

# Usability Study of a Tool for Patients' Access Control to Their Health Data

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**Keywords:** Patient Empowerment, Access Control, Audit Trail, GDPR, Prototype, Usability, SUS.

**Abstract:** Considering the need that is expected for the institutions to be compliant with the new legislation we intended to create a tool (MyRegister) that will allow patients to know which professionals accessed their health data in healthcare institutions where they have had previous contact. Before development we decided to create a functional prototype to validate the user interface of the tool with real users. We created an evaluation instrument consisting of 4 tasks and a SUS 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, while the SUS score of 79.5 in 100 is a result that shows good usability. Regarding the performed tasks, 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 and test its usability as well as user experience in real environments with a wider and more heterogeneous sample.

## 1 INTRODUCTION

Every day health professionals are in contact with the information systems that keep the personal information of each of the patients of the health institution. Personal Health Information (PHI) of patients can be viewed, created, edited and even eliminated without the patient's knowledge and the disclosing of purpose of that access by the professional. Data protection legislation and health data such as Health Insurance Portability and Accountability (HIPAA), the United States of America legislation and more recently General Data Protection Regulation (GDPR), the European Union legislation are intended to ensure that patients have access to information about who accesses their PHI because it is a patient's right (Tovino, 2016; Jornal Oficial da União Europeia, 2016). However nowadays it is very difficult for the patient to have access to this information, it is a time consuming and complicated process and is often difficult to obtain due to the lack of proper control mechanisms. In order to comply with the European requirements of the legislation in force, GDPR, institutions have to change some of their usual behavior, namely auditing require-

ments (Gonçalves-Ferreira et al., 2018).

### 1.1 Audit Trails

The records that show who accessed, what, when and what operations were made are called audit-trails (Cruz-Correia et al., 2013). Knowing what health professionals have accessed regarding the health data of patients may be challenging, even when institutions' systems keep the access logs of health professionals. 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. Audit trail systems can help institutions to be compliant with GDPR (Cruz-Correia et al., 2013).

### 1.2 Patient Empowerment

When empowerment is in the health environment, it focus on patient empowerment, and can be interpreted as the activity of including the patient as

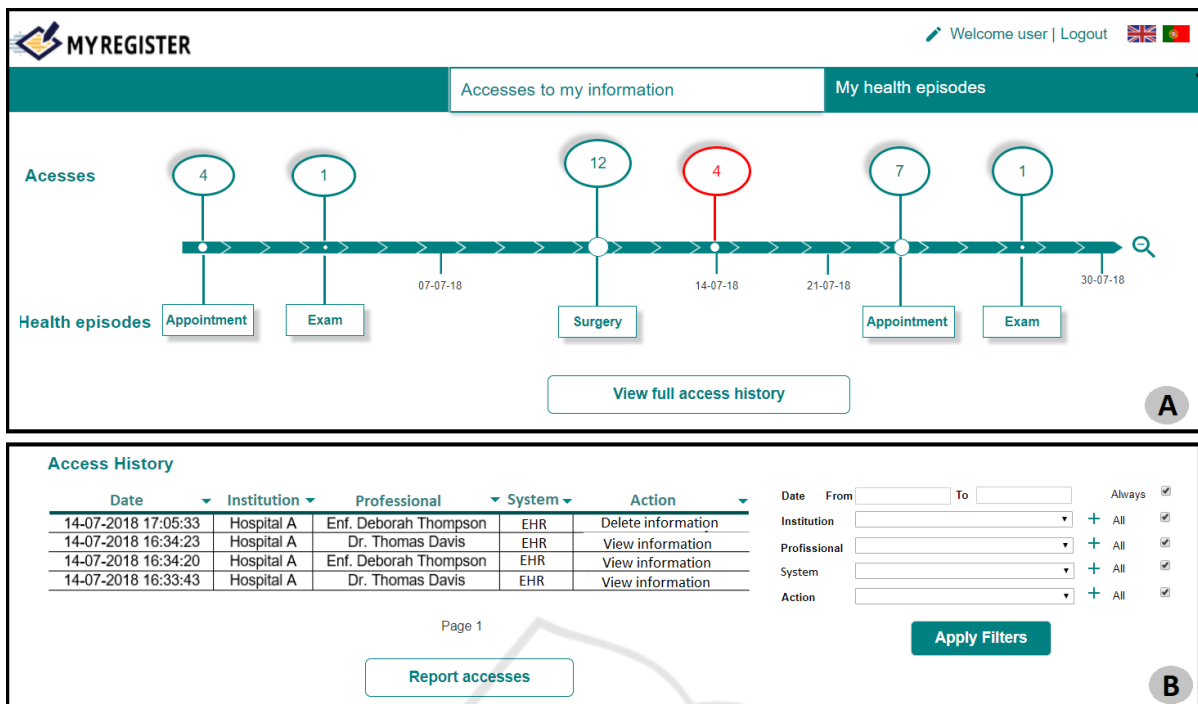


Figure 1: Prototype images: A: Homepage that allows the user to view the accesses made in the last month, year etc.; B: Detailed page of accesses made on a specific day.

an autonomous and informed individual with certain responsibilities that allows him/her to participate in his/her health decisions (Schulz and Nakamoto, 2013). 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 and improve their healthcare outcomes. GDPR is aligned with the idea of patient empowerment as that it allows patients to access their health data and to know which health professionals also accessed it (Jornal Oficial da União Europeia, 2016).

### 1.3 MyRegister

Considering the need that is expected for the institutions to be compliant with the new legislation in force and the results obtained in the questionnaire carried out in (Reis et al., 2018) where was shown that 90.7% of the 589 participants recognized that a tool to control healthcare providers accesses would be important, and 71.5% of them agreed that they would use that tool, we intended to create a tool that com-

plies with both. The tool we intended to create will allow patients to know which professionals accessed their health data in institutions where they have had previous contact. We intend to base our tool on the information gathered by the HS.Register audit trail (Gonçalves-Ferreira et al., 2018). HS.Register is an audit trail that collects events, logs and HL7 messages from hospital information systems. We intend to collect in our tool (MyRegister) 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 agree to use and enroll in our tool.

The main features of MyRegister are:

- present the health professionals who accessed the patient's health information, the date of access, the system in which it was accessed and the action taken (visualization, edition, elimination or creation);
- present the health events performed by the patient (consultations, exams, surgeries, etc.);
- present scheduled future patient health events;
- allow to report to the health institution accesses that are suspected to be undue;
- provide alarmistic to alert the patient when an access to patient's information is made;

- provide alarmistic to alert the patient that he/she has scheduled a health episode;

MyRegister will be possible to use by any patient of the Portuguese national health system (NHS) and therefore needs a greater focus on usability of the tool. Before development we decided to create a functional prototype, Figure 1, to validate the user interface of the tool with real users. Figure 1 represents 2 distinct pages of the tool, the one marked with the letter A shows the homepage that consists of a timeline where it is possible to visualize the accesses made. In red are marked the accesses that are outside a context of health episode and possibly are undue. The second page, marked with the letter B, shows a detailed page of the accesses of a specific day where it is possible to see the information of each access. It is also possible to filter the access information through the boxes on the right side of the page, and report the accesses through the "report accesses" button.

#### 1.4 Usability Evaluation

We consider the importance that is prototyping a tool that is intuitive and provides the user with a pleasant experience. 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.

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 im-

portant 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 users' satisfaction (Rogers et al., 2011).

For the evaluation of usability validated questionnaires are often used all over the world. As an example the SUS questionnaire was used in (Konstantinidis et al., 2016) and (Triantafyllidis et al., 2014) as a usability evaluation tool. The SUS questionnaire is translated into Portuguese and validated by (Martins et al., 2015) and is composed by 10 statements about the user opinion of the product use. Each statement is associated by the user to a level of agreement, based on a likert scale. To calculate the final score of the SUS each level of agreement is assigned to a value. 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.

With all these important issues in view, the aim of this study is to evaluate the usability of a tool in which patients will be able to monitor health professionals accesses to their health data in healthcare institutions. We intended to collect feedback from user tests to optimize our tool (MyRegister) according to the obtained results and understand if it is possible to create a tool usable and user-friendly to the patients where they can understand easily the information that is given to them.

## 2 METHODOLOGY

In order to evaluate the functional prototype we decided to present the study participants with four tasks to accomplish. These tasks were triggered by four main questions corresponding to the main features of the tool.

Participants had the functional prototype created through the Justinmind software, which allows interactions between 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 the users 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 presented four questions:

**Q1:** How many abnormal accesses were made in July 2018 and what were the names of the health professionals who did them?

**Q2:** How many accesses were made where information was eliminated in Hospital B?

Table 1: Participants' Demographic Information.

	G	Age	Academic Qualifications	Occup.	Pers. PC	Use the PC	Use bank webpage	Use finance webpage	Use PDS webpage
1.A	F	18-30	Master/PhD	Worker	Yes	Always	Frequently	Never	Sometimes
2.A	M	30-50	Master/PhD	Worker	Yes	Always	Sometimes	Frequently	Never
3.A	M	18-30	Master/PhD	Worker	Yes	Always	Always	Frequently	Rarely
1.B	F	18-30	Secondary	Student	Yes	Frequently	Never	Never	Rarely
2.B	F	18-30	Secondary	Student	Yes	Always	Rarely	Never	Never
3.B	F	18-30	Secondary	Student	Yes	Always	Rarely	Never	Sometimes
1.C	F	30-50	Post-grad	Worker	Yes	Frequently	Always	Always	Sometimes
2.C	F	30-50	Bachelor's	Worker	Yes	Always	Always	Always	Sometimes
1.D	F	50-60	Secondary	Worker	Yes	Rarely	Never	Never	Never
2.D	M	50-60	Secondary	Worker	Yes	Frequently	Never	Never	Never

**Q3:** At what time was the doctor appointment on 01-07-2018?

**Q4:** Knowing that on 14-07-2018 Dr. Thomas Davis, your surgeon, needed to access your health information to add a report of a surgery, find the accesses on the 14-07-2018 and report those which you consider suspicious/abnormal.

We asked them to speak out loud and explain the difficulties they were encountered 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 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 an open 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 asked the participants to fill out a questionnaire with sociodemographic information. This information allows us to characterize the population that was evaluating our prototype (age, academic qualifications, technical habits, use of similar webpages etc.).

## 2.1 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 are enough to find 80% of usability problems, because the first participants usually find the most serious problems. Less new usability problems are found by the following participants. From the social demographic questionnaire analysis we decided to create 4 different groups, each group had between 2 and 3 participants.

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 1. Groups are presented in table 2.

Table 2: Evaluation Groups.

Group	Description	n
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

## 3 RESULTS

### 3.1 Results of the Performed Tasks

During the accomplishment of tasks notes were taken regarding the behavior of the participants with the

prototype. After the evaluation of the prototype with the first 4 participants (participants 1.B; 2.B; 3.B; 1.C), we immediately identified 3 major problems:

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

From the previous three problems we consider that the first two were 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 and to solve the second problem we chose to include a title for the filters functionality in order to draw attention and explain their existence. The prototype with the changes was presented to the remaining of the participants.

The major problems found in the remaining of participants' evaluation (participants 1.A; 2.A; 3.A; 2.C; 1.D; 2.D) were:

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

From the previously identified problems we verified that the two problems identified and changed in the prototype in the first 4 participants' evaluation (difficulty in returning to the home page and lack of use of the filter functionality) were solved. The problem of the difficulty in understanding the difference between accesses and health episodes occurred still remained with this participants that also identified 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 3 we present the answers where C= correct answer and I= incorrect answer for each participant, the percentage of correct answers of each group and we also present the percentage of correct answers for the total of participants. We can verify 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 the first 4 participants did not show evidence of having interfered with the answers given by the participants.

Table 3: Results: task answers.

Participant	Q1	Q2	Q3	Q4
1.A	C	C	C	I
2.A	C	C	C	C
3.A	C	C	C	C
Group A	100%	100%	100%	66%
1.B	C	C	C	I
2.B	I	C	C	C
3.B	C	C	C	I
Group B	66%	100%	100%	33%
1.C	C	C	C	C
2.C	I	C	C	C
Group C	50%	100%	100%	100%
1.D	I	C	C	I
2.D	C	C	C	C
Group D	50%	100%	100%	50%
Total	70%	100%	100%	60%

Table 4: Results: task time (seconds).

Participant	Q1	Q2	Q3	Q4
1.A	78	47	29	83
2.A	48	63	41	73
3.A	45	46	50	92
Group A Median	57	52	40	83
1.B	99	95	97	200
2.B	59	128	48	199
3.B	35	133	128	175
Group B Median	64	119	91	191
1.C	61	86	102	204
2.C	99	94	69	189
Group C Median	80	90	86	197
1.D	167	84	154	203
2.D	78	73	65	129
Group D Median	123	79	110	166
Total Groups Median	77	85	78	155

In table 4 we present the time (in seconds) that 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 partici-

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. Also as shown in table 4, 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, as shown in table 4, 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.

### 3.2 Results of the SUS

To calculate the SUS score to 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 to the answer) minus 1;
- For the statements 2, 4, 6, 8 and 10: 5 minus value assigned (1 to 5 according to the answer).

In table 5 we present each 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 5: Results: SUS.

Participant	SUS Score
1.A	87,5
2.A	65
3.A	85
Group A	79,17
1.B	55
2.B	75
3.B	80
Group B	70
1.C	92,5
2.C	95
Group C	93,75
1.D	70
2.D	90
Group D Score	80
Total Score	79,5

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 Accesses" 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 DISCUSSION

This study 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 using 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 delayed 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 take more 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. 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 that were given by the participants, would 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.

## 5 LIMITATIONS

The major limitation of the study 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.

## 6 CONCLUSIONS

We conclude that it is possible to create a usable and user-friendly tool that allows patients to monitor the access that is made to their health information. With the increasing demand for the use of safe systems that promote patient empowerment, a tool to monitor access to patient health information that is a growing need in health institutions, is essential and should be used by all patients. With this study we realized the major problems in our prototype and we also collect suggestions from the users to move forward into creating the tool with a more solid baseline.

## ACKNOWLEDGEMENTS

This work is supported by the MSc in Medical Informatics of the University of Porto, Portugal (<http://mim.med.up.pt>). The authors would also like to acknowledge the project Demonstrador

HS.REGISTER, supported by Norte Portugal Regional Operational Programme (NORTE 2020), under the PORTUGAL 2020 Partnership Agreement, through the European Regional Development Fund (ERDF).

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