked to the participants who had someone in their care if the tool could be useful for greater control of the person they care, 83% think so.

E. Tool Characteristics

Concerning the tool characteristics, the first question was to select the two preferred modes to view the information, the answer chosen by most participants was the web page option (473 selections), as shown in figure 1.

When asked about what information they would like to access on the tool (by selecting the four most preferred answers), the most preferred answer was "name and health professional's profile" (505 selections), followed by "history of patient's events (doctor's appointments, medical exams, surgeries etc.)" (435 selections), then "reason for access" (406 selections). All results can be seen in figure 2.

As to alerts, most participants (69.7%) would like the tool to notify them when someone accesses their health information. Results for this answer are presented in table I.

When faced with the question if they would use a tool with the characteristics previously mentioned 71.5% confirm that they would, 26.6% are not sure and only 1.2% would not use it.

Considering that in a total of 589 participants, 401 confirmed they would use the tool, we can assume with a confidence level of 95% that if a tool with these functionalities was made available, between 64.1% and 72.1% of the representative population of our sample would use it. Those

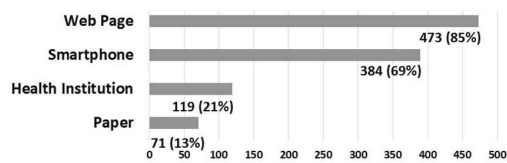


Figure 1. Modes to view the tool. Multiple choice allowed.

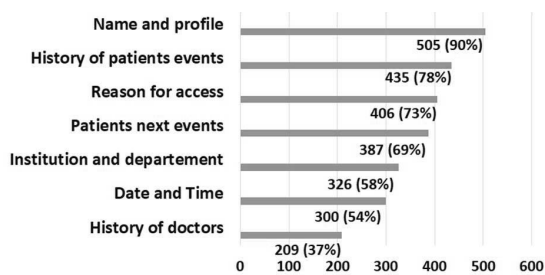


Figure 2. Information to view on the tool. Multiple choice allowed.

who answered that they would use the tool, 43.9% would use it monthly, 24.9% weekly, 21.9% semi-annually and 5.2% annually, as presented in table I.

About the 5% of participants who do not consider the tool important, reviewing the answers of their questionnaire we found interesting answers. In the statement "I am concerned that a health professional, with whom I have never had contact with, can see my health information", 71% of them strongly disagree or disagree in part with the statement, the same results have been revealed in the other two statements about health students seeing their health information and about their health data being used in pharmaceutical studies. Also, 50% of these participants did not believe in the importance of the history accesses tool of the national health portal. Even though 57% of these participants strongly agree or agree in part that they give importance to the protection of their health data, they stated that it is no problem for them to have their health information accessed whenever and by whoever wants to, so they are not interested in having a tool that shows them those records.

F. Analysing Groups

In order to understand if the groups of people we came across, had different knowledge and different perspectives in this issue we calculated the medians of the answers to some questions and compared them in the different groups. The selected questions were the statements to agree or disagree on and the question about the importance of the tool. We present the results in table III, they are shown as median values [first quartile value; third quartile value]. The statements and questions analysed were: "I know which of my information health institutions have", "I know which health professionals have access to my health information", "I am concerned that a health professional, with whom I have never had contact, can see my health information", "I am concerned that my health data is viewed and studied by students (medicine/ nursing/ diagnostic

technicians etc.)", "I am concerned that my health data will be used for studies in the pharmaceutical industry", "I consider the protection of my health data important" and "Do you consider important the existence of a platform for patients to know all the health professionals who see and/or change their health information in different hospital systems?". Also, the answers were transform in ordinal numbers to calculate the median, for the 6 statements the correspondent answer is: 1- Strongly agree; 2 - Agree in part; 3 - Does not agree or disagree; 4- Disagree in part; 5 - Strongly disagree. To the question "Do you consider important the existence of a platform for patients to know all the health professionals who see and/or change their health information in different hospital systems" the answer correspondent is: 1- Yes; 2 – Do not know or do not want to answer; 3 – No.

Comparing the health group with the non-health group, these groups were created considering the answers from the question "Are you a health professional, a student in health area, or neither?" given in the questionnaire, most of the medians between the groups were not significant. However, the median of the answers to "I know which of my information health institutions have" and "I know which health professionals have access to my health information" were shown to be significant. The health group agrees more with those statements than the non-health group, so participants in the health area seem to be better informed about what information is kept by the healthcare institutions and what types of health information do health professionals have access to. Regarding the remaining questions, no statistically significant differences were found between the medians in both groups, as described in table III.

Another defined group was based on the data obtained from the question about whether participants had ever heard of GDPR. Participants with positive responses were allocated to one group, and those with negative responses to another. For the purpose of this analysis participants who did not know or did not want to answer were not taken into account. When the medians were analysed considering these defined groups, two of the questions were significantly different. One of those is the statement concerning health information being used for pharmaceutical industry studies. The median of those who know about GDPR reflects higher concern than those who do not know about the legislation. Also, the statement that emphasizes the concern of participants in the protection of their health data, presented a median that shows more concern in participants who are aware of the legislation, as presented in table III.

The next two comparison groups were based on the participants' habit of changing passwords, for these groups the answers to the question "Do you usually change the passwords of your email and/or facebook?" were used. One group comprises respondents with the habit of changing passwords "at least once a month" and "at least once a year". The other group is composed of participants who answered they change passwords "only when others have access to the password" and "never or rarely". Participants who did not know or did not want to answer were not taken into account.

TABLE III. MEDIAN COMPARISON BETWEEN GROUPS (HEALTH PARTICIPANTS VS NON-HEALTH PARTICIPANTS; GDPR KNOWLEDGE VS NON-GDPR KNOWLEDGE; REGULAR CHANGE IN PASSWORDS VS NON REGULAR CHANGE IN PASSWORDS)

	Health (n=222)	Non-health (n=367)	P value	GDPR (n=110)	Non-GDPR (n=476)	P value	Passwords (n=179)	Non-passwords (n=380)	P value
I know which of my information health institutions have.	2 [2;4]	3 [2;4]	0.000	2 [2;4]	2 [2;4]	0.731	2 [2;4]	3 [2;4]	0.103
I know which health professionals have access to my health information.	2 [1;4]	3 [2;4]	0.002	2 [1;4]	2 [1;4]	0.609	2 [1;4]	2 [1;4]	0.144
I am concerned that a health professional, with whom I have never had contact, can see my health information.	3 [2;4]	3 [2;4]	0.658	3 [2;4]	3 [2;4]	0.359	2 [2;4]	3 [2;4]	0.046
I am concerned that my health data is viewed and studied by students.	4 [2;5]	3 [2;4]	0.200	3 [2;4]	4 [2;5]	0.602	3 [2;4]	4 [2;5]	0.025
I am concerned that my health data will be used for studies in the pharmaceutical industry.	4 [2;4]	3 [2;4]	0.391	2 [1;4]	3 [2;4]	0.044	3 [2;4]	3 [2;4]	0.115
I consider the protection of my health data important.	1 [1;2]	2 [1;3]	0.229	1 [1;2]	2 [1;3]	0.001	1 [1;2]	2 [1;3]	0.005
Tools Importance.	1 [1;1]	1 [1;1]	0.069	1 [1;1]	1 [1;1]	0.054	1 [1;1]	1 [1;1]	0.084

Median [Q1;Q3]

Considering the results available in table III, the group that changes passwords regularly shows greater concern in having health professionals with whom they have never had contact with to see their health information. Also in the statement “I am concerned that my health data is viewed and studied by students” the median is significantly different in the analysed groups. The participants of the group that do not change passwords regularly are not as concerned about their health data being seen by health students as the group that changes passwords regularly. Also, the statement about the concern of participants in the protection of their health data, presented a median that shows more concern in participants who change regularly their passwords, as presented in table III.

IV. DISCUSSION

In general, we can consider that although the vast majority of participants did not show great knowledge about the legislation (81%), about half do not know about the use of their data (52%) nor which professionals access that data (53%), more than 90% consider important the existence of a tool to view who accessed their health information.

A. Legislation awareness

Even when the new regulation comes into force in May 2018 the lack of knowledge regarding that legislation is evident, possibly justified by the lack of information from mass and social media. This can also justify the lack of interest that some people have in protecting their health data. Nevertheless, questionnaire results show that although participants have little knowledge on privacy and data protection (19%) they realize the importance of a tool to search who accesses and uses their health data.

A study by Tierney et al. to health professionals revealed that 46% of participants strongly agreed or agreed in part that the information present in an EHR is owned by the patient, this indicates that the rest are not aware of the legislation [10]. Comparing with our study these results are higher, however this difference in results can be justified by the difference in

population and also the fact that the question is considerably different. Nevertheless, in both studies is recognizable that legislation is not yet widely known by ordinary citizens.

Being more informed and more concerned about the use of their data, those who know GDPR, consider the pharmaceutical studies possibly something secondary to their health care and therefore are more concerned with the use of their data for this specific purpose.

B. Health Information Access Awareness

Health professionals and non-health participants are more concerned (46% e 33% respectively) when compared to health students (26%), about students in health areas viewing their health information. This is an expected result since students are in fact those who use and need the data to study.

Considering the 93% of health professionals who believe that an access control tool would be important for the patient, we can say there was a great adherence on the part of health professionals in our study. Slightly different from Tierney et al. study in which 54% of health professionals strongly agree or agree in part that it is ok for patients to have control of who saw their EHR (electronic health record) but only 42% strongly agree or agree in part on this being a good thing for patients [10]. Since the Tierney study was conducted a few years ago (3 years), this difference in results can be justified by the increase in the disclosure of data protection information. Another justification may be the difference in population. The need to keep the patient to rely and trust on health professionals and their work, more than ever, may be a factor for the health professional to accept this transparency of information. The fact that health group participants are more familiar with health systems that keep patient's information and all the dynamic of health institutions, can justify the greater knowledge that they consider to have about what they are and who sees their health information.

Those who change passwords regularly show more concern about data security and privacy and they do not want "strangers" to see their most personal information. For this reason, they are more worried than health students and health professionals, who they have never had contact with, to see their health information.

C. Tool Characteristics

From the questions about the characteristics of the tool it was found that the preferred way to use the tool was through a web page. Considering the frequency that the user would use the tool, it makes sense that that is an easier way to access data without being intrusive into the user's life. Also considering that our sample had a very technological background it was expected that this option would be preferable to them. The questionnaire also allows us to realize that the most important information in the tool for a user would be the name and profile of the healthcare professional who accessed the information, followed by the patient's own events (like doctor appointments, exams, etc.) and the reason for seeing the information. When these three pieces of information are combined the user can more easily understand whether the access to his/her information was made in the context of a health episode or not. Therefore, this is a mandatory requirement for the development of a new tool in order to promote patient's empowerment.

D. Limitations

One limitation of this study is the number of responses to the questionnaire which manifested a very low response rate (1.8%), only 589 out of 33404. This value can be justified by the fact that the questionnaire was sent through an institutional email that is often recipient of questionnaires for the same purpose, which leads to students' disinterest to answer and also the existence of emails that are not used by the students. Our population was students of higher education in a metropolitan area, and although this can be one of the target audiences for the tool, we would need to test with the general public. This will be approached in future work. Because our sample is very homogeneous and has mostly the same personal characteristics, like age, academic qualifications and technological habits, it is not possible to aggregate and compare responses of participants with those attributes. In addition, although the results are positive regarding the participants' intention to use the tool, more research is needed to confirm this assertion.

V. CONCLUSIONS

GDPR forces that healthcare institutions must maintain records of all processing activities and be able to easily report on personal data use and processing compliance. The implementation of software tools that provide detailed audit logs including changes and usage are essential to automate this process and guarantee logs integrity.

The results of this study show that participants would have a great interest in having access to such tool giving us the

motivation to continue with this research and in the future to give patients the opportunity to have access and benefit from it. With the results of the questionnaire, we intend to develop that tool. The development of this tool will be done side by side with stakeholders, and will take into account a very strong component of security and privacy that is clearly necessary given the personal and sensitive information that it comprises. We also intend to focus on the usability of the tool so that it is easily used by anyone regardless of their age, technical expertise or knowledge of existing legal requirements.

ACKNOWLEDGMENT

The authors would like to acknowledge the projects NanoSTIMA (NORTE-01-0145-FEDER-000016), and ODISSEIA - Oncology Disease Information System [POCI-05-5762-FSE-039021]. Both projects are financed by the North Portugal Regional Operational Programme (NORTE 2020), under the PORTUGAL 2020 Partnership Agreement, and through the European Regional Development Fund (ERDF) and European Social Fund (ESF) respectively.

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7.2 Questionnaire

Privacidade dos dados de saúde

O seguinte questionário insere-se no âmbito de uma tese do mestrado em Informática Médica da Faculdade de Medicina da Universidade do Porto.

Tem como objetivo avaliar a pertinência e definir o público alvo de uma ferramenta para o utente, baseada na demonstração dos acessos dos profissionais de saúde às informações de saúde de todos os utentes.

Este questionário é anónimo e pede-se que seja preenchido com algum cuidado e sinceridade.

Agradeço desde já o tempo despendido,
Sandra Reis

***Obrigatório**

1. 1. Qual a sua faixa etária? *

Marcar apenas uma oval.

- <18 anos
- 18-30 anos
- 30-40 anos
- 40-60 anos
- 60-70 anos
- >70 anos

2. 2. Qual o seu género? *

Marcar apenas uma oval.

- Feminino
- Masculino

3. 3. Qual a sua escolaridade? *

Marcar apenas uma oval.

- 2.º ciclo do ensino básico
- 3.º ciclo do ensino básico
- Ensino secundário
- Licenciatura/ 1º Ciclo
- Mestrado/ 2º Ciclo
- Doutoramento/ 3º Ciclo

4. 4. A sua profissão é no âmbito da saúde? *

Marcar apenas uma oval.

- Sou profissional de saúde
- Sou estudante de uma área de saúde
- Não

5. 5. Tem alguém a seu cuidado? **Marcar apenas uma oval.*

- Criança(s)
- Idoso(s)
- Criança(s) e idoso(s)
- Não

6. 6. Com que frequência utiliza um smartphone para consultar o seu e-mail? **Marcar apenas uma oval.*

- Nunca
- Até uma vez por ano
- Uma/duas vezes por mês
- Uma/duas vezes por semana
- Diariamente

7. 7. Com que frequência utiliza o computador no seu local de trabalho/estudo? **Marcar apenas uma oval.*

- Nunca
- Até uma vez por ano
- Uma/duas vezes por mês
- Uma/duas vezes por semana
- Diariamente

8. 8. Costuma alterar as palavras-passe do seu e-mail e/ou facebook? **Marcar apenas uma oval.*

- Nunca ou raramente
- Apenas quando terceiros tiveram acesso à palavra-passe
- Periodicamente a partir de uma vez por ano
- Periodicamente a partir de uma vez por mês
- Não respondo/ Não aplicável

9. 9. Com que frequência se deslocou a um centro hospitalar, centro de saúde ou clínica no último ano? **Marcar apenas uma oval.*

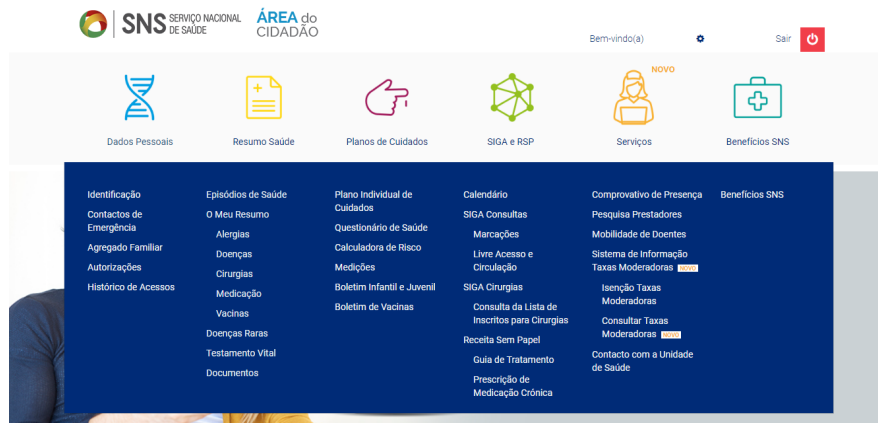
- Nenhuma vez
- 1 vez no último ano
- Entre 2 a 6 vezes no último ano
- Entre 6 a 12 vezes no último ano
- Mais de 12 vezes no último ano

10. 10. Resposta de acordo com o seu nível de concordância *

Marcar apenas uma oval por linha.

	Discordo totalmente	Discordo parcialmente	Não discordo nem concordo	Concordo parcialmente	Concordo totalmente
Sei que informações minhas as instituições de saúde têm	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Sei que profissionais de saúde têm acesso às minhas informações de saúde	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Preocupa-me saber que um profissional de saúde, com quem nunca tive contacto, possa ver as minhas informações de saúde	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Preocupa-me que os meus dados de saúde sejam visualizados e estudados por alunos (medicina/enfermagem/técnicos de diagnóstico etc.)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Preocupa-me que os meus dados de saúde sejam usados para estudos da indústria farmacêutica	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
Dou importância à protecção dos meus dados de saúde	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

11. 11. Já alguma vez utilizou o portal do utente do Serviço Nacional de Saúde? *



Marcar apenas uma oval.

- Sim
- Não
- Não sei/ Não quero responder

12. 12. Sabia que o portal do utente permite aos utentes verem que profissionais de saúde acederam às suas informações na Plataforma de Dados da Saúde (PDS)? *

Histórico de Acessos

O RSE foi concebido em colaboração com a Comissão Nacional de Proteção de Dados (CNPD) e mereceu a respetiva autorização no dia 30 de abril de 2012.

O processamento de dados, através do RSE, encontra-se assim autorizado pela CNPD, observa as condições de privacidade e de segurança por esta entidade exigida. Será progressivamente extensível às instituições de saúde habilitadas para esse efeito e nos moldes de segurança e privacidade impostos pelo Ministério da Saúde.

Procurar:

Data	Instituição	Tipo de episódio	Profissional
01-01-0001 00:00:00	XXXXXXXXXXXX		Dr. XXXXXXXXXXXX
01-01-0001 00:00:00	XXXXXXXXXXXX		Enf. XXXXXXXXXXXX
01-01-0001 00:00:00	XXXXXXXXXXXX		Enf. XXXXXXXXXXXX

A Mostrar de 1 até 3 de 3 registos

◀ Anterior Seguinte ▶

Marcar apenas uma oval.

- Sim
- Não
- Não quero responder

13. 13. Considera essa funcionalidade importante? *

Marcar apenas uma oval.

- Sim
- Não
- Não sei/ Não quero responder

14. 14. Já ouviu falar do novo regulamento geral de proteção de dados (RGPD) a entrar em vigor em 2018? *

Marcar apenas uma oval.

- Sim
- Não
- Não sei/ Não quero responder

15. 15. Sabia que o novo regulamento geral de proteção de dados (RGPD) refere que os utentes têm o direito de acesso a todas as suas informações de saúde (registos clínicos/exames etc.)? *

Marcar apenas uma oval.

- Sim
- Não
- Não quero responder

16. 16. Já alguma vez assinou um consentimento informado numa Instituição de Saúde? *

Marcar apenas uma oval.

- Sim
- Não
- Não sei/ Não respondo

17. **17. Considera importante a existência de uma plataforma que apresente todos os profissionais de saúde que vêm e/ou alteram as suas informações de saúde nos diferentes sistemas hospitalares? ***

Marcar apenas uma oval.

- Sim
- Não *Pare de preencher este formulário.*
- Não sei/ Não quero responder

18. **18. Considera que uma plataforma desse género lhe poderia dar maior controlo das suas informações de saúde? ***

Marcar apenas uma oval.

- Sim
- Não
- Talvez
- Não sei/ Não quero responder

19. **19. No caso de ser cuidador (de idosos ou de crianças), consideraria esta plataforma importante para o controlo das informações de saúde da pessoa que cuida? ***

Marcar apenas uma oval.

- Sim
- Não
- Talvez
- Não sei/ Não aplicável

20. **20. Como preferia ter acesso a essa informação? (selecione as 2 opções que preferir) ***

Marque todas que se aplicam.

- Aplicação para smartphone
- Página web
- Papel
- Na sua Instituição de Saúde
- Outro: _____

21. **21. Que informação gostaria de ver nessa plataforma? (selecione as 4 opções que preferir) ***

*

Marque todas que se aplicam.

- Nome e perfil do profissional que acedeu às informações (ex: Maria Costa, Médica Obstetra)
- Hora e data de quando acederam às informações
- Instituição e departamento do profissional que acedeu às informações
- Motivo porque acederam às informações
- Histórico dos médicos com quem já teve contacto
- Histórico de eventos do utente (consultas, exames e análises realizados, cirurgias etc.)
- Próximos eventos do utente (consultas, exames e análises realizados, cirurgias etc.)
- Outro: _____

22. 22. Gostaria de receber alertas quando alguém acedeu às informações? *

Marcar apenas uma oval.

- Sim
- Não
- Não sei/ Não quero responder

23. 23. Tendo em conta as características anteriormente referidas/escolhidas da ferramenta, utilizá-la-ia? *

Marcar apenas uma oval.

- Sim
- Não
- Talvez
- Não sei/ Não quero responder

24. 24. Se sim, com que frequência? *

Marcar apenas uma oval.

- Semanalmente
- Mensalmente
- Semestralmente
- Anualmente
- Não aplicável

25. 25. Espaço para sugestões no âmbito deste tema

Powered by



7.3 Requirements

Functional Requirements

1. MyRegister first page

ID: R01

Title: Explanation

Description: The tool should be able to show on an initial screen an explanation to the user that allows him/her to understand how and for what purpose the tool works.

Aim: This explanation allows the user to understand the purpose of the tool before registration.

ID: R02

Title: Demo Account

Description: The tool should allow authentication to the platform through a demo account.

Aim: This demo account allows the user to understand what the tool provides without having to authenticate and then decide whether to go to an institution to request their registration or not.

ID: R03

Title: Demo Account - functions

Description: The demo account should allow the user to have access to all the functions of the tool with difference of the displayed data being non-real data.

Aim: This demo account has exactly the same functionality as a real account, allowing the user to browse the tool as if they were viewing their own data.

2. Create an account

ID: R04

Title: User Account

Description: The tool should allow to create a new account on the web page.

Aim: A user has to create a new account so that he/she can access his/her personal health information maintaining his privacy.

ID: R05

Title: Institution selection for user Registration

Description: The tool should allow to select, from the institutions presented, the institution to which the user wishes to access his/her information.

Aim: A user should only be able to create a new account when associated to an institution that the tool recognizes and can request the user's information.

ID: R06 Title: User Registration

Description: The tool should allow the registration in the web-page through the SNS's number, the code given in the institution and the choice of a password.

Aim: To complete de registration the user has to provide his/her SNS number and access code given by the institution to confirm his/her identity, for the next logins to facilitate the login of the user he/she should choose a password to be replaced by the code.

ID: R07

Title: User Registration – optional

Description: The tool should allow the user the possibility of putting his/her email and/or phone number.
Aim: If the user wishes to receive alerts in the future, he/she can, at the time of registration, place his/her email and or phone number.

3. Login

ID: R08

Title: User login

Description: The tool should allow to login into the webpage using the patient's SNS number and the password chosen (considering that the user has already been registered).

Aim: The user has to be able to login to view the tool's information.

ID: R09

Title: User Information

Description: The tool should be able to present the institution's information as updated as possible depending on user's SNS number registered.

Aim: All the information presented should only be the information of the user with the number of SNS registered in the tool, allowing the privacy of information for each of the users.

4. Homepage

ID: R010

Title: Timeline

Description: The homepage should present a timeline with accesses and health episodes made.

Aim: This timeline will allow the user to easily understand if an access made occur in the context of a health episode.

ID: R011

Title: Timeline statistic

Description: The tool should calculate whether an access occurred outside the context of the episodes and show it in the timeline.

Aim: This allows the user to more easily identify possible suspect accesses.

ID: R012

Title: Navigation bar

Description: The tool should be able to present to the user the following areas:

- Profile area;
- Access history;
- Past health episodes;
- Future health episodes;
- Contacts and support;
- Definitions;
- About the tool;
- Privacy policy;
- Legislation information.

Aim: These areas should allow the user to easily know where the information he/she needs is.

5. Profile

ID: R13

Title: Profile

Description: The tool should be able to present a user profile area containing:

- Name;
- SNS number;
- Family doctor;
- Institutions in which the tool collects information;
- Email (if given by the user);
- Phone number (if given by the user).

Aim: This area allows the user to consult his/her information.

ID: R14

Title: Profile – edition

Description: The tool should allow the user to be able to edit and add the information given by him/her, that is:

- Email;
- Phone number.

Aim: This option allows the user to edit the information made available by him/her. The remaining of the information cannot be changed.

ID: R15

Title: Profile - picture

Description: The tool should allow the user to use a profile photo and change it whenever he/she wants. This picture should be uploaded from the computer or directly through the camera.

Aim: The user should be able to insert a photo in his/her profile homepage.

6. Access History

ID: R16

Title: Access History

Description: The tool should be able to present all accesses made to the user information and each access should present:

- Date – when it was performed;
- Professional – who performed it;
- System – system where was performed;
- Institution – where was performed;
- Action – which action was performed.

Aim: This page allows the user to view all accesses made to any user information (administrative or medical) to his/her existing information in the institution or institutions associated with his/her account.

ID: R17

Title: Accesses from timeline

Description: Through the accesses shown in the timeline it should be possible to see only those selected showing:

- Date – when it was performed;

- Professional – who performed it;
- System – system where was performed;
- Institution – where was performed;
- Action – which action was performed.

Aim: Allows the user to immediately see the information only of the selected accesses in the timeline.

ID: R18

Title: Filters

Description: The tool should allow to filter the accesses by:

- Institutions;
- Time;
- Professional who accessed the information;
- Action done in the access (CRUD (Create, Read, Update or Delete)).

Aim: This option allows the user to filter the accesses as he/she prefer to easily see the information.

ID: R19

Title: Access History page – report access

Description: The tool should allow the user to report any access that he/she believes is suspicious.

Aim: This option allows the user to send a message to the institution that in his/her point of view that as an access that should not be done by the professional. This report is not a formal complaint, only a warning to the institution that there is a possibility of undue access to the patient's clinical information.

7. Past health episodes

ID: R20

Title: Past episodes' page

Description: The tool should allow to view all user's health episodes already performed (past episodes) and present for each of the episode:

- Date – when it was performed;
- Professional – who performed it;
- Institution – where was performed;
- Episode – what was performed;
- Description of the episode if it exists - for example in a surgery "knee surgery".

Aim: This page allows the user to consolidate all the episodes that he/she performed at the institution/s. The description allows the user to understand better the episode that occur and relate it with accesses made in the institution. Episodes are doctor appointments, surgeries, performed analysis and exams, nursing care, among others.

ID: R21

Title: Past episodes' filters

Description: The tool should allow to filter the past episodes by:

- Institutions;
- Time;
- Professional.

Aim: This option allows the user to select easily the episodes he/she wants to see.

8. Future health episodes

ID: R22

Title: Future episodes' page

Description: The tool should allow to view all future user's health episodes and present for each of the episode:

- Date – when will it be performed;
- Professional – who will perform it;
- Institution – where will it be performed;
- Episode – what is going to be performed;
- Description of the episode if it exists - for example in a surgery “knee surgery”.

Aim: This page allows the user to have access to all the episodes already scheduled in the institution(s). Episodes are doctor appointments, surgeries, performed analysis and exams, nursing care, among others.

ID: R23

Title: Future episodes' filters

Description: The tool should allow to filter the future episodes by:

- Institutions;
- Time;
- Professional.

Aim: This option allows the user to select easily the episodes he/she wants to see.

ID: R24

Title: Add future episode

Description: The tool should allow the user to add a new health episode to the future episodes' list.

Aim: This option allows the user to add episodes that are not integrated with the tool, allowing him/her to have his/her health agenda updated.

9. Contacts and Support

ID: R25

Title: Contacts

Description: The tool should allow to view the contact information of the institutions to which the user is associated.

Aim: This page allows the user to have access to institution's contacts easily.

ID: R26

Title: Support

Description: The tool should allow the user to send a message to the help desk reporting a problem.

Aim: This allows to report problems with the tool or ask something he/she does not know how to do.

10. Definitions

ID: R27

Title: Definitions page

Description: The tool should allow to select the options that the user authorizes or not. By default, all authorizations should be negative.

Aim: This page allows the user to have control over the tool.

ID: R28

Title: Definitions page – email

Description: The tool should allow the user to authorize to receive emails when new accesses to his/her clinical information are done and/or when a new health episode is scheduled.

Aim: This allows the user to receive alarmistic in his/her email.

ID: R29

Title: Definitions page – phone number

Description: The tool should allow the user to authorize to receive SMS's when new accesses to his/her clinical information are done and/or when a new health episode is scheduled.

Aim: This allows the user to receive alarmistic in his/her phone.

ID: R30

Title: Email alert

Description: The tool should alert the user sending an email when new accesses to his/her clinical information are made and/or when a new episode is scheduled. Aim: This allows the user to receive alarmistic in his/her email.

ID: R31

Title: SMS alert

Description: The tool should alert the user sending a SMS when new accesses to his/her clinical information are made and/or when a new episode is scheduled.

Aim: This allows the user to receive alarmistic in his/her phone.

ID: R32

Title: Definitions page – institutions

Description: The tool should allow the user to add more institutions to his/her account.

Aim: This allows the user to view their accesses and episodes from more than one institution by selecting the institution and writing the respective code given by the institution.

ID: R33

Title: Definitions page – institutions elimination

Description: The tool should allow the user to eliminate the institutions he/she has access to.

Aim: This allows the user to not access information from a particular institution he/she does not want to.

ID: R34

Title: Definitions page – institutions re-registration

Description: After elimination of an institution the tool should allow the user to register the institution again, but the procedure should be as if is a new institution, that is ask for the institution's code.

Aim: To confirm identification is necessary for the user to ask by the code in person.

ID: R35

Title: Definitions page – email and phone necessity

Description: The tool should provide the user with a warning that he/she needs to fill in their email or phone number to receive emails or SMS respectively when they have not already done it.

Aim: This allow the user to realize that it is necessary to fill in their information in order to be alerted.

11. About

ID: R36

Title: About page

Description: The tool should provide the user with a page that explains the details about the tool and the company that produce it.

Aim: This allow the user to consult information about the tool.

12. Privacy Policy**ID: R37**

Title: Privacy Policy page

Description: The tool should provide the user with privacy policy that explains to the user how his/her data is being use.

Aim: This allow the user to consult information about the privacy policy about his/her data.

13. Legislation information**ID: R38**

Title: Legislation information page

Description: The tool should provide the user with a page that gives information about patients' rights according to the legislation.

Aim: This allow the user to consult information about the legislation and understand why this tool is useful for legislation compliance.

14. Logout**ID: R39**

Title: Logout

Description: The tool should allow the user to log out in all tool's pages.

Aim: This requirement allows the user to logout every time he/she wants it.

ID: R40

Title: Logout automatically

Description: The tool should log out automatically every time that the user closes the tool page.

Aim: This requirement forces the user to login every time he/she closes the tool and maintain the security against non-authorize people.

ID: R41

Title: Logout timed

Description: The tool should log out automatically after 1h of user inactivity in the tool.

Aim: This requirement forces the user to login every time he/she stops using the tool for more than a 1h while maintaining the security against non-authorize people.

15. General**ID: R42**

Title: Language

Description: The tool should be presented in Portuguese and English.

Aim: This allows the main users (Portuguese) an easy reading but also allows their use to foreigners who

already have number of SNS.

ID: R43

Title: Print

Description: The tool should allow the user to print the data available to him/her.

Aim: User may feel comfortable analysing the accesses data in paper.

ID: R44

Title: Password recovery

Description: The tool should allow a user to recover a forgotten password.

Aim: When a user does not know his/her password he should have the ability to recover it.

ID: R45

Title: Password change

Description: The tool should allow a user to change his/her password.

Aim: When a user wishes to change his/her password he should have the ability to change it maintaining all security requirements.

Security requirements

1. Authentication

ID: SR01

Title: Authentication method

Description: The tool should allow authentication through username and password, the username being the SNS number.

Aim: This allows the user to authenticate with his/her SNS number and a password he/she chooses.

ID: SR02

Title: Authentication request

Description: In the alteration of personal data, namely password or other data considered sensitive, the tool should request again the presentation of the authentication data.

Aim: This allows the user to prevent others from attempting to change their personal data when they have access to their account.

ID: SR03

Title: Protection of Authentication Parameters

Description: The tool should securely store all data or parameters used in the authentication process.

ID: SR04

Title: Authentication information

Description: Once an authentication has been successfully performed, the tool should display the following information to the user:

- date and time of last successful authentication;
- date and time of unsuccessful authentication attempts after the last successful authentication.

Aim: This action could alert the user if someone login in his/her account without him/her knowing.

ID: SR05

Title: Login attempts

Description: The tool should have mechanisms to block a user's account after a maximum of 5 followed

invalid login attempts.

Aim: The tool should be able to detect when someone unauthorized is trying to access a user's account, and then block this count until the identity of the user is confirm.

2. Passwords

ID: SR06

Title: Password security

Description: The tool should preclude the following security controls:

- Quality of the password: the quality of the password should be checked at the moment of its definition by the user, requiring the use of at least 8 characters of which mandatory use of 3 of the following: uppercase, lowercase letters, numbers or symbols;
- Maximum Password Age: Users should exchange their passwords within a maximum period that does not exceed 1 year;
- Minimum Password Age: Users shouldn't be able to exchange their password in less than a day;
- The password exchange processes should require that the new password be different from the previous one;
- It is recommended to implement SALT techniques for coding the password.

Aim: Considering that the information in the tool is highly sensitive is important that the users account is protected with a strong password.

ID:RS07

Title: Password recovery

Description: The tool should provide a form of access recovery to credentials with strong authentication.

Aim: Allowing the user to ask for the forgotten credentials but without losing the initial security on the password.

3. Data

ID: SR08

Title: Notify to those responsible for information security

Description: The tool should ensure processes of automatic and effective notification to those responsible for information security, whenever anyone tries to make improper access to the data.

Aim: This allows the insurance that when someone tries to access data that they are not authorize someone is alerted.

ID: SR09

Title: Backups

Description: The tool should be able to generate a backup automatically.

Aim: Allows assurance that no tool information is lost.

ID: SR10

Title: High availability

Description: The tool should guarantee a high availability service.

Aim: Allows to minimize the possibility of the tool losing service.

ID: SR11

Title: Integrity in data recovery

Description: The tool should guarantee the integrity of the information in generating and restoring the backup, generating an alert in the episode of a failure.

Aim: Allows the assurance that the information is always backed up correctly, and if not, alerts are send.

ID: SR12

Title: Non-repudiation

Description: The tool should guarantee non-repudiation when a user has performed an action.

Aim: This guarantees that when a user performs an action he/she cannot denied it.

ID: SR13

Title: Auditability

Description: The tool should enable the storage of the following accesses of the tool itself: failed and successful logins, creation of data, change of data, elimination of data and view of data.

Aim: Every access made has to be saved and stored.

ID: SR14

Title: Auditability – retention

Description: The retention period for audit files and access logs should be 10 years.

Aim: This period is legislated and allows the guarantee that the accesses made are stored.

ID: SR15

Title: Users management

Description: The tool should allow the management (creation, inactivation and modification) of users in order to control the access to the tool.

Aim: An authorized person should have the ability to make changes in the accounts of the users.

Usability Requirements

ID: UR1

Title: Interface color

Description: The tool's interface should be able to be used without any color, using color only to categorize, differentiate and highlight the information, not giving information through color.

Aim: In order to prevent that "color blind" users miss some information this requirement should be used.

ID: UR2

Title: Interface information

Description: The tool's interface should present the most important information for the user with higher visibility than the information less important (as logos, versions etc.).

Aim: This allows the user to use the tool more efficiently, viewing more easily the information that is important to him/her.

ID: UR3

Title: User's memory minimized

Description: When editing a field, the tool should maintain the previous text to facilitate the filling.

Aim: This requirement allows to decrease user's memory need to use the tool, for example when he/she is editing an e-mail frequently he/she just wants to change a few characters and not all of them.

ID: UR4

Title: Consistency - language

Description: The tool should present a consistency terminology of words.

Aim: This requirement allows the user to be more confident when using the tool because he/she knows that the same command/action has the same effect.

ID: UR5

Title: Consistency - place

Description: The tool should present the same information in the same place in the different pages.

Aim: This requirement allows the user to recognize easily the actions to perform.

ID: UR6

Title: Feedback - tasks

Description: The tool should keep the user inform on the tasks he/she is performing.

Aim: This requirement allows the user to understand how he/she is using the tool, so the feedback should be not online negative but also positive.

ID: UR7

Title: Feedback – response time

Description: The tool should inform the user that a task is still occurring when the results don't appear in less than 3 seconds.

Aim: This requirement allows the user to understand that a task is being perform and the system is responding, preventing the user from starting to take other actions when the system is still processing the previous one.

ID: UR8

Title: Feedback – failure

Description: The tool should inform the user that a failure is occurring and present the origin and/or problem identification when possible.

Aim: This allows the user to understand why the system is failing and if it is a problem that he/she can or not resolve.

ID: UR10

Title: Exists evidence

Description: The tool should clearly show the user how to exit the page or come back to the previous one.

Aim: This increase the user's sense of control, allowing the user exit easily for example in case he/she is afraid of losing or changing data.

ID: UR11

Title: Error messages

Description: The tool should present error messages to the user following this conditions:

- error message should be written clearly to avoid confusion in the user;
- error message should help the user to solve his/her problem;
- error message should be polite, not intimidating either make the user feel guilty.

Aim: This allows the user to understand that an error occur but does not make him/her uncomfortable.

ID: UR12

Title: Help

Description: The tool should present a page where the user can search for documentation that can help him/her to understand the tool.

Aim: This allows the user to better understand the tool.

ID: UR13

Title: Unsolicited pop-ups

Description: The tool should not display windows or pop-ups when not requested by the user.

Aim: This requirement allows users not to be disturbed or distracted with information that is not in the sequence of their original activity.

ID: UR14

Title: Task sequence

Description: The tool should allow the user to perform tasks in the same sequence and in similar conditions.

Aim: As the user learns a sequence of certain behaviours, they will have a better performance in the use of the tool if it presents the tasks in the same or similar ways.

ID: UR15

Title: Response time

Description: The tool should respond to a user request within a maximum of 5 seconds measured in the user interface.

Aim: If the response time for a request is too long the user will click more times and/or give-up on the task.

ID: UR16

Title: Feedback - timeout

Description: The tool should inform the user that the page is automatically logging out of user's account.

Aim: The user should be informed that after a period of time of not using the account it will automatically log out for security reasons.

ID: UR17

Title: Read Information

Description: The tool should present the information so that it can be easily read both on the web page and printed.

Aim: This allows the user to easily read the information on the web and also if he/she wants to print the information.

ID: UR18

Title: Print Information

Description: The tool should print exclusively the part of interest to the user (accesses to his/her information/episodes etc.) so that it is printed properly.

Aim: This allows the correct printing of the necessary information to the user, namely with suitable margins and size.

ID: UR19

Title: Multitasking while reading

Description: The tool should not present other tasks to the user when the user is reading important information.

Aim: This facilitates the user's reading process.

ID: UR20

Title: Help terminology

Description: The tool should display in the help page a terminology that the user can easily understand to describe the elements and characteristics of the tool.

Aim: This will provide the user with a language that is more directed to their knowledge, facilitating the understanding of the tool.

ID: UR21

Title: Non-text elements

Description: The tool should always provide text equivalent to non-textual elements.

Aim: This allows for improved accessibility for users, always clarifying what the graphic elements mean.

ID: UR22

Title: Browsers

Description: The tool should be compatible with the most common browsers (Chrome 65, Safari 11, Chrome 66, Firefox 59, IE 11, Chrome 56, Chrome 49, UC 11, Chrome 64 and Safari 10).

Aim: This allows the tool to be used without problems by most users.

ID: UR23

Title: Tools value

Description: The tool should clearly and prominently display the value and purpose of the tool in the homepage.

Aim: This allows the user to identify, when he/she first enters the site, the purpose of the tool and quickly understand if it is or not of interest to him/her.

ID: UR24

Title: Important information - place

Description: The tool should provide the most important information at the top of the page and avoid the need to scroll.

Aim: This facilitates the visualization of the information, since the users usually look to the top of the page starting from the left side to the right.

ID: UR25

Title: Structured information

Description: The tool should present the information in a structured way to facilitate comparison.

Aim: When the information is structured, for example in tables, it becomes easier for the user to compare and relate information.

ID: UR26

Title: Information alignment

Description: The tool should present the information and elements aligned consistently, either horizontally or vertically.

Aim: Users often prefer to see the information aligned in order to better understand their purpose and what they refer to.

ID: UR27

Title: Responsive layout

Description: The tool should use a fluid and responsive layout that automatically adjusts itself to the monitor in which it is being used.

Aim: This requirement allows the user to view the tool interface always with quality and in a more efficient way, regardless of the monitor that is used or device (mobile phone, tablet or computer).

ID: UR28

Title: Heading and element in the wrong place

Description: The tool should ensure that no headers or other elements are displayed in a way that might lead the user to believe that the page has reached its end or start when it is not true.

Aim: Some headers and elements induce the user to the idea that the page is in the beginning or the end, when they are not really there, the user may not see all the information available.

ID: UR29

Title: Feedback – user’s location

Description: The tool should inform the user where he/she is on the webpage.

Aim: This allows the user to understand where he/she is in the tool, how he/she get there and what may do next.

ID: UR30

Title: No horizontal scroll

Description: The tool should use an appropriate layout in order to avoid the need for horizontal scrolling.

Aim: The need to use horizontal scrolling makes the tool display process slower and the user unhappy.

ID: UR32

Title: Pages not scrolling

Description: When the information to be presented is extensive, the tool should present by pages instead of scrolling.

Aim: It becomes easier for the user to find the information they need from page to page than scrolling through to the entire page.

Requirements’ sources

HHS.gov. (2018). HHS.gov Web Standards. Retrieved August 14, 2018, from <https://webstandards.hhs.gov/>

ISO/IEC. (2011). ISO/IEC 25010:2011 Systems and software engineering – Systems and software Quality Requirements and Evaluation (SQuaRE) – System and software quality models.

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ISO/IEC. (2016). ISO 27799:2016 Health informatics – Information security management in health using ISO/IEC 27002.

Lúcio Da Silva, M. (2013). Manual de Certificação para Sistemas de Registro Eletrônico em Saúde (S-RES) CERTIFICAÇÃO 2013 Editor. Retrieved 2018-07-03, from http://www.sbis.org.br/certificacao/Manual_Certificacao_SBIS-CFM_201_v4-1.pdf

Microsoft. (2018). Best Practices for Enforcing Password Policies. Retrieved 2018-07-04, from <https://technet.microsoft.com/us/library/ff741764.aspx> Nielsen, J. (1994). Usability engineering. Elsevier.

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W3Counter. (2018). W3Counter: Global Web Stats. Retrieved May 15, 2018, from <https://www.w3counter.com/globalstats.php>

7.4 Mockups

The first page that is displayed when you enter the web page is the following figure, 7.1. On this page you can login, create an account and view the platform through a demo account. Also is provided a simple explanation of what MyRegister is.

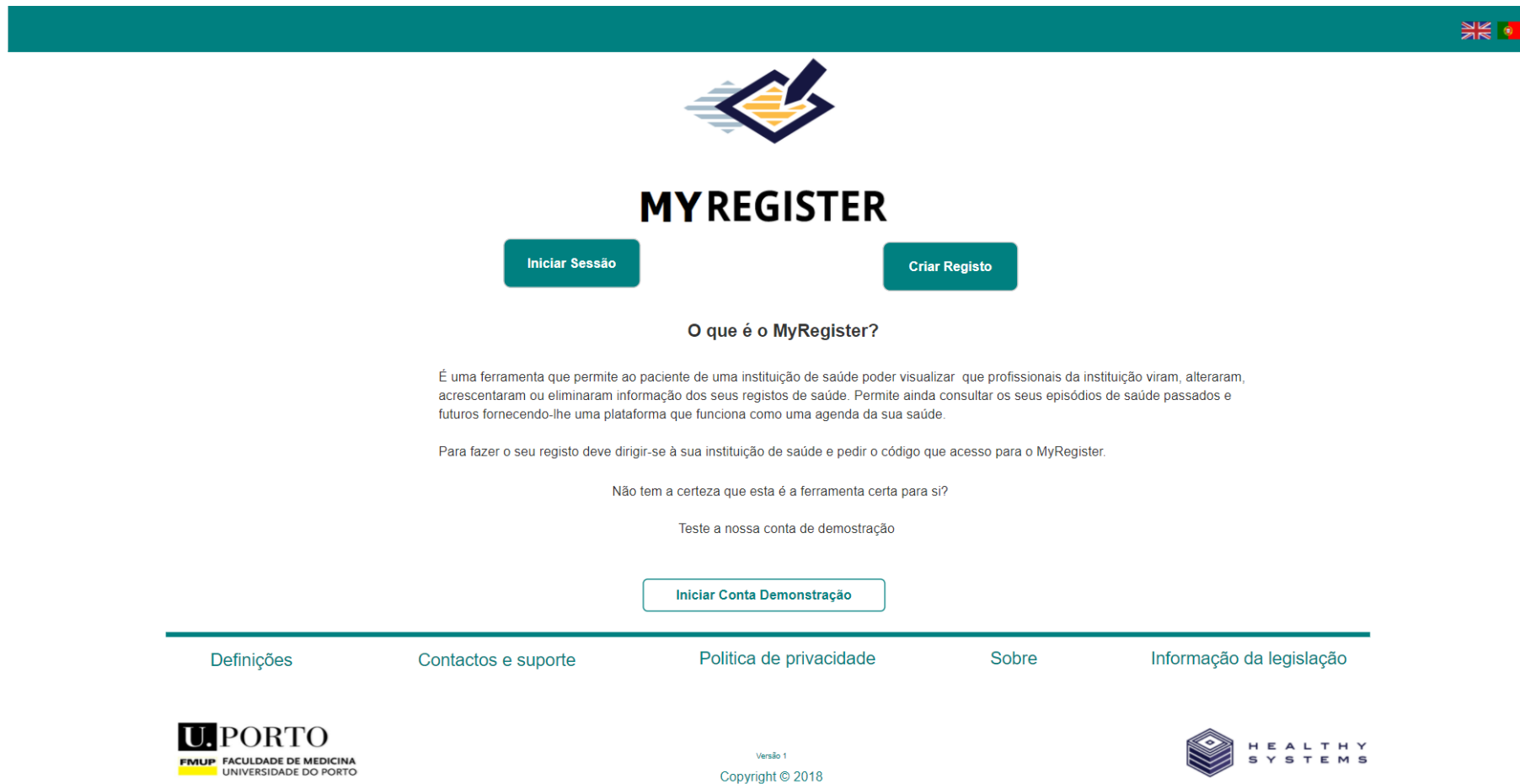




Figure 7.1: First page mockup

This page, figure 7.2, is the account creation page, in this you will have to fill out the submitted form to proceed with the creation of account, using the code provided by the health institution.

MYREGISTER

Bem-vindo  

► **Criar Conta**

Nº de utente SNS

Código da instituição

Instituição a que quer aceder

Palavra-passe

Deve ter mínimo 8 caracteres e pelo menos três dos quatro seguintes: números, caracteres especiais, letras maiúsculas e letras minúsculas

[Voltar](#) [Criar Conta](#)

[Definições](#) [Contactos e suporte](#) [Política de privacidade](#) [Sobre](#) [Informação da legislação](#)

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HEALTHY SYSTEMS

Figure 7.2: Create an account mockup

On the page shown in figure 7.3 we can see what happens if the password entered does not meet the security requirements, the text will be highlighted red for the user to comply with. We also present for observation, the list of institutions to select. (Institutions not presented in this list do not have the HS.Register and therefore it is not possible to collect patient information in them).

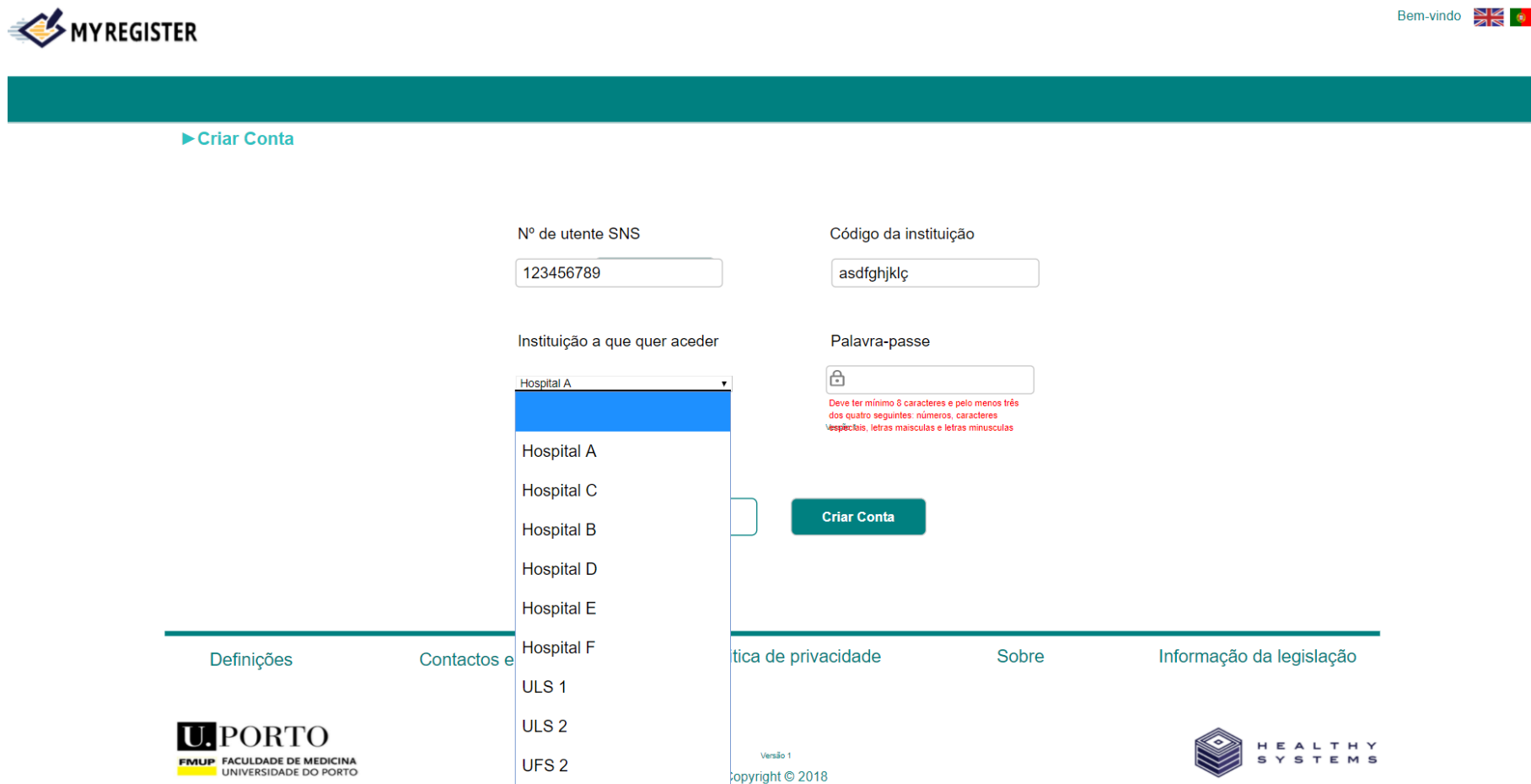


Figure 7.3: Create an account mockup - observation

If you already have an account created the page displayed will be as following, figure 7.4, here you must enter the credentials for the login.



Bem-vindo 

► Início de sessão

Nº de utente SNS

Palavra-passe

Esqueceu-se da palavra-passe?

[Voltar](#)

[Iniciar Sessão](#)

[Definições](#)

[Contactos e suporte](#)

[Política de privacidade](#)

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Figure 7.4: Login mockup

If the credentials placed are wrong« the page presented is the one of figure 7.5.



Bem-vindo  

► Início de sessão

Dados Incorretos ×

Nº de SNS ou palavra-passe incorretos.

Cancelar Tentar de novo

Esqueceu-se da palavra-passe?

Voltar

Iniciar Sessão

-
- [Definições](#)
 - [Contactos e suporte](#)
 - [Politica de privacidade](#)
 - [Sobre](#)
 - [Informação da legislação](#)



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Figure 7.5: Failed login mockup

When you are already logged in (or after account creation) the tool homepage is shown, as in figure 7.6. A timeline is presented, this relates the accesses made to clinical information and health episodes, allowing you to have a first perception of the use of your PHI. Through this timeline it is possible to select each one of the presented events (accesses or health episodes) and to see in detail its information. For you to be able to see all the accesses that have been made to the information is through the button of access history present on the page.

From this page forward you will have in all the pages of MyRegister the navigation bars. Through the top navigation bar (in green) you can view the main pages: the first button corresponds to the homepage, which displays the timeline and allows you to view all accesses; the second button allows to see the past and future health episodes. At the top of this navigation bar we have buttons that allow you to go to your profile, log out or consult the help page. In the bottom navigation bar is where you can consult the definitions of the tool, the contacts and support page, the privacy policy page, the page about the tool and company that created it and lastly a page about information of the legislation.

Último início de sessão com sucesso: 17-06-2018
Última tentativa de início de sessão falhada após última sessão com sucesso: 23-06-2018

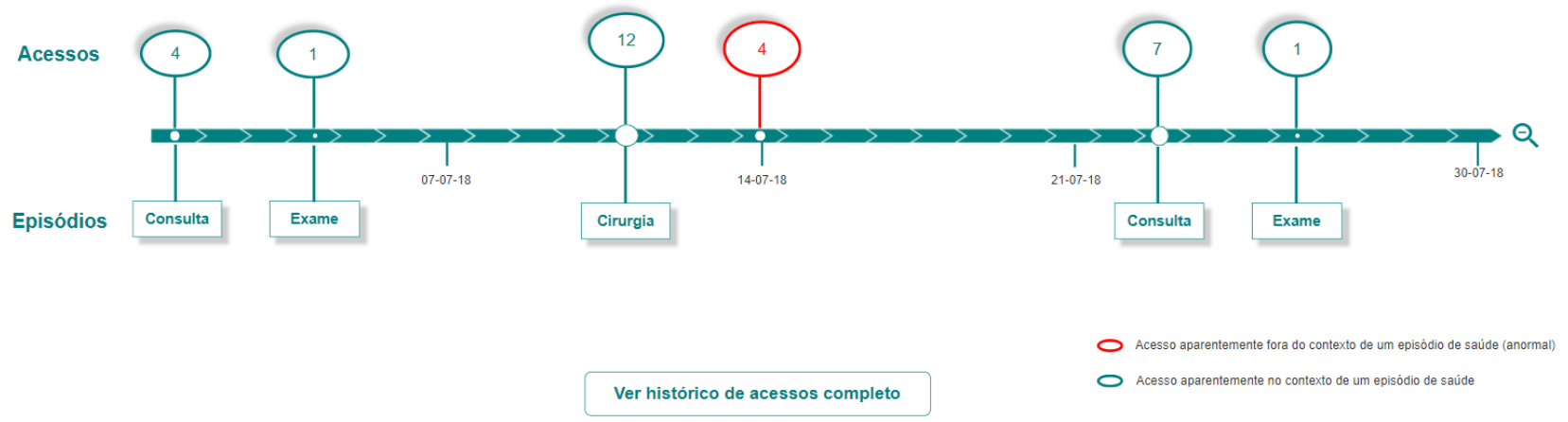


Figure 7.6: Homepage mockup

When you select a set of accesses from the ones presented in the timeline, you are shown only those that relate to that day. In figure 7.7 we can see the accesses made on 07-14-2018. In this page it is possible to use the filters and change the accesses that are presented, being able to choose by dates, health professional that acceded, institution, system and/or action executed in the information. In each page of accesses presented it is possible to report one or more accesses that it considers suspicious, this report will be sent to the institution, not constituting a formal complaint.



[Ajuda](#) [Bem-vindo Anna](#) | [Terminar Sessão](#)  

Os acessos à minha informação

Os meus episódios de saúde

► **Histórico de Acessos**

Data	Instituição	Profissional	Sistema	Ação
14-07-2018 17:05:33	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Eliminar informação
14-07-2018 16:34:23	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Visualizar Informação
14-07-2018 16:34:20	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Visualizar Informação
14-07-2018 16:33:43	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Visualizar Informação

Data De Até Sempre
 Instituição + Todos
 Profissional + Todos
 Sistema + Todos
 Ação + Todos

Aplicar Filtros

Página 1

Reportar Acessos

[Definições](#)

[Contactos e suporte](#)

[Política de privacidade](#)

[Sobre](#)

[Informação da legislação](#)



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Figure 7.7: Accesses from 07-14-2018 mockups

When selecting the button to make the report of access, the page shown is like the figure 7.8, in this it is possible to select the accesses that are considered suspicious and send a message explaining why you find them suspects or add relevant information to the institution. After making the report the page presents the accesses with a call to attention that allows to identify which were the accesses reported, as in figure 7.9.

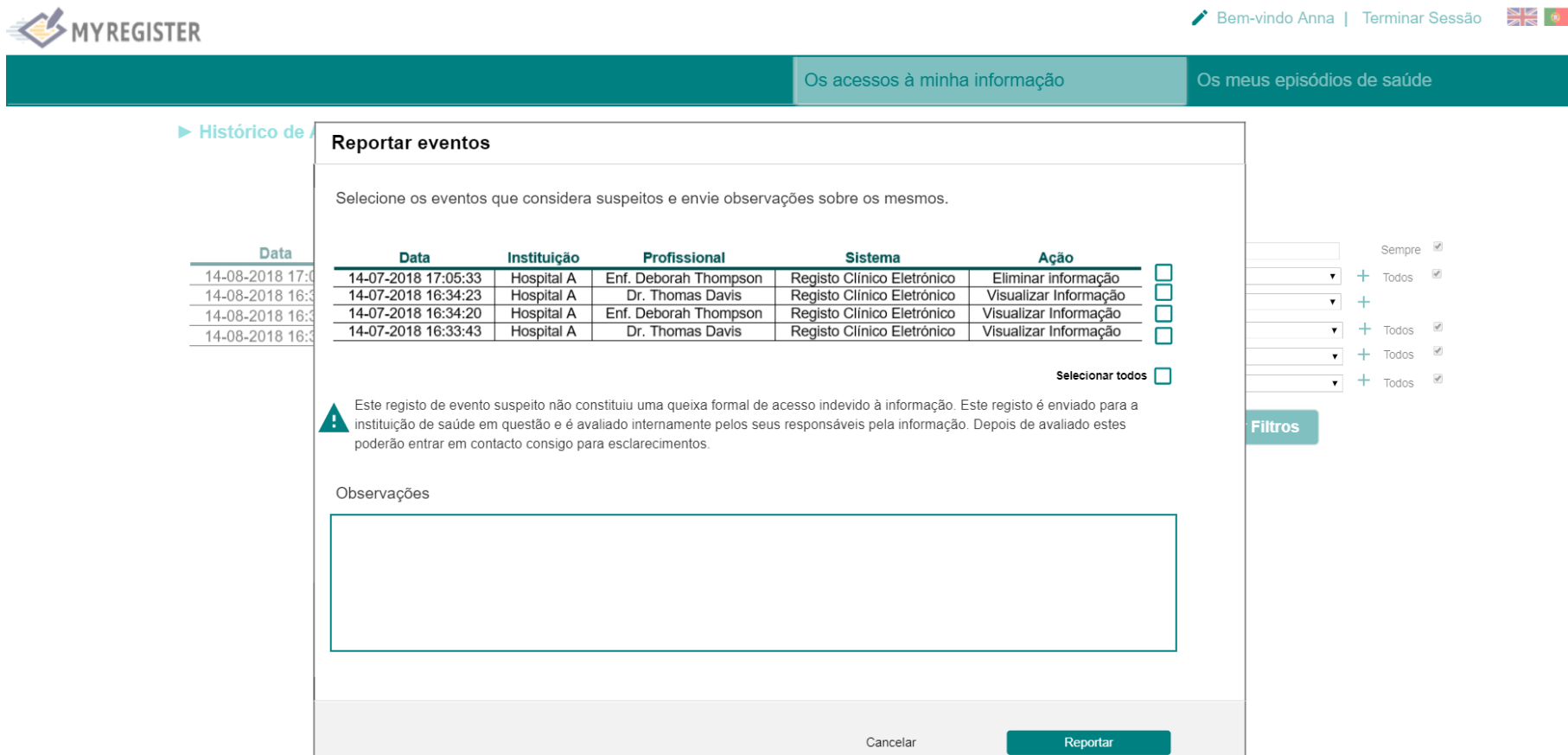


Figure 7.8: Report accesses mockup

► Histórico de Acessos

Data	Instituição	Profissional	Sistema	Ação
14-07-2018 17:05:33	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Eliminar informação
14-07-2018 16:34:23	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Visualizar Informação
14-07-2018 16:34:20	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Visualizar Informação
14-07-2018 16:33:43	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Visualizar Informação

Data De: 08/14/2018 Até: Sempre
 Instituição: + Todos
 Profissional: + Todos
 Sistema: + Todos
 Ação: + Todos

Aplicar Filtros

Página 1

[Reportar Acessos](#)

Figure 7.9: After reporting accesses mockup

From the homepage it is possible to access besides a specific day to all accesses made in your information. The page in figure 7.10 shows all accesses by pages. As previously stated it is possible to filter the information and report suspicious accesses.

The screenshot shows the MYREGISTER application interface. At the top, there is a navigation bar with the MYREGISTER logo on the left and user information on the right: "Bem-vindo Anna | Terminar Sessão" and flags for the United Kingdom and Portugal. Below the navigation bar, there are two tabs: "Os acessos à minha informação" (selected) and "Os meus episódios de saúde".

Under the "Os acessos à minha informação" tab, there is a section titled "Histórico de Acessos". It contains a table with the following columns: Data, Instituição, Profissional, Sistema, and Ação. The table lists 30 rows of access records, including dates, hospital names, professional names, system types, and actions like "Eliminar informação" or "Adicionar informação".

To the right of the table is a filter panel with dropdown menus for "Data", "Instituição", "Profissional", "Sistema", and "Ação". Each dropdown has a "+ Todos" option and a checked checkbox. Below the filters is a blue button labeled "Aplicar Filtros".

At the bottom of the table, there is a pagination indicator "Página 1 > >". Below the table, there is a blue button labeled "Reportar Acessos".

Data	Instituição	Profissional	Sistema	Ação
12-07-2018 13:05:33	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Eliminar informação
15-06-2018 16:34:23	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Adicionar informação
15-06-2018 16:34:20	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Adicionar informação
15-06-2018 16:33:43	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Adicionar informação
15-06-2018 16:33:34	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Adicionar informação
15-06-2018 16:33:16	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Adicionar informação
15-06-2018 16:31:29	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Adicionar informação
15-06-2018 16:31:33	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Adicionar informação
15-06-2018 16:31:53	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Adicionar informação
12-06-2018 18:10:34	Hospital A	Enf. Deborah Thompson	Registo Clínico Eletrónico	Adicionar informação
09-06-2018 12:18:45	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Adicionar informação
09-06-2018 12:01:36	Hospital B	Dr. Thomas Davis	Registo Clínico Eletrónico	Eliminar informação
09-06-2018 09:27:55	Hospital B	Dr. Thomas Davis	Registo Clínico Eletrónico	Eliminar informação
09-06-2018 12:14:16	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Adicionar informação
09-06-2018 12:13:26	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Editar informação
09-06-2018 12:13:59	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Editar informação
09-06-2018 12:12:46	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Adicionar informação
09-06-2018 12:11:19	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Editar informação
09-06-2018 12:11:13	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Adicionar informação
09-06-2018 12:08:34	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Adicionar informação
09-06-2018 12:05:34	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Editar informação
09-06-2018 12:05:43	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Editar informação
09-06-2018 12:01:36	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Eliminar informação
09-06-2018 09:27:55	Hospital A	Dr. Thomas Davis	Registo Clínico Eletrónico	Eliminar informação
11-05-2018 05:25:49	Hospital B	Dr. Kenneth Mitchell	Radiologia	Eliminar informação
11-05-2018 05:25:45	Hospital B	Dr. Kenneth Mitchell	Radiologia	Eliminar informação
11-05-2018 05:24:28	Hospital B	Dr. Kenneth Mitchell	Radiologia	Eliminar informação
11-05-2018 05:22:38	Hospital B	Dr. Kenneth Mitchell	Radiologia	Eliminar informação
11-05-2018 05:22:23	Hospital B	Dr. Kenneth Mitchell	Radiologia	Eliminar informação
22-04-2018 15:55:54	ULS C	Enf. Jennifer Taylor	Patologia Clínica	Adicionar informação
02-04-2018 07:21:23	Hospital B	Dr. Malcom Smith	Laboratório	Eliminar informação

Figure 7.10: All accesses mockup

Also from the homepage it is possible to access the health episodes, if you select the button of the episodes of the navigation bar will appear the option of past or future health episodes, as shown in figure 7.11. It is also possible to access the past episodes if we select one of the timeline episode.

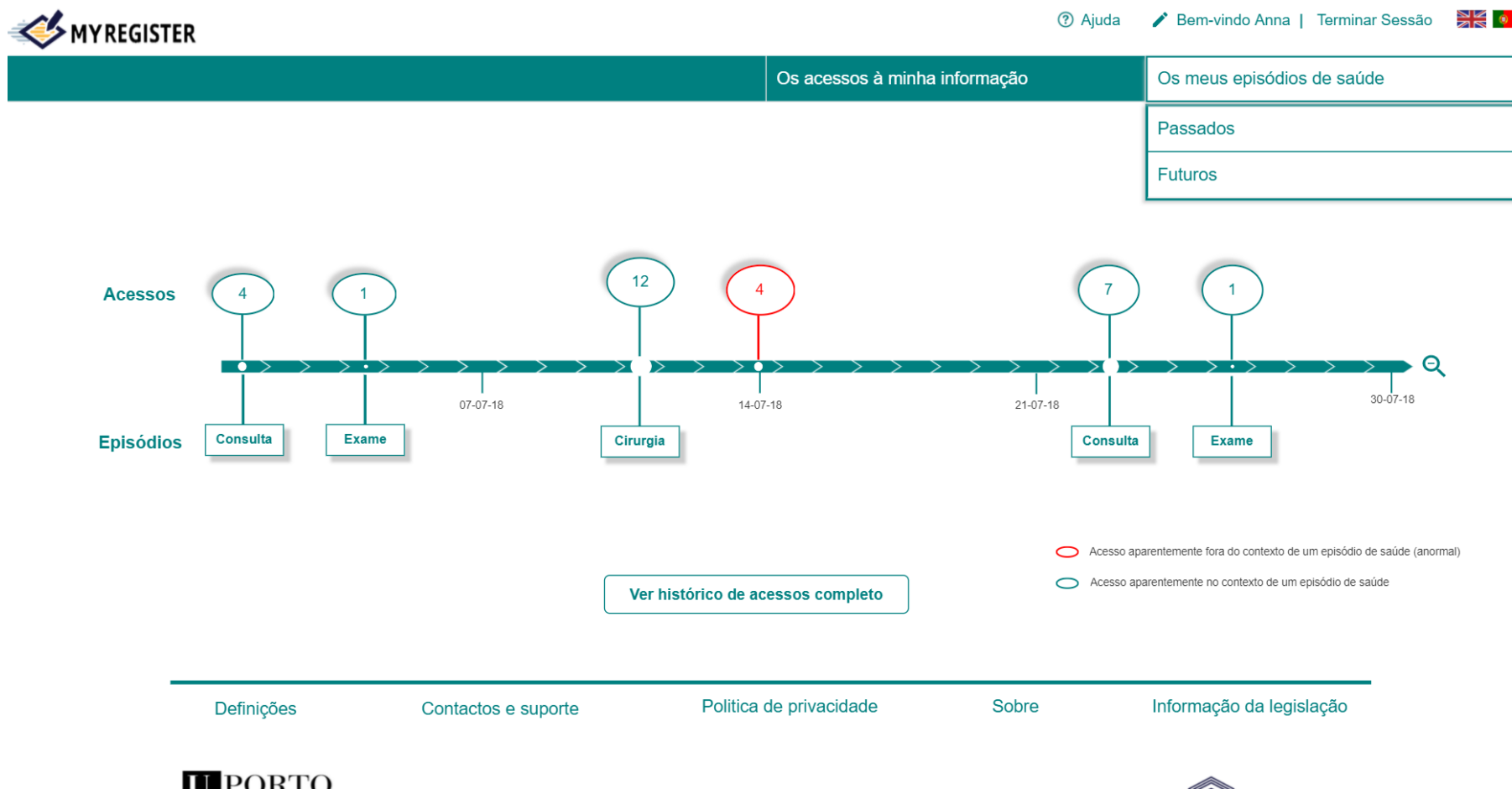


Figure 7.11: Past or future health episodes mockup

If you click on past health episodes, the figure 7.12 will appear, here it is possible to view the episode history and see in detail each one of them as shown in the figure. If you select future health episodes you will see a page like figure 7.13 which will also show in detail each of the episodes scheduled. Both pages allow you to filter the episodes by institution, health professional and date.

The screenshot displays the MYREGISTER interface. At the top, there is a navigation bar with the MYREGISTER logo on the left and user options on the right: 'Ajuda', 'Bem-vindo Anna | Terminar Sessão', and flags for the United Kingdom and Portugal. Below the navigation bar, there are two tabs: 'Os acessos à minha informação' and 'Os meus episódios de saúde', with the second tab being active.

Under the active tab, there is a section titled '▶ Histórico de episódios de saúde'. This section contains a list of health episodes, each represented by a teal bar with the episode name and date, and a dropdown arrow. The episodes listed are:

- Exame Radiologia (26-07-2018)
- Consulta Cardiologia (23-07-2018)
- Cirurgia (11-07-2018)
- Exame Radiologia (04-07-2018)
- Consulta Cardiologia (01-07-2018)
- Consulta Cardiologia (05-06-2018)

To the right of the list is a filtering panel with the following options:

- Data:** 'De' and 'Até' input fields, with a 'Sempre' checkbox checked.
- Instituição:** A dropdown menu with a '+ Todos' checkbox checked.
- Profissional:** A dropdown menu with a '+ Todos' checkbox checked.
- An 'Aplicar Filtros' button.

Below the list, the details for the selected episode (05-06-2018) are shown:

- Hora: 14:30h
- Instituição: Hospital A
- Profissional de saúde: Dr. Thomas Davis
- Descrição: -

At the bottom of the page, there is a footer with navigation links: 'Definições', 'Contactos e suporte', 'Política de privacidade', 'Sobre', and 'Informação da legislação'. A pagination indicator 'Página 1 > >|' is also present.

Figure 7.12: Past health episodes mockup

► Futuros episódios de saúde

Consulta Cardiologia 22-10-2018 ▾

Exame Radiologia 25-10-2018 ▾

Cirurgia 16-11-2018 ▾

Hora: 08:00hh

Instituição: Hospital A

Profissional de saúde: Dr. Thomas Davis

Descrição: Ambulatório Cateterismo cardíaco

Consulta Cardiologia 03-12-2018 ▾

Data De Até Sempre
Instituição + Todos
Profissional + Todos

Aplicar Filtros

Adicionar eventos

Figure 7.13: Future health episodes mockup

Through the page of future events it is possible to add an event that is not integrated automatically (for example of another institution that does not have HS.Register). Just add the event by filling in the form as in figure 7.14. After inclusion of the event it will appear in the page of future events as represented in figure 7.15, this event is possible to edit unlike those that are integrated.

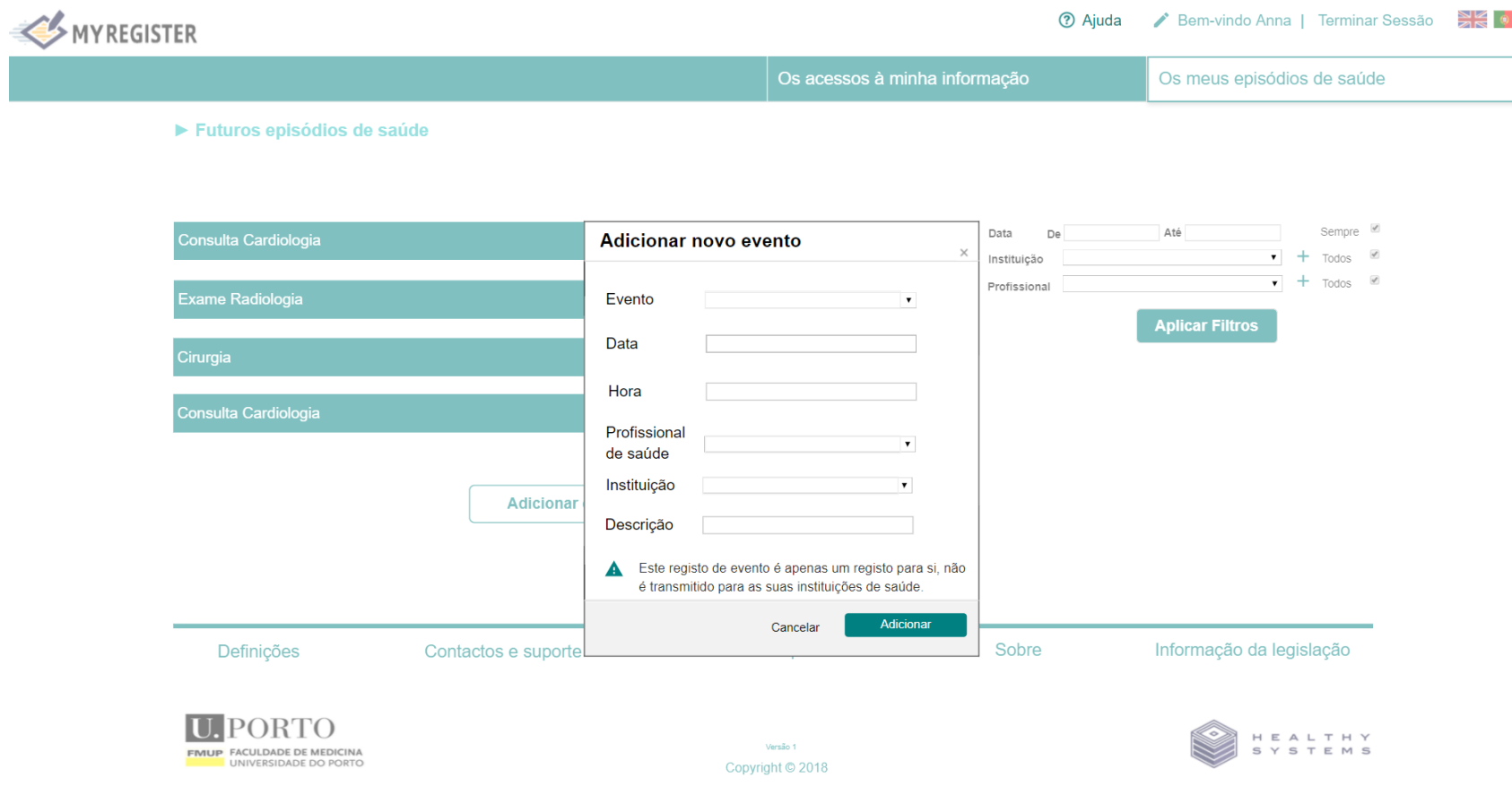


Figure 7.14: New health episode mockup

► Futuros episódios de saúde

Dentista	10-10-2018  ▼
Consulta Cardiologia	22-10-2018 ▼
Exame Radiologia	25-10-2018 ▼
Cirurgia	16-11-2018 ▼
Consulta Cardiologia	03-12-2018 ▼

Data De Até Sempre
Instituição + Todos
Profissional + Todos

Aplicar Filtros

Adicionar eventos

Figure 7.15: Future events page with new health episode mockup

In figure 7.16 we can consult the profile of the user, here it is possible to edit some information and include a photo. To get to this page just click on the edit symbol next to the name (upper right corner of the page).

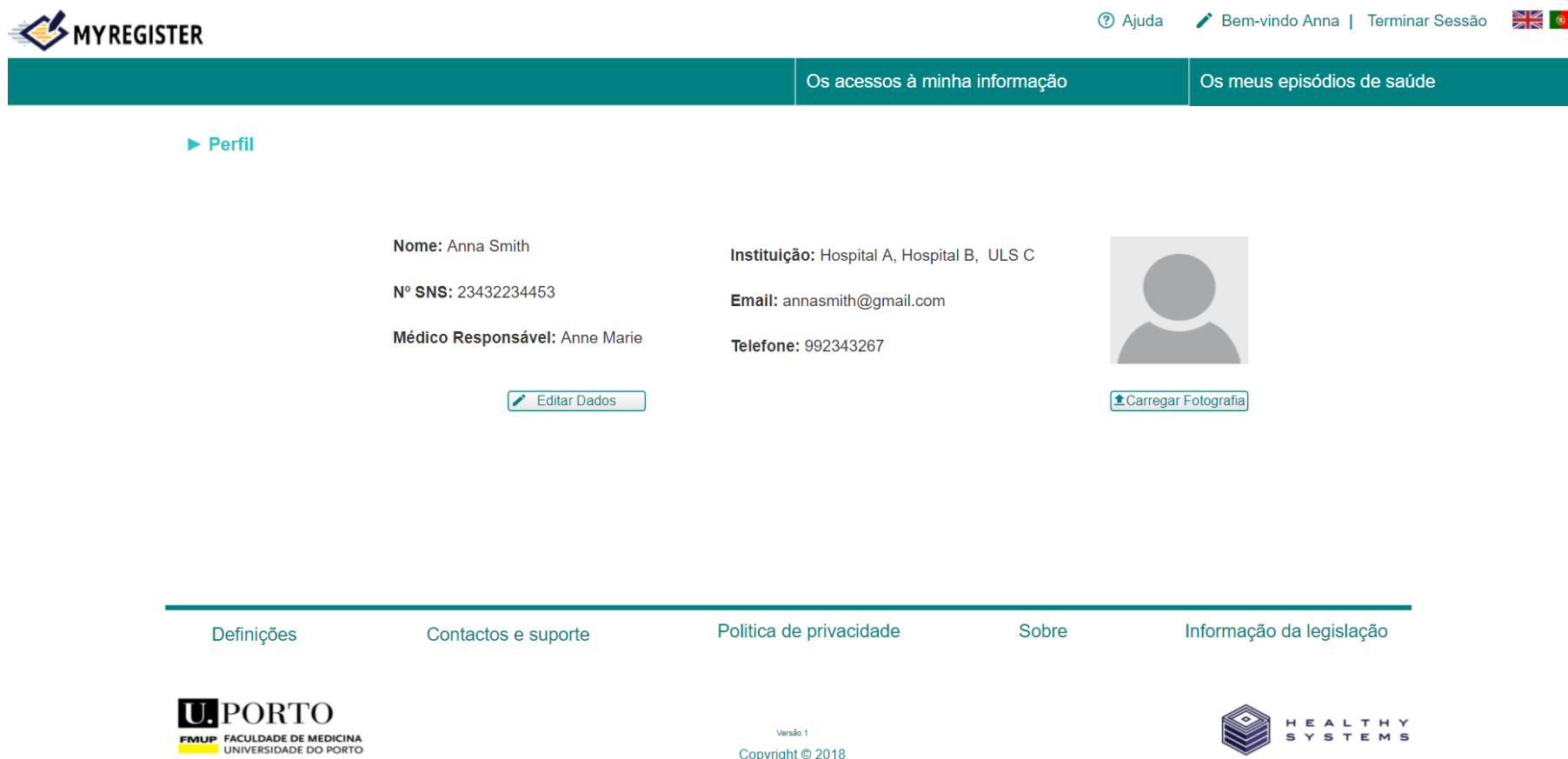




Figure 7.16: Profile mockup

In figure 7.17 we present the definitions page. On this page you can configure the MyRegister alarm system and add or delete institutions for MyRegister to access your information.

MYREGISTER ? Ajuda | Bem-vindo Anna | Terminar Sessão  

Os acessos à minha informaçãoOs meus episódios de saúde

▶ Definições

1. Alarmística

Enviar email de alerta quando for feito um acesso

Enviar email de alerta quando existir um novo episódio

Enviar SMS de alerta quando for feito um acesso

Enviar SMS de alerta quando existir um novo episódio


[Guardar Alterações](#)

2. Instituições

Hospital A <input checked="" type="checkbox"/>	Eliminar Instituição
Hospital B <input checked="" type="checkbox"/>	Eliminar Instituição
ULS C <input checked="" type="checkbox"/>	Eliminar Instituição


[Adicionar nova instituição](#)

[Definições](#) [Contactos e suporte](#) [Política de privacidade](#) [Sobre](#) [Informação da legislação](#)



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Figure 7.17: Profile mockup

The 4 remaining pages: Contacts and Support, Information of the Legislation, About and Privacy Policy for being information pages and usual in all the web pages are not shown here, having the same layout as the rest of the tool.

7.5 Prototype evaluation protocol

Realização de tarefas

1. Quantos acessos anormais foram feitos no mês de julho de 2018 e quais os nomes dos profissionais de saúde que os fizeram?

R: _____

2. Quantos foram os acessos onde foi eliminada informação no Hospital B?

R: _____

3. A que horas foi a consulta do dia 01-07-2018?

R: _____

4. Sabendo que no dia 14-07-2018 o Dr. Thomas Davis, o seu cirurgião, necessitou de aceder à sua informação de saúde para acrescentar um relatório de uma cirurgia, aceda aos acessos do dia 14-07-2018 e reporte aqueles que considera suspeitos/anormais.

R: _____

Questionário de Satisfação

		Discordo completamente	Discordo parcialmente	Não concordo nem discordo	Concordo parcialmente	Concordo completamente
		1	2	3	4	5
1	Acho que gostaria de utilizar este portal com frequência	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2	Considerei o portal mais complexo do que necessário	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3	Eu achei o portal fácil de usar	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4	Acho que necessitaria de ajuda de um técnico para conseguir utilizar o portal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5	Considerei que as várias funcionalidades do portal estavam bem integradas	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6	Achei que este portal tinha muitas inconsistências	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7	Suponho que a maioria das pessoas aprenderia a utilizar rapidamente este portal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8	Considerei o portal muito complicado de utilizar.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9	Senti-me muito confiante a utilizar o portal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10	Tive que aprender muito antes de conseguir lidar com este portal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Sugestões: _____

Questionário de informação sociodemográfica

Género: Masculino Feminino

Idade: 18-29 30-49 > 60

Escolaridade: Ensino Básico Ensino Secundário Licenciatura Mestrado ou Doutoramento Outro _____

Ocupação: Trabalhador(a) Doméstico(a) ou Desempregado(a) Estudante Outro _____

Possui um computador pessoal? Sim Não

Qual a frequência com que:

	Nunca 1	Raramente 2	Às vezes 3	Frequentemente 4	Sempre 5
Utilizo o computador	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Utilizo o Portal web do banco para consulta de dados/movimentos	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Utilizo o Portal das finanças para realização do IRS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Utilizo a Plataforma de dados de saúde (Portal do utente)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

7.6 Task notes

Participant 1.B:

Question 1 - Easily noticed where the accesses were, analyzed the caption and answered.

Question 2 - Difficulty in noticing where the information from Hospital B is. Difficulties to turn back the pages. Does not use the filters. Answered through the full history of accesses counting them.

Question 3 - Difficulty in understanding the difference between accesses and health episodes, try to look in the page of the accesses. After several attempts, uses the page from past episodes and answers.

Question 4 - Difficulty in understanding the difference between accesses and health episodes. Difficulty in noticing where the reporting button was. Indecision in which the suspicious accesses were, chooses the access in which information was deleted because to the participant, deletion is suspicious.

Participant 2.B:

Question 1 - Easily noticed where the accesses were, answered only one access because it saw an access where information was deleted.

Question 2 - Difficulty in noticing where the information for Hospital B is. Difficulties to go back on the pages (tried several buttons to return to the homepage). Does not use filters. Answered through the full history of accesses counting them.

Question 3 - Difficulty going to the homepage, when was on the homepage answered correctly right away.

Question 4 - Difficulty in understanding the difference between access and health episodes. Looks for access information on the pages of health episodes. When returns to the homepage the participant quickly executed the task correctly.

Participant 3.B:

Question 1 - Easily noticed where the accesses were, analyzed the caption and answered.

Question 2 - Difficulty in noticing where the information for Hospital B is. Difficulties to go back on the pages. Does not use filters. Answered through the full history of accesses counting them.

Question 3 - Difficulty in understanding the difference between access and health episodes. Analyzes for a while the homepage and finds the information to answer correctly.

Question 4 - Difficulty in understanding the difference between access and health episodes. Indecision in which the suspicious accesses were, chooses the access in which information was deleted because to the participant, deletion is suspicious.

Participant 1.C:

Question 1 - Understood the information very quickly and answered correctly.

Question 2 - Difficulty in understanding that there is more information than the one presented in the previous question. Difficulties to go back on the pages. Use the filters but suggests that they should have a title.

Question 3 - Difficulty in understanding the difference between access and health episodes. Used the navigation bar to go to past episodes and answers.

Question 4 - Difficulty in understanding what to answer. Re-read the question several times until understanding it. Indecision on which the suspicious accesses are but chooses the right accesses.

Participant 1.A:

Question 1 - Difficulty in understanding the timeline and its associated dates. The participant managed to answer by reading the caption.

Question 2 - Uses the access history and easily realizes the need to use the filters.

Question 3 - Quickly gives the correct answer.

Question 4 - Has trouble finding the report button. It considers all the accesses suspicious because they are marked as abnormal, not interpreting the text presented.

Participant 2.A:

Question 1 - Easily responds correctly.

Question 2 - The participant has difficulty understanding what to do. Accesses the full access history and counts the accesses. Question 3 - Difficulty in understanding the timeline and the date. After identifying the date answers correctly.

Question 4 - Has trouble finding the report button. Analyzes the accesses and answers correctly.

Participant 3.A:

Question 1 - Easily responds correctly.

Question 2 - Easily realizes the need to use the filters and answers correctly.

Question 3 - Initially, has some difficulty in understanding that is on the accesses page. When at the homepage, answers correctly.

Question 4 - Has trouble finding the report button. Analyzes the accesses and answers correctly.

Participant 2.C:

Question 1 - Analyzes the homepage and identifies only one access by seeing only one box in red. When the participant selects to see the names realizes that there are 4 accesses.

Question 2 - The participant has difficulty in realizing that there are more accesses than those presented in the previous question. Returns to the homepage and through the access history counts the accesses.

Question 3 - Tries to see through the access history. Goes back to the homepage and answers correctly.

Question 4 - Has difficulties to find the requested accesses again. When the participant finds the access has trouble finding the report button. Analyzes the accesses and responds correctly.

Participant 1.D:

Question 1 - Analyzes the homepage with many difficulties. Identifies only one access because it is where information was deleted.

Question 2 - Identifies the accesses through the access history counting the accesses. It mentions difficulty in counting accesses because the information is too clustered.

Question 3 - Tries to see through the accesses. Goes back to the homepage, uses the navigation bar and responds correctly although with some difficulties.

Question 4 - Easily find the requested accesses. Has trouble finding the report button. Analyzes accesses and only chooses the access where information has been deleted.

Participant 2.D:

Question 1 - Easily responds correctly.

Question 2 - Identifies the accesses through the access history counting the accesses.

Question 3 - Initially has some difficulty in understanding that is on the accesses page. When goes to the homepage answers correctly.

Question 4 - Analyzes the accesses and answers correctly.

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