

# Audit trails in Patient Portals

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## Declaration

I declare that the work described in this dissertation is, except where otherwise stated, entirely my own work, and has not been submitted as an exercise for a degree at this or any other university.

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## Abstract

Ireland is currently in the process of developing a nationwide patient portal that allows patients to remotely access their medical records. This is necessary since it complies with the latest GDPR requirements.

In the US, a study has been carried out to find out whether allowing patients to decide who accesses their EHR is a good idea. This study took into consideration what patients wanted, created an interface that allowed them to control their data, and showed it to Doctors, Nurses and other staff. The results of this study shed a light to how divided opinions are. The one detail that the study failed to comment on, is whether Healthcare providers agree with patients being notified of the interactions with their data.

## Research Question

The hypothesis of this study is that there are good reasons to consider notifying patients about activity related to their data as a way to mitigate discord around the possibility to give patients full control over their data. The goal of this dissertation is to determine a possible common ground where both patients and Healthcare providers feel comfortable

## Literature Review

A literature review was carried out to understand Patient Portals and its Ethical considerations, review the studies carried out in the US regarding patient controlled medical records, Audit Trails and its possible utilization in patient portals and the desires of patients with regards all of the above topics.

## Methodology

A first qualitative study was carried out in order to determine the desires of patients with regards to the topics of confidentiality, patient portals and the design preferences for an app that allows them to see who has been interacting with their records.

Patient personas were created to inform and inspire the creation of a demonstration app that would be used to show to Healthcare providers.

A second qualitative study was carried out in order to capture the impressions of Healthcare providers. The study consisted in interviews following a demonstration of the app.

## Conclusion

The hypothesis of the dissertation was that there are good reasons to further explore the possibility to include Audit Trails in Patient Portals. It was found that this is true, provided that both, patients and providers are included in the process of design.

## Contents

1	Introduction .....	1
1.1	Overview .....	1
1.2	Abbreviations .....	1
1.3	Background .....	2
1.4	Research Question .....	4
1.5	Why ask the question?.....	5
1.6	Research objectives .....	5
1.6.1	First Study .....	6
1.6.2	Personas.....	6
1.6.3	Second Study.....	6
1.7	This dissertation.....	7
1.7.1	Introduction .....	8
1.7.2	State of the Art.....	8
1.7.3	Research Method.....	8
1.7.4	Results.....	8
1.7.5	Conclusions .....	8
1.7.6	Discussion.....	8
2	State of the Art.....	9
2.1	Introduction .....	9
2.2	Literature review.....	10
2.2.1	Introduction .....	10
2.2.2	Patient Portals.....	11
2.2.3	Ethics and Patient Portals .....	15
2.2.4	Access Control.....	19
2.2.5	Access Notification.....	20
2.2.6	Patients' desires.....	24
2.2.7	Conclusion.....	25
3	Research Methodology .....	26
3.1	Introduction .....	26
3.2	Meeting with patients.....	27
3.2.1	Presentation.....	28
3.3	Questionnaire .....	32
3.3.1	Part 1 .....	32
3.3.2	Part 2.....	32

3.3.3	Part 3 .....	33
3.3.4	Part 4 .....	33
3.4	Personas .....	33
3.4.1	Jane: .....	33
3.4.2	Tom: .....	34
3.4.3	Sandra: .....	34
3.5	Demonstration app .....	34
3.5.1	Overview .....	34
3.5.2	Reference App:.....	35
3.5.3	Demo App .....	36
3.6	Provider Interviews .....	42
3.6.1	Overview .....	42
3.6.2	Preparation .....	43
3.6.3	During the interview .....	43
3.6.4	Interview cheat sheet .....	43
3.6.5	Topics .....	45
3.6.6	Random number generator .....	46
4	Results .....	47
4.1	Introduction .....	47
4.2	First Study .....	47
4.2.1	Results.....	47
4.2.2	Analysis .....	48
4.3	Second Study.....	56
4.3.1	Reaching out .....	56
4.3.2	Responses .....	57
4.3.3	Positive or negative feelings? .....	57
4.3.4	Spontaneous mentions of topics .....	58
4.4	Conclusion.....	61
5	Conclusions .....	61
6	Discussion.....	62
6.1	Is Healthcare genuinely keeping up? .....	63
	References .....	65
	Appendix .....	70
	INFORMED CONSENT FORM FOR IRISH FIBROMYALGIA SUPPORT GROUP RESPONSIBLE (First Study) .....	70
	Background .....	70

Permission Request.....	70
Data protection .....	70
Conflict of interest .....	70
DECLARATION: .....	70
Statement of investigator’s responsibility:.....	71
INFORMED CONSENT FORM (First Study).....	72
Background .....	72
Participation.....	72
Data protection.....	72
Conflict of interest .....	72
DECLARATION: .....	72
INFORMATION SHEET FOR IRISH FIBROMYALGIA SUPPORT GROUP RESPONSIBLE (First Study) .....	74
Background .....	74
Permission Request.....	74
Data protection .....	74
Conflict of interest .....	74
INFORMATION SHEET FOR PROSPECTIVE PARTICIPANTS (First Study) .....	75
Background .....	75
Participation.....	75
Data protection.....	75
Conflict of interest .....	75
Questions (First study).....	76
Second Study contact message.....	0
INFORMED CONSENT FORM (Second Study).....	1
Background .....	1
Participation.....	1
Audio recordings.....	1
DECLARATION: .....	1
Statement of investigator’s responsibility:.....	2
INFORMATION SHEET FOR PROSPECTIVE PARTICIPANTS (Second Study) .....	3
Background .....	3
Participation.....	3
Audio recordings.....	3
Conflict of interest .....	3
First Study Answers parts 1 and 2.....	0
First Study answers part 3.....	1



## Table of Figures

<i>Figure 1 finding the common acceptable ground with the rights of patients and Healthcare Providers</i> .....	5
<i>Figure 2 a diagram of the structure of this dissertation</i> .....	7
<i>Figure 3 Literature Review mind map</i> .....	11
<i>Figure 4 a representation of the logic behind the methodology</i> .....	27
<i>Figure 5 Diagram of the logic path of the Demo App</i> .....	37
<i>Figure 6 First page of the Cheat Sheet</i> .....	44
<i>Figure 7 Second page of the Cheat Sheet</i> .....	45
<i>Figure 8 Results of question 1</i> .....	49
<i>Figure 9 Results of question 2</i> .....	49
<i>Figure 10 Results of question 3</i> .....	50
<i>Figure 11 Results of question 4</i> .....	51
<i>Figure 12 Results of question 5</i> .....	51
<i>Figure 13 Results of question 6</i> .....	51
<i>Figure 14 Results of question 7</i> .....	53
<i>Figure 15 Results of question 8</i> .....	53
<i>Figure 16 Results of question 9</i> .....	54
<i>Figure 17 Results of question 10</i> .....	54
<i>Figure 18 Results of question 11</i> .....	55
<i>Figure 19 Results of question 12</i> .....	55
<i>Figure 20 Graph of the frequency of spontaneous mentions</i> .....	60

## Table of Tables

<i>Table 1 Glossary of abbreviations</i> .....	2
<i>Table 2 Literature review search terms</i> .....	9
<i>Table 3 Synthesis of the presentation</i> .....	32
<i>Table 4 Examples of the dynamic menus</i> .....	39
<i>Table 5 Examples of events list pages</i> .....	41
<i>Table 6 Examples of Profile screens</i> .....	42
<i>Table 7 Results of the first and second sections of the questionnaire in percentages</i> .....	48
<i>Table 8 Results of the third section of the questionnaire</i> .....	48
<i>Table 9 Breakdown of positive, negative and neutral opinions</i> .....	57
<i>Table 10 List of spontaneous mentions with the criteria they are based</i> .....	59

# 1 Introduction

## 1.1 Overview

This chapter first provides a glossary of abbreviations as well as a description of the background of the research, where a brief explanation of the context in which the idea of this dissertation originated. Second, it elaborates on the research question as well as the motivations behind its formulation. Later the objectives are laid out for the research in general as well as the individual goals of the studies required to achieve the primary purpose of the dissertation. Finally, the chapter will include a description of the dissertation and its chapters.

## 1.2 Abbreviations

Abbreviation	Meaning	Details
PP	Patient Portal	An interface that allows patients to interact with their electronic health records
AC	Access Control	Concept of allowing patients to decide who can create, edit and/or view their health record
AN	Access Notification	Concept of allowing patients to know who has created, edited and/or viewed their health records
EHR	Electronic Health Record	Records related to a person's health that transcends a single institution and includes the entirety of the Healthcare System of a country.
EPR	Electronic Patient Record	Records related to a person's health that resides in an institution, for example a hospital. This can be understood interchangeably with EMR

<b>EMR</b>	Electronic Medical Record	Records related to a person's health that resides in an institution, for example a hospital. This can be understood interchangeably with EPR
<b>GP</b>	General Practitioner	A community based doctor that serves as a first medical contact for patients.
<b>N</b>	Nurse	Healthcare professional skilled in caring for the sick or infirm
<b>Admin</b>	Administrative Staff	A person that is employed in administrative tasks in the healthcare sector, but is not considered part of the medical staff.
<b>AI</b>	Artificial Intelligence	Computer systems able to perform tasks that normally require human intervention
<b>BI</b>	Business Intelligence Tools	Application software that can extract, process and create reports for business intelligence.

*Table 1 Glossary of abbreviations*

### 1.3 Background

It sometimes may be taken for granted, but in this country, inhabitants are exceptionally fortunate to have access to decent Healthcare. In one way or another everyone who's been seen by a physician will have some kind of record in the provider's files. These records, in most hospitals, are paper files in folders that have to be physically stored and retrieved from a maze of paperwork. Paper records are slow to use, expensive to maintain and impracticable to be safely shared between

institutions. They also belong to the institution, but the information in the records, however, belongs to the patient.

As a response to this problem, most developed countries are adopting Electronic Health Records. Commonly known as EHR systems, this new technology continues to overcome difficulties and prove that its benefits outweigh its drawbacks. The positive effects of EHR's on cost, quality of care and patient safety have been carefully studied.

All around the world national healthcare systems are in various degrees of adoption of EHR's and Ireland is taking significant steps to stay up to date. In December 2016, the first babies with a Unique Patient Identifier were born in Ireland, and it has become apparent that software companies are investing heavily in the sector.

On the 28<sup>th</sup> of September 2017 the first meeting of the group Access to Information, part of eHealthIreland a Patient Portal pilot presented the NM-CMS National Patient Portal Pilot. This presentation highlighted the benefits, goals and possible future phases of the programme.

“Goals:

- Implement a patient to facilitate the health service’s strategic objective of improving the quality of patient care and strengthening preventive care services.
- Engage patients and their family members in their health and healthcare through the portal.

Benefits:

- Increased access and visibility of health information should lower waiting times as people become more engaged with the service and manage their appointments.
- Providing patients with education on relevant topics and current medical conditions is a critical part of patient engagement and preventive care services.
- Streamline hospital visits thereby improving OPD appointments and waiting lists.
- Reduced call volume to/from providers as patients use the portal.
- Convenient to patients.
- Increase efficiency and productivity to both patients and healthcare providers.”

(eHealthIreland Office of the CIO, 2017)

Among the list of possible future phases, the document states that the portal could "allow user to view audit trail which keeps track of when data was accessed and changes applied".

With all the stated benefits this will bring, this new technology can also create problems. The most recurrent concerns among both providers and patients are in the field of privacy and confidentiality.

Any information, however sensitive, could potentially be accessed by anyone in the health sector. Patients who are healthcare professionals could find it difficult to discuss, for instance, mental health issues if that meant that future employers could have access to these notes. They might think twice before entrusting their doctor with information they want to keep private.

In the US, a study has been carried out to find out whether allowing patients to decide who accesses their EHR is a good idea. This study took into consideration what patients wanted, created an interface that allowed them to control their data, and showed it to Doctors, Nurses and other staff. The results of this study shed light on how divided opinions are, and possibly what it would take for a patient portal with this type of functionality to be successfully implemented. Unfortunately, the study that recorded the impressions of healthcare providers to a system that allows granular control of the patient's data failed to enquire about the disclosure of Audit Trails to the patients. (Caine, et al., 2015) (Tierney, et al., 2015) (Caine & Tierney, 2015) (Schwartz, et al., 2015).

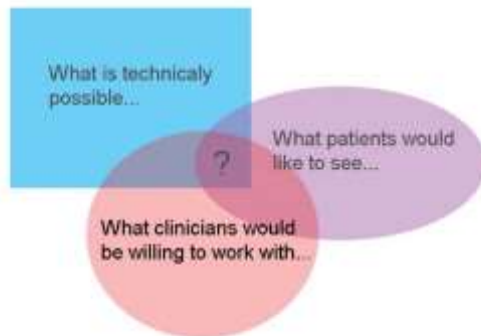
#### 1.4 Research Question

The research question for this dissertation originated from the interaction with a patient when participating in a workshop developing personas for the eHealthIreland Personas and Scenarios programme. In the development process, it was mentioned that the patient should be able to know if the provider interacted with the patient's medical records. A short literature review on the subject revealed little information about the possibility to include Audit Trails in patient portals.

**How would Healthcare providers feel about patients being able to access audit log events directly from their patient portal?**

The technical feasibility of systems that capture data access events is widely known. Systems with audit logging facility maintain metadata records of "what", "when", "how" and even sometimes "why" users create, edit, read or delete information (COACH, 2014). Audit logs cannot be modified by any user, and their metadata can be admitted in court, provided that it has been obtained lawfully (Hansen & Pratt, 2018). The matter of ownership and rights over the data captured by audit logs seems to fall on a grey area, where the rights of privacy of the users, in this case, medical staff, overlap the rights of patients to be notified of any access to their records. In Canada, for example, principle 9 of the Personal Information Protection and Electronic Documents Act states that individuals need to be informed of the existence, *use and disclosure* of their personal information (Office of the Privacy Commissioner of Canada, 2016). The key in this argument is in the words "*use and disclosure*". Depending on whose interpretation it is, this could mean that if a medical secretary accesses a patient's demographics for correspondence purposes, the patient should be explicitly

informed of it. In practice, this may seem impossible without the inclusion of Audit Trails into a Patient Portal. However, to protect employee confidentiality, a 2014 guideline for audit trails in EHR's clearly state that "Patients do not have the right to direct access to the audit log itself" (Canada's Health Informatics Association, 2014). As represented in **Error! Reference source not found.**, instead of focusing on the clash between the rights of these two parties, this dissertation intends to find out if Ireland can find an acceptable common ground of information sharing.



*Figure 1 finding the common acceptable ground with the rights of patients and Healthcare Providers*

## 1.5 Why ask the question?

The Department of Health's Statement of Strategy 2016-2019 has included as part of its strategic objectives to "Create a more responsive, integrated and people-centred health and social care service" (Department of Health, 2016). IPPOSI (Irish Platform for Patient Organisations, Science & Industry) and eHealth Ireland are no exception to this.

eHealth Ireland's Lighthouse Projects (eHealth Ireland, n.d.) owe their success to developing the system "with patient input from day one" (IPPOSI, 2016). In May 2017 phase one of a research project led by IPPOSI developed a definition which states that "person-centred co-ordinated care [...] demonstrates respect for my preferences, building care around me and those involved in my care" (IPPOSI, 2017). It seems logical to think that some level of patient access control will be introduced in the near future.

"Engaging patients in self-care and empower them to make a more active role in their healthcare management" (eHealth Ireland, 2017) is stated as the purpose of the national online site "MyHealthPortal". This dissertation aims at contributing our knowledge when deciding whether an alternative to full granular Access Control is worth exploring.

## 1.6 Research objectives

As mentioned in the research question, the objective of this dissertation is to capture the impressions of healthcare providers to the possible introduction of a Patient Portal that allows

patients to see who has been interacting with their health records. A secondary objective is to determine factors that could contribute to a successful implementation of such a system.

### 1.6.1 First Study

The objectives of the first study are to compare the desire and opinion of patients regarding privacy and confidentiality, with the findings in the literature and international experiences. If possible, this study will attempt to determine whether the concerns about an EHR that makes it easy to share medical information among professionals, outweighs the perceived advantages in the patient's mind.

Primarily the intention is to determine the level of trust in the Healthcare System on behalf of patients. Whether patients subscribe to the "Need to know" principle and whether they trust that this principle is being respected. Secondly, the idea is to determine if there is a difference between the level trust patients put on Doctors, Nurses or Administrative staff. This would go hand in hand with the desire of granularity in control expressed in the US-based studies found in the literature (Caine & Hanania, 2013).

The first study will also serve as an aid to determine the parameters in which a hypothetical app or part of a patient portal would operate. The idea is to establish the types of information to display and whether the most basic elements of an Audit Trail are enough to reassure patients of their privacy. Also, it will enquire about the patient's interest in having the possibility to report inappropriate activity directly from the app.

### 1.6.2 Personas

The first objective for creating patient personas is to serve as inspiration in the development of the Demo App, which will be used to demonstrate the concept to providers in the second study. The intention is to reflect as faithfully as possible, the motivations of patients in their interest for an app that allows them to view who has been interacting with their Health Records.

A secondary objective of the creation of the patient personas is to help prepare the interview questions for the second study. For instance, where a patient might like the app due to concerns about their work colleagues looking at their record, the interviewer will consider it as a follow-up question or scenario.

### 1.6.3 Second Study

The second study will attempt at recording the first impressions of healthcare providers, more specifically GP's and Nurses, Secretaries and Receptionists working in GP practices.

The interviews will attempt to gain a preliminary understanding of any concerns staff might have about the introduction of a portal that allows patients to know about any activity related to their data. The interviewer will formulate the questions with the idea of finding any concerns about the types of data that the hypothetical app would display. The interview will also aim at finding any concerns about the functionalities of the app, whether it is a reporting facility or the display of providers' professional profiles. In the case of finding any concerns in any of the areas, the interviewer will try to explore any alternative that the interviewees might find acceptable.

Finally, the second study will attempt to determine whether there is a difference in opinion when asking providers to momentarily leave their position as providers and place themselves as patients. Whether the idea seems appealing, given that professionally they are likely to be affected, should any breach of their privacy occur. Also, it will attempt to determine whether an app like the proposed would affect their relationship with their Healthcare Providers.

### 1.7 This dissertation

This dissertation is divided into six chapters with further and more detailed information in the appendix section (Figure 2below).

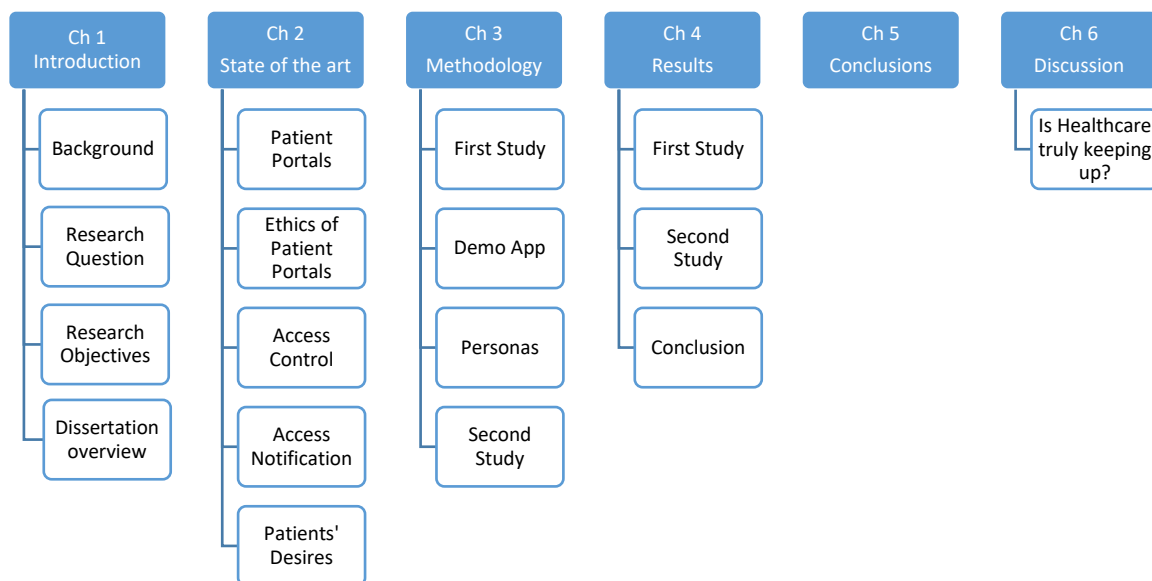


Figure 2 a diagram of the structure of this dissertation



### 1.7.1 Introduction

This chapter introduces the research background, the research question, motivation and the particular objectives of the subsections in the dissertation as well as a description of the document in which this section resides.

### 1.7.2 State of the Art

This chapter includes the literature review including the topics of Patient Portals, Ethics of patient portals, Access Control, Access Notification and what has been determined nationally and internationally about patients' desires regarding privacy in Healthcare.

### 1.7.3 Research Method

This chapter provides information about the methods used in the two studies as well as the criteria and development process of an app designed to exemplify a hypothetical privacy section of a portal or app. It also details the patient personas utilised in the process of design.

### 1.7.4 Results

This chapter details the results of the questionnaire in the first study as well as the findings of the interviews with the providers.

### 1.7.5 Conclusions

This chapter summarises the findings of the dissertation

### 1.7.6 Discussion

This chapter explores possible requirements for a successful implementation of a patient portal and factors to take into account.

#### 1.7.6.1 *Is healthcare keeping up?*

This subsection discusses the exciting possibilities of Artificial Intelligence and the deep conceptual dilemmas it might bring to the healthcare community.

## 2 State of the Art

### 2.1 Introduction

This chapter consists of the review of the literature carried out for this dissertation. The findings of the literature review include secondary research on:

- Patient Portals
- Ethics and Patient Portals
- (Patient) Access Control
- Access Notification (to patients)
- Patients' desires (regarding Patient Portals)

The initial literature review terms are indicated in Table 2

<b>Data privacy</b>	Data protection, Personal Information, Sensitive information, Private information, Information Safety, Fair Information Practices, Freedom of Information, Data Governance, Patient Confidentiality
<b>Audit trails</b>	Audit trails, Audit Logs, Event Log, Audit Events, Event Recording, Digital Audits, Guidelines for Audit Trails, Audit trails in Healthcare
<b>Health Records</b>	Medical Records, Health Records, Patient Records, Medical Charts, Medical Records, Electronic Health Records, Electronic Patient Records, Electronic Medical Records
<b>Patient portal</b>	Patient Portals, Patient portal, Patient app, Patient site, Patient interface, Patient dashboard
<b>Patient Centred Care</b>	Provider-patient relationship, Patient-Centered Care, Patient-Centric, Person-Centred Care, Patient Inclusion, Patient Empowerment, Patient-Centred Design, User-Centred Design, Patient-Centred Care, Person Centred Care, Patient-Centred Design, User Centred Design
<b>Bioethics</b>	Bioethics, Medical Codes of Practice, Doctors Codes of Conduct, Ethical Medicine, Ethics in Medicine, Ethics in Healthcare, Bioethics, Hippocratic Oath, Nurses Codes of Conduct

Table 2 Literature review search terms

## 2.2 Literature review

### 2.2.1 Introduction

With the intention of informing this dissertation an initial review of the literature, industry guidelines and reports, websites and articles, was carried out. The purpose of this stage was to gain knowledge of the work already carried out on the following topics:

- Patient Portals: A review of the technological state of the art, its adoption on behalf of healthcare systems worldwide and its potential benefits and possible drawbacks.
- Bioethics: An overview of the concept, principles and possible areas of conflict concerning EHR, Patient portals. Current affairs at the time of writing the dissertation in relation to privacy and confidentiality and the effects of ethically questionable designs called for further investigation of Privacy Paradox, Navigational Frictions and deceiving user interfaces.
  - Data Protection: Mainly related to the rights of data subjects regarding their privacy and confidentiality. Subsequent searches were carried out to understand to a certain extent the obligations of data controllers.
  - Ethics in design: Ethical design issues related to current global events that pose moral and ethical examination.
- Access Control: Literature related to the idea of allowing patients to have control and possession of their medical records. This search triggered a further investigation of the ethical aspects of the topic.
- Audit trails: The history, basic principles and current use in general. Further emphasis was put into its use in Healthcare and the range of possible applications to the technology.
- Patient-Provider Relationship: Mainly concerning the paradigm of patient-centred care.
- Patient Desires: Interactions with participants revealed a need to cover a review on the desires of patients for a patient portal.

At the end of the literature review, it became evident that the topic of Privacy and Confidentiality was connected to every topic as portrayed in Figure 3. In this figure, Privacy and Confidentiality in healthcare can be found at the centre of Audit Trails, Data Protection, Patient Portals, Medical Records, Bioethics and Patient-Provider relationship.

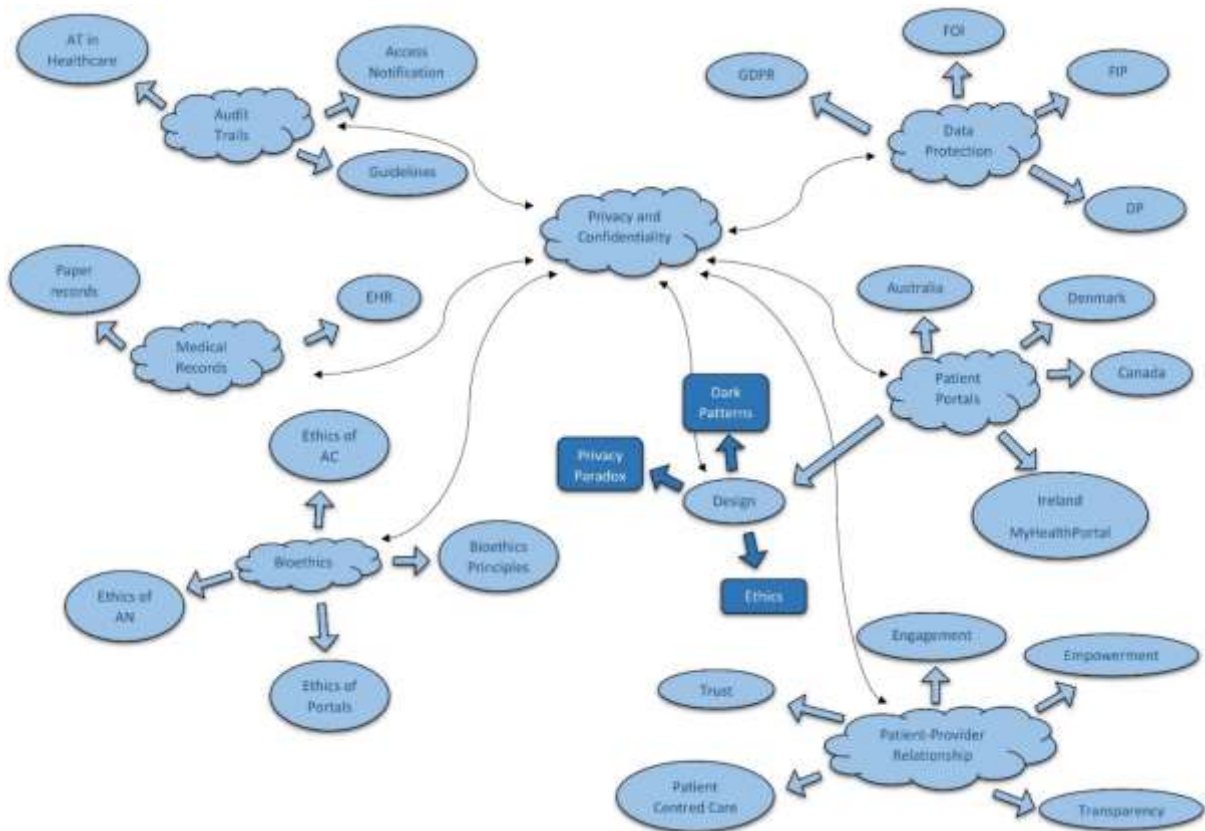


Figure 3 Literature Review mind map

## 2.2.2 Patient Portals

### 2.2.2.1 Overview

In light of the consensus regarding patient engagement and patient empowerment, it cannot be denied that Patient Portals have been recognised as a crucial tool to achieve these standards.

US government site HealthIT.gov (Office of the National Coordinator for Health Information Technology, n.d.) defines a patient portal as "... a secure online website that gives patients convenient, 24-hour access to personal health information from anywhere with an Internet connection". With the hegemony of mobile technology, this definition needs to be broadened to include mobile applications or any other form of human interface, like VR or AR. Not broadening our definition would not only leave future forms of human interfaces but also it would neglect to include designs that enable patients with accessibility challenges. Perhaps the definition should be updated to "... a secure online **interface** that gives patients..."

### 2.2.2.2 Criticism to Patient Portals

Over the last decade challenges have been made to the effectiveness of patient portals, perhaps the most compelling, question its effects on patient outcome. In a systematic review (Goldzweig, et al., 2013), no significant evidence was found that access to patient portals improved patient outcome,

satisfaction or adherence to treatment. The study points out, however, that there was more acceptance by younger patients with computer literacy skills.

Experts in specific disciplines have made further questioning of the efficacy of patient portals. In a qualitative study on the impacts of unrestricted access to EHR information in an Oncology (Alpert , et al., 2018) department, patients reported negative emotions when viewing results that might seem adverse. The report also raised concerns about patients' lack of computer literacy and had mixed opinions on whether it should be used as a tool for communication with the patient.

Healthcare professionals have consistently expressed concerns about the patient's capacity to process the information in their EHR. Countless articles, arguments and studies point out that providers are unsure that patients can handle the information in their health records. An example of these concerns has been stated in a focus group study (O'Leary, et al., 2016). Interviews with providers revealed concerns about patients facing high volumes of information that might overwhelm them.

Perhaps a more practical barrier lies within developers, who are not, in most cases trained in medicine or even familiar with the ethical principles that rule it. In the US, for example, HIPAA does not provide a framework for developers to base their design of patient portals. In her doctoral thesis Terese Otte-Trojel (Otte-Trojel, 2015) pointed out that developers do not know "What" "When" and "How" to include information in patient portals as a result of this guideline vacuum.

### *2.2.2.3 Advantages of Patient Portals*

As it may be expected voices of criticism against the adoption of patient portals have been met with arguments highlighting their benefits. Mainly studies carried out in recent years point out benefits in social accessibility, ethical progress, patient communication and in meeting patient desires.

A recent survey of 323 patients and 389 care partners revealed that the use of patient portals allowed for integrated health care for older or less educated patients. Allowing care partners to get involved and enhance patient outcomes (Wolff, et al., 2016).

As a tool of communication, patient portals have proven to be well received. Rigby et al., (2015) emphasise how interactive portals enhance communication between patients and professionals. As it has been pointed out, communication is viewed as a fundamental part of a patient-centred strategy to healthcare. The authors also add that Portals are an effective way to achieve greater equity, better patient satisfaction, better outcomes and efficiency.

In a focus group study conducted on hospital-based patient portals (O'Leary, et al., 2016) patients reported the portal to be useful, yet they expressed a desire for more information to be included in

the application. Almost in contradiction to professionals concerns about the patient's capacity to handle health information, patients reported that they would like to see additional detail about medications, test results and proposed that the app should have a way to record their questions.

The overwhelming evidence supports the notion that patients want portals. Even when patients do not fully trust that their privacy will be protected appropriately, users continue to take advantage of the service. In an article published in the Journal of Medical Internet Research (Vodicka, et al., 2013) concluded that patients would access their patient portal, even though they manifest concerns about their privacy online.

#### *2.2.2.4 Examples from other countries portals*

Despite criticism, countries who have been investing into eHealth for decades have considered Patient Portals and seem to have already decided what to include in their portals and what to leave out.

##### *2.2.2.4.1 Canada*

Canadian patient portals are an example of healthcare systems making a serious attempt at catching up with other industries, like banking etc. Canadians have consistently adopted Patient Portals regardless of the regional differences across the country (Gheorghiu & Hagens, 2017). Canada Health Infoway clearly states their acceptance of the correlation between the use of patient portals and patient empowerment, patient-centric healthcare and engagement. They provide substantial documentation to link the above with positive patient outcomes (Infoway, 2018).

Despite the success of the Canadian health portal, no references to disclosing audit trails to patients have been found. It seems that in Canada the argument is settled for internal control of privacy when it comes to access management.

Audit Trails in the Canadian EHR have been designed to accommodate the logging of transactions that can track what personal Health information was accessed and when, as well as what user has accessed each patient's health information and when.

A total of 86 security requirements were specified in the Privacy and Security Considerations (Canada Health Infoway Inc, 2018), with countless other considerations encompassing Business Continuity, Information Security Incident Management, user's Access Control, Etc. However, no mention is made of patients controlling access to their personal data. This is no surprise since in 2014 Canada's Health Informatics Association (COACH, 2014) explicitly states that "Patients do not have the right to direct access to the audit log itself". Given this, it is logical to conclude that Canada

seems to have adopted an approach to patient engagement that also excludes Access Notification in their agenda.

#### 2.2.2.4.2 Australia

In contrast with the Canadian example, a more audacious approach to patient portals has been taken by the Australian healthcare system. Australia's patient portal is called My Health Record. In April 2018 it was reported that 5.5 million patients could use it to view their records, decide what is uploaded to it, and who can access this information. Complete Access Control can be achieved through the creation of a Record Access Code that patients can share with different providers, therefore preventing others from accessing it (except for emergencies). Patients can also limit access to their information by flagging pieces of information as "Limited Access". Another means to ensure privacy is through the notification of access events. Any access event that patients might consider inappropriate is forwarded to the Australian Privacy Commission for investigation. However, no functionalities seem to have been added to the interface to facilitate this. It seems that the debate on Access Control and Access Notification is settled in this country.

#### 2.2.2.4.3 Denmark

Denmark's National Patient portal is called Sundhed. It pioneered access to health information for patients as early as 2003. The portal's information page reports of a 45% adoption (Sundhed, 2016). The site declares that the portal's purpose is to "Bring together relevant information from all parts of the health service"; "Offer a shared platform of communication"; "Empower patients by offering maximum insight and transparency in the healthcare sector" and "Offer health care providers easy access to clinical information about their patients' medical history". Due to being such an early adopter, it is understandable that among the list of functionalities of the website, no mention is made about patients controlling access to their information or being notified of events regarding their data. The review of the literature indicated no signs of any intention on behalf of the Danish Healthcare System to move towards Access Control or Access Notification.

#### 2.2.2.4.4 Ireland

Undoubtedly the most relevant to this dissertation is the status of the Irish Patient Portal. Current efforts are being made in the development of a patient portal that allows patients to access their medical data. EHealth Ireland's National Patient Portal aims at facilitating this with the purpose of fostering patient engagement in their health and provide better patient care and preventive care services.

The programme Access to Information currently overviews, among other programmes, the development of MyHealthPortal (eHealthIreland, 2018). Currently, as a pilot project, the system

focuses on maternity service users, allowing them access to personal medical reports and upcoming appointments. For user identification, the system utilises My GovID, and swiftQueue to manage appointment bookings. In future phases of the project patients will be able to view referrals and corresponding messages, laboratory and radiology results and many other functionalities. Among these, the portal will allow patients to view an audit trail of what data was accessed and what changes were applied to it. It is not clear through the literature precisely what information will appear in the Audit Trail functionality.

### 2.2.3 Ethics and Patient Portals

#### 2.2.3.1 Bioethics

Four principles of ethics were first laid out in 1979 by Beauchamp and Childress (2012) in what is considered the basis of the field of Bioethics. In their book, the authors distinguish the principles of respect for autonomy, nonmaleficence, beneficence and justice.

The idea of not causing harm has been around since the very foundation of medicine in the Hippocratic Oath. It indicates that healthcare professionals should act in a way that does not cause harm to their patients. Perhaps exploring this principle in more detail, the literature specifies the importance of professionals making decisions according to their best judgement. This implies a level of risk assessment based on the knowledge available at the time of making the decision.

A direct step from the principle of nonmaleficence is that of beneficence. Physicians are expected to maximise the benefits to the patients as a result of their actions. This principle, of course, is not exempt from ambiguous interpretations and conflicts with other principles.

Beauchamp and Childress propose the respect for autonomy as direct opposition to the sometimes paternalistic interest in beneficence. According to the authors, persons should be treated as autonomous actors, and those whose autonomy is diminished have the right to be protected. As a result of this, arguments for effective tools of patient education have been made.

When contemplating the distribution of benefits and burden of research, healthcare professionals are expected to apply the principle of justice. Again, there may be different takes on this principle, mostly based on the values of a society in a determined location, at a determined time. For instance, some can understand this justice as giving each person an equal share of both burden and benefits. Some can understand justice as distributing the above according to the individual needs and capabilities. Others can interpret this principle based on the person's individual effort while others can decide it according to merit.



Further work by the authors added the principle of health maximisation, referring to an obligation towards enhancing public health, and the principle of efficiency. This latter principle demands cost-benefit analyses on behalf of professionals when deciding public health policies in a resource-limited healthcare system.

#### *2.2.3.2 Applying ethics in Portal designs*

There is a generous number of articles and studies that deal with ethical issues regarding patient portals. Most of them centre around the conflict of respecting patients autonomy by disclosing medical information as it becomes available; and nonmaleficence, as concerns about causing patients distress or confusion when receiving information beyond their understanding.

In agreement with the previous difficulties in designing the specifics of patient portals (Otte-Trojel, 2015), in an article published in AMA Journal of Ethics (Davis & Smith, 2016) it is stated that there are no guidelines on determining delay periods when disclosing information. The article provides the example of doctors not having time to prepare to deal with the emotional distress caused by an adverse report. Notably, for example in the case of pathology studies results that require further testing before taking action, based on Bayesian reasoning.

Bayes theorem describes the probability of an event, given what is known about the conditions related to that event. For instance, a patient could see in the lab results in their Patient Portal that they tested positive for a rare and devastating disease. The patient carries out a search on the internet about the test in their results and finds out that the test has a sensitivity of 99%. It would be entirely understandable for the patient to be agitated, but a doctor could have explained that at that point in time there would be no reason to be too upset. If the frequency of a disease in the population is 1 in 1000, that is the probability of the patient prior to having the test was 0.001%, the doctor can explain that the actual probability of having the disease is only 9% and that they need to carry out another independent test before making any decision. It is in these unintuitive circumstances that the immediate reassurance of a doctor who's had time to prepare for liaising with the patient becomes essential.

These ethical concerns can be mitigated through the implementation of a well-designed user-centred patient portal. Patient preferences regarding the time and method of delivery of information vary from patient to patient and understanding it may be the key to success. Agility in design also seems to be crucial since, each patient as their treatment develops can change their mind regarding their preferences (Choudhry, et al., 2015). It is evident that a design that allows patients to adjust these type preferences is necessary.

Another critical topic in the ethical design of patient portals lies in the protection of privacy and confidentiality. An article in 2015 (Ozair, et al., 2015) provides an overview that is consistent with most of the literature (Vodicka, et al., 2013), (Cyber Dialogue & Institute for the Future, 2000), (Acquisti, et al., 2017) that mentions patient concerns about EHR's. The main ethical challenges are in Privacy and Confidentiality; the risk of security breaches; data inaccuracies and the need for adequate audit trails that allow effective controls in cybersecurity. The article does not mention the possibility of turning users into agents of these controls. By being notified of events in their data and being able to flag what seems inappropriate, it seems reasonable to believe that security can be enhanced while being assured of their privacy.

#### *2.2.3.3 Privacy and Confidentiality in Healthcare*

The central principle of privacy states that individuals have the right to deny disclosure of their information. Healthcare providers who hold patient records are therefore considered data controllers and are bound by the 1988 and 2003 Data Protection acts and since May 2018 the General Data Protection Regulation (GDPR).

To the Irish Healthcare Industry, Personal Health Information (PHI) includes all the documentation produced in the provision of healthcare services that can be identified to an individual (HIQA, 2012). Healthcare Providers have the obligation, not only to guarantee confidentiality but also ensure data quality and availability.

Confidentiality in Healthcare is consistently acknowledged as a cornerstone of the practice of Medicine. The Guide to Professional Conduct and Ethics for Registered Medical Practitioners is one of the documents that provide an ethical and legal framework in Ireland (Medical Council, 2009).

The NHO Code of Practice for Healthcare Records Management (HSE, 2007) gives a more thorough detail of the responsibilities of providers regarding Confidentiality. This guideline acknowledges that in some areas patients can be provided with their records, using midwifery as an example, yet it clarifies that except in some occasions, “a healthcare record must not be given to a patient”.

Patients, according to this document need to request their records “by way of a written request under the Administrative Access Policy, the Freedom of Information Acts 1997 and 2003 and the Data Protection Acts 1988 and 2003.” No further reasoning for this decision is provided in this document.

#### *2.2.3.4 GDPR and Patient Portals*

Up until 2018 Ireland's legislation regarding Data Protection and Data Privacy was determined by the Data Protection Act (1988-2003) and the rights of data subjects to access that information was

covered by the Freedom of Information Act (1997-2003). Although relatively appropriate at their time, the accelerated pace of change in technology quickly proved that this legislation would fall short of addressing Irish citizens' and organisations' concerns. In May 2018 the General Data Protection Regulation, a regulation in European Union Law, provided up-to-date parameters in the regulation of citizens' rights and a simplification in the regulations for international business.

The most relevant parts of chapter 3, which deals with rights of the data subject, can be found in section 2 and 3: "Information access to personal data" and "Rectification and erasure". Article 15 deals specifically with the right of access by the data subject. This article grants data subjects the right to "obtain from the controller confirmation as to whether or not personal data concerning him or her are being processed". Furthermore, it states that data subjects have the right to "access to the personal data", and also the "right to lodge a complaint with a supervisory authority". At first glance, there doesn't seem to be a significant difference with the previous legislation. However, the article further states that "the controller shall provide a copy of the personal data undergoing processing. For any further copies requested by the data subject, the controller may charge a reasonable fee based on administrative costs." This provision, together with section 4 of Recital 63 (Intersoft Consulting, 2018), which states "Where possible, the controller should be able to provide remote access to a secure system which would provide the data subject with direct access to his or her personal data, make it extremely difficult to make a case against the deployment of a Patient Portal.

#### *2.2.3.5 Potential design grey areas*

Developments in user interface designs in the last few years have brought a new level of interpretation to Google's motto "don't be evil" (Google Inc., 2017).

Increasingly often users encounter interfaces that appear at first sight as examples of "bad design" with confusing links and misleading buttons. A distinction between "bad design" and "evil design" has been pointed out by Harry Brignull in his website (Brignull, 2016). In his publication, Brignull distinguished twelve different types of "Dark Patterns". These are specially designed to deceive the user into doing what the company wants or simply creating frictions to veer users' decisions into what the website wants. Examples of these techniques are called "Bait and Switch", "Confirmshaming", "Roach motel" and more relevant to this dissertation "Privacy Zuckering" where the privacy default of a website is set to share more than the majority of users would choose.

At first glance, it seems unthinkable that healthcare providers would use any Dark Patterns when designing patient UI's. However, it does not take much to imagine that insurance companies, for example, could be tempted into using these tricks. A web article by JB Rubnovitz (2018) exposes the use of deceptive patterns and algorithms that prevent users from making claims in certain cases.

Whether these practices are legal or not, they could sometimes have a devastating impact on patients. Unfortunately, terms like "Blackhat design" can never be applied to a practical example since, in every case, a shade of "grey" will always be more accurate.

Insurance companies are not the only entities that have been said to practice dark pattern strategies to achieve certain user behaviours. In the United States, reports have been made of scandalous deceiving examples of tricks to undermine adherence to the Affordable Care Act. The article by Sam Stein about the changes to the ACA website reveals the removal of links that lead to "Facts and Figures", a page that provides evidence of the benefits of the program. The article also mentions the changes made to a page titled "Empowering Patients". This page presents two links, one of which leads to a set of articles which are openly hostile to the program itself (Stein, 2017).

As in many cases with ethical considerations, there may be some cases where the use of Dark Patterns might be debatable. If it is in the best interest of the patient not to access specific information, but the withholding of it cannot be justified as being dangerous to the patient, one could debate whether to utilise dark pattern techniques. For example, if a patient is prescribed a placebo, it would probably be best if the patient is unaware. Providing a false description of the placebo probably would not be ethical, so subtle frictions to dissuade the patient to further learn about the medication could be ethically justified.

## 2.2.4 Access Control

### 2.2.4.1 Overview

In the context of Patient Portals and the decisions made about data governance, this dissertation uses the term "Access Control" as privileges given to the data subject to decide who can create, view and edit information in their Electronic Health Record. In the literature, this concept can also be found as "Granular Control", as in the case of the Regenstrief studies (Caine & Hanania, 2013), or included in a broader concept, "Personal Health Information Data Management" (Civan, et al., 2006).

In Healthcare, the level of patient-centredness is an aspect to consider when assessing an institution's quality of care. Taking into account each patient's needs is nowadays considered essential when designing systems of care. In April 2014 results from a stakeholder consultation for the European Commission revealed proposed giving patients both Access Control and Access Notification (Deloitte Centre, 2015).

The Irish Health system is no exception in accepting patient centeredness as a measure of excellence, also putting the service user at the centre of its focus (HIQA, 2017). As one of its steps to

ensure patient-centred care, and also as one of the means to comply with the GDPR provisions of users' rights, the HSE has taken its first steps in developing a nationwide Patient Portal. Access Control, as defined in this section, does not seem to be on the agenda in the introduction of this technology. Instead, there seem to be plans to allow patients the possibility of Access Notification (eHealthIreland Office of the CIO, 2017).

Even though the newly introduced GDPR legislation allows and in some ways it can be argued that it suggests it, the healthcare system in Ireland seems to have taken a stand on the argument on Access Control and will not likely introduce such provisions in its portal project.

#### *2.2.4.2 Ethical Considerations with Access Control*

The main argument between those who support Access Control in a Patient Portal and those who do not are based mostly on the ethical principles of "Respect for autonomy", "Beneficence" and "Nonmaleficence".

Some argue that in a healthcare system that takes Patient Centeredness seriously, the move away from a paternalistic approach to the patient-provider interaction outweighs the possible risks of causing harm or missing opportunities of care. A Patient Portal that respects patients' autonomy should allow them to decide who views their data while providing them with information of the risks associated with the restriction of specific information to their providers. From this point of view, there is no reason to deny a patient Access Control, as long as provisions are made to enable them to make those decisions in an informed way. These arguments in favour of AC also state that a patient who feels in control of what happens with their data is much more likely to fully disclose information in the confidence of the examination room (Caine & Tierney, 2015).

On the other hand, opposite views to this debate argue that apart from the obvious risks to harm that can originate when patients withhold information from their care providers, the fear of litigation can also have harmful consequences to the trust between patient and provider. The adverse effects can be accentuated particularly when, due to jurisprudence developments, providers are found not liable in a medicolegal court. Tierney (2015) predicts that this situation can lead to "sloppy, unsafe care".

#### *2.2.5 Access Notification*

##### *2.2.5.1 Audit Trails*

It is generally understood that Audit Trails (AT) are a series of documents (Paper or electronic) that allows an auditor or examiner to trace data from a user to a source document (Dictionary, 2018).

Firms, particularly in the financial sector, have been using Audit Trails to put in practice unbiased internal controls for decades.

From the point of view of information and communications technology, Audit Trails consist in a chronological log of system activities performed by any user and system and application processes. Technically it does not contain personal information. Instead, it stores metadata that points to specific events, documents and users.

Audit Trails help an organisation mitigate security and confidentiality risks, ensuring that the disclosure of information is consistent with the purpose of the collection of such information. Integrity and availability are also risks that are mitigated by the existence of an Audit Trail. In many cases, certain types of information are required to be stored reliably for undetermined periods of time.

#### *2.2.5.2 Audit Trails in Healthcare*

In her book, *Fundamentals of Law for Health Informatics and Information Management*, Brodnik (2009) defines AT as a "record that shows who has accessed a computer system, when it was accessed and what operations were performed". Having a tool to keep track of the above details is crucial when implementing good access management practices.

In Ireland, the National General Practice Information Technology Group, also known as GPIT, provides accreditation to practice software systems ensuring that practice management systems support the needs of Irish General Practice. It also coordinates the development of these systems with the HSE information systems and creates a pathway for further developments in Healthcare Information Systems. In its 2007 requirements for certification, the group provides a list of 29 conformance criteria for audit trails to achieve compliance.

Although the original purpose of Audit Trails is compliance and security controls, healthcare organisations have used them in various functions that require a level of information controls. Perhaps one can identify three main areas to which Audit Trails can bring solutions.

First and foremost they serve as an electronic security measure. Through Audit Trails, digital security personnel can detect anomalies, intrusions, unauthorised attempts at access and other weakness identification tasks. Digital forensics is a well-established field in computer science although some may argue that its decline is now underway (Garfinkel, 2010).

As a secondary function it is acknowledged that Audit Trails can assist in operational contingency measurements, such as disaster mitigation; bug detection; or as a means to maintain the integrity of records when performing tasks of data migration, record imports and system updates.

Further uses for Audit Trails depend in large on the architecture and design of the records itself. A CIO could make the executive decision to keep the components of the log to a minimum to minimise system and storage requirements, while others might consider that the uses for their AT are worth the extra investment in IT resources. Decisions when setting up even the most basic elements of an AT need to be considered carefully. Fields like User ID, Event Date/Hour, Patient ID and Information Accessed are perhaps considered essential. Simple fields like Event Date/Hour, for instance, can be stored in many different formats. Based on the original design of the system, timestamps can be logged including minutes, seconds, and milliseconds. A seemingly trivial decision can determine whether the AT will be used to track application processes or only human interactions.

The above limiting factors can be aggravated by examples of organisational cultures that don't appreciate the potential of this technology. In an analysis of hospital Audit Trails (Correia, et al., 2013), interviews revealed a poor engagement with the technology on behalf of five different CIO's. The report also highlights examples of IT departments merely disabling the functionality due to system performance and storage limitations. In other cases, the logs are just not accessible to those who could benefit from it.

Despite all the difficulties the Healthcare Industry seems to have a grasp of the potential of Audit Trails in more than security tasks. Cutting edge software advances made Process Mining (Lang, et al., 2008) or in managing information in clinical trials (Chen, et al., 2009) possible.

#### *2.2.5.3 Audit Trails and Business Intelligence*

Of all the alternative uses for Audit Trails, perhaps the most straight-forward is by applying off the shelf analytic tools to the data. In the last few years, Business Intelligence tools have been increasingly used in healthcare organisations. The potential of BI solutions must not be underestimated due to their ability to adapt to organisational changes quickly. An interesting example of this technology dates as far back as 2001 when a patent was granted for an online analytic tool that uses Audit Trails to create adaptive evolutionary process modelling for businesses. This technology overcomes obstacles like data incompleteness, gaps or low quality by approaching the process modelling from an "A posteriori" evolutionary approach. The product claims to be able to achieve high quality of models, even in a rapidly changing environment (Agrawal, et al., 2001).

#### *2.2.5.4 Audit Trails in Patient Portals*

Portal Design Architects who decide not to provide Access Control to patients face significant challenges to gain the trust of patients. The lack of previous experiences and guidelines when designing patient portals can leave developers in absolute uncertainty. Also determining what

patients want versus what they need and what they can understand, could turn challenges into tribulations.

Allowing patients to see who interacted with their EHR, whether it is creating, viewing, editing or deleting (Access Notification), is often considered as one element of granting Access Control. However on its own, regarding its potential to cause harm, Access Notification may present a much more acceptable alternative.

Much of the literature supports the inclusion of Access Notification in Patient Portals. In an article in 2006 (Civan, et al., 2006) researchers used a Participatory Design method to create a Personal Health Information Management tool. The article concluded that individuals have a desire to control their information. Participants designed systems that allowed them to control what information goes in their record and who has access to the information in it. Their vision was that of a system that notified them when events occurred with their data and that allows them to append entries to the records.

More recently a publication by consultancy agency Deloitte (Deloitte Centre, 2015) identifies barriers to the deployment of mobile health technology. It points out that the results from a consultation by the European Commission proposes to "give patients control over their personal data, specifically the kind of information he/she wants to share, while maintaining the right not to share, as well as enabling the patient to see who is using data and for what purposes".

The desires of the patients in this matter are consistently in favour of Access Notification. When interviewed in a study by Caine, et al. (2015), 80% of the patients stated that they wanted to be notified of accesses to their EHR. Unfortunately, when Tierney, et al. (2015) consulted with providers no specific mention was made of Access Notification.

#### *2.2.5.5 Ethical considerations*

Healthcare providers' rights to privacy need to be taken into consideration. Almost universally (Canada's Health Informatics Association, 2014), (Data Commissioner, 2018), when setting up an audit trail, it is a requirement that employees are notified and reminded of the existence of such logging of their activities. However, in all the reviewed cases the audit trail was not intended to be disclosed to the public.

Considerations also need to be made to the possibility of generating extra workload on providers due to excess of queries on behalf of patients. The principles of efficiency and respect for autonomy can enter into conflict. Any inefficiency generated as a result of Access Notification will be a strong argument against the benefits of empowerment, trust, etc.



### 2.2.6 Patients' desires

To create a demonstration app that gives providers the possibility to interact with the Access Notification system it is necessary to establish the parameters on which it would operate. The hypothetical app would be considered as part of the patient portal, and it would be designed to reflect the desires of the patients.

#### 2.2.6.1 Secondary research

Upon previous research on the desires of patients when designing a patient portal, it became evident that patients want Access Control; the possibility to share their information with other patients; and the possibility to interact with their providers by asking questions and carrying out administrative tasks. The review of the literature also revealed that patients want their privacy concerns addressed. These concerns include distrust of websites regarding the handling of data breaches and fears of their data being accessed by parties not involved in their direct care (Cyber Dialogue & Institute for the Future, 2000).

A research article published in the Journal of American Medical Informatics Association (Caine & Hanania, 2013) established that patients want “granular control” of their data. The research revealed that from a total of 30 interviews, no patient wanted to share all their information indiscriminately to all potential recipients. The research also revealed that patients want the sensitive information in their records, but they want to be able to control it. This coincides with previous research that indicated the same and goes further emphasising the need of addressing users' need to be reassured on the topics of security (Civan, et al., 2006).

At this stage of the secondary research, a discrepancy between patients' attitudes and behaviour became apparent.

According to Vodicka, et al. (2013) in a study patients showed signs of distrusting many of the websites used to access their doctor's notes and were not aware of the level of privacy protection they were entitled. Likewise, an early survey on the topic (Cyber Dialogue & Institute for the Future, 2000) reported that patients were unaware of their privacy rights and the means to ensure it. In addition to these concerns, the study by Cyber Dialogue found that 70% were worried about insurance companies using this data against them, and 80% reported being concerned about employers using this data.

Despite these concerns about long-term, life-affecting misuses of their medical records, Vodicka's article highlights that patients overwhelmingly used the portals regardless. This dichotomy is further

explored by Acquisti, et al. (2017) exposing three main reasons for its origin: Uncertainty, Context-dependency and malleability.

The authors refer to uncertainty as to the lack of knowledge of the extent of data that is collected. Users do not know how much data is collected and are unaware of the policies companies have regarding the handling of their data.

By context-dependence, the article explains that, depending on the context in which the privacy choice is presented, individuals' attitudes range from highly private to completely unconcerned.

As malleability, the article refers to the disparity of privacy protection expertise between users and companies who depend on data disclosure. This becomes evident when users significantly end up disclosing more than they initially intend (Norberg, et al., 2007). It usually results in design features that deliberately confuse users into disclosing personal information, mentioned in the section "Potential design grey areas" above.

#### 2.2.7 Conclusion

The introduction of patient portals into Electronic Health Records is necessary and imminent in Ireland. Patients want control of their data since they are concerned about their privacy and confidentiality. Also, patients want to be protected, but they are not likely to go to extreme lengths to do so.

It is possible to create a system that grants granular control of patients' medical information, and it would be an effective way to reassure patients of their confidentiality. However, there are very genuine concerns about the safety of such a system on behalf of doctors.

Including Audit Trails in Patient Portals can be justified ethically and it has been proven that Audit Trails can be used in other areas with the purpose of optimising processes. Some countries have included the concept of Access Notification in their portals, but there are also reasonable cases where this has been left out.

## 3 Research Methodology

### 3.1 Introduction

Two research studies were carried out in this dissertation. The first study compared the desires of a group of patients with a study carried out in the US (Caine & Hanania, 2013) and other literature. With the information gathered a prototype of an app which informs patients of any events regarding their data was created. Based on the recurring interests of the participants of the first study, three patient personas were created to aid in the design of the second study. The second study recorded the impressions on behalf of Healthcare professionals after viewing a demonstration of the proposed app. The Trinity College Research Ethics Committee approved both studies on the 5<sup>th</sup> of April 2018. Each stage of this dissertation has the purpose of informing or influencing another stage as represented in Figure 4.

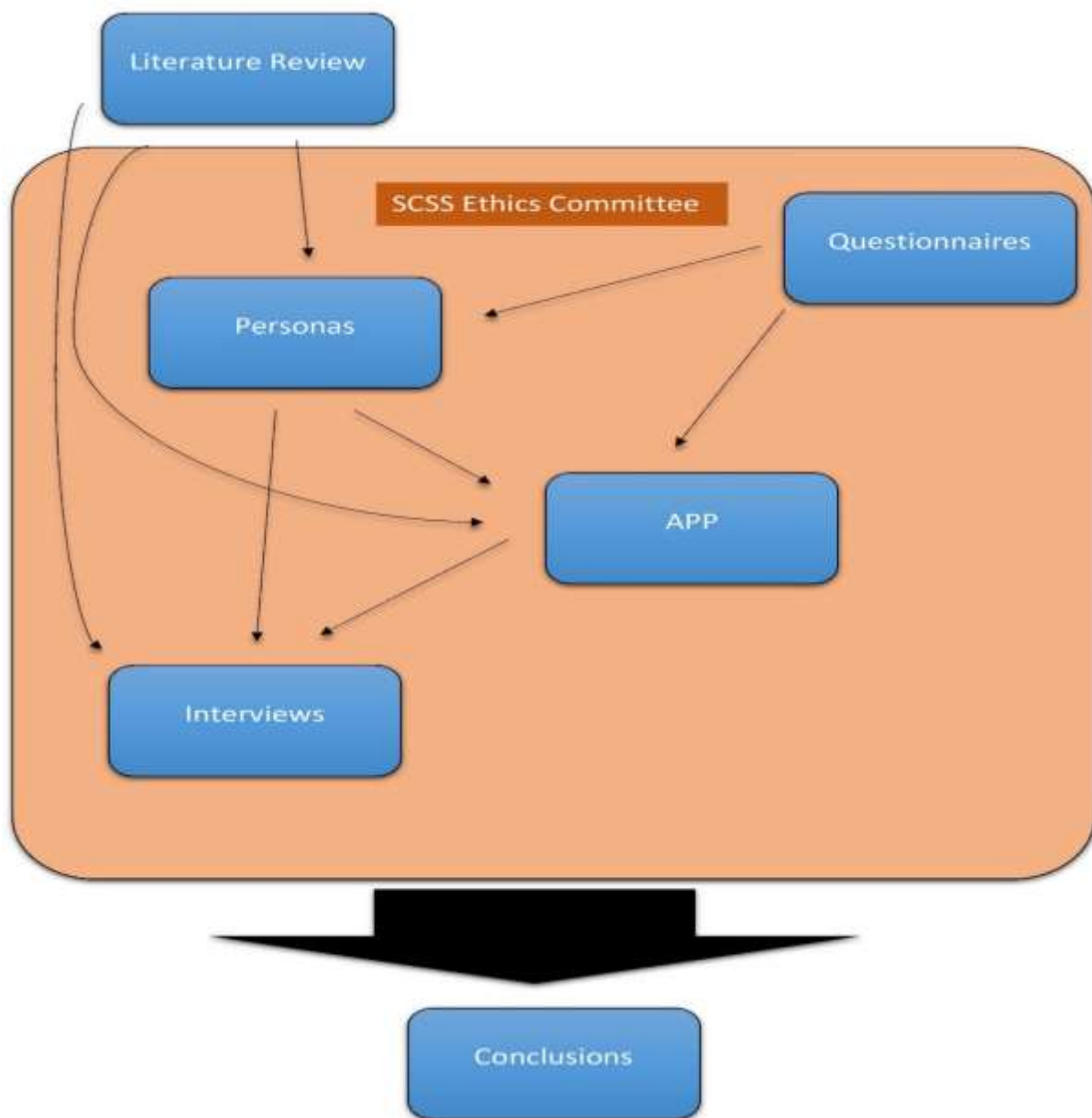


Figure 4 a representation of the logic behind the methodology

### 3.2 Meeting with patients

The researcher met with members of a chronic patient support group. The meeting took place at their regular meeting venue. A presentation of the topic was carried out touching the concept of medical records, sensitive information, the Irish EHR project, and data governance over medical records. The presentation also included the topics of Access Control, its controversial nature and Access Notification as a possible way to circumnavigate the conflict.

### 3.2.1 Presentation

The presentation consisted of fourteen slides. The time allocated for the first six slides averaged thirty seconds each. Slides seven and eight would require a full minute of speaking each. A further 2 minutes was allocated for slides 9, 10 and 11. It was estimated that the explanation of slide 12 would require 2 minutes. Finally, the last two slides would not require more than a minute each. Humour was included in some of the slides to create an atmosphere of casual relaxation.

The topics covered in each of the slides are specified in Table 3

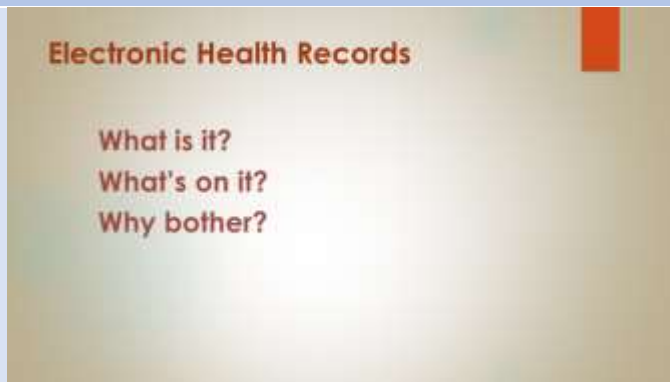
<p>Introduction of the researcher</p>	
<p>A brief recap of what a medical record is and the types of entities that can hold such records. It is expected that participants have a comfortable level of familiarity with this topic, however, some misconceptions might be clarified.</p>	
<p>A brief description of the categories of information that are widely accepted as sensitive. At this slide the researcher will clarify that this does not constitute the only information that patients might consider sensitive and highlight the</p>	

subjective nature of the topic. (Carr, 2010)

A brief recognition of the advantages of paper versus electronic. At this point the researcher would entice participants to add their thoughts on paper records, since it is expected that they must have felt frustration at some time in their treatment.



A brief explanation of the concept of EHR, the information contained in it and the reasons to invest in the technology as a nation.



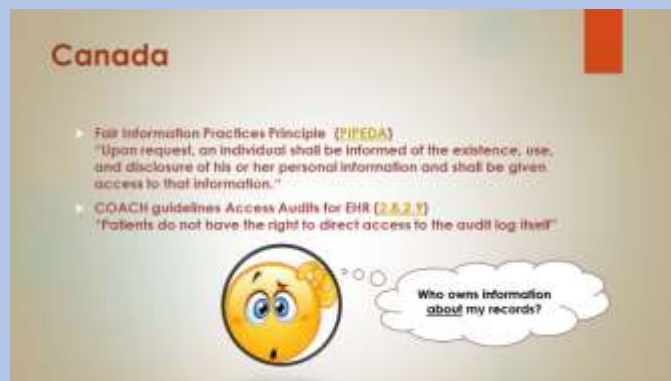
Before this slide is presented the researcher would ask the participants' understanding of data governance in this context. It will be made clear that whether it is in the form of paper or electronic, the hospital owns the records, but the patient owns the information in it.



An explanation of the main points to be taken into account from the Freedom of Information Act (1997/2003), the Data Protection Act (1988/2003) and the principle of “Need to know” specified by the Data Protection Commissioner.



A presentation of the possible contradiction found in the literature. The researcher will take time to introduce the question about the rights of data subjects on the metadata referring to their information. (PIPEDA, 2016) (COACH, 2014)



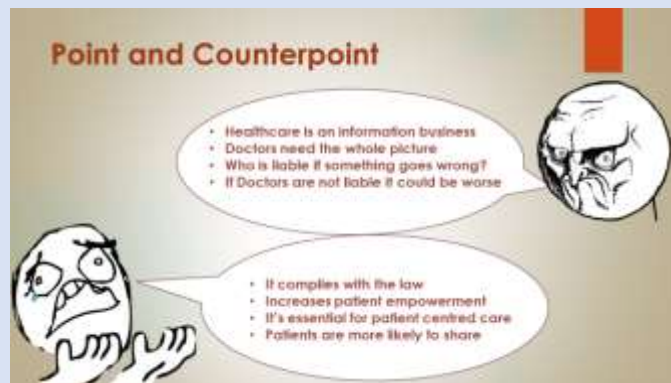
A brief presentation of the interface developed by the previously mentioned interface. (Caine, et al., 2015)



A further example of the interface developed by the Regenstrief studies. (Caine, et al., 2015)



A detailed explanation of the main points brought up by the authors of the article “Point and Counterpoint” by Caine and Tierney (2015). The emphasis would be placed in the fact that no resolution seems to have been found to the discussion.



- Healthcare is an information business
  - Doctors need the whole picture
  - Who is liable if something goes wrong?
  - If Doctors are not liable it could be worse
- It complies with the law
  - Increases patient empowerment
  - It's essential for patient centred care
  - Patients are more likely to share

An image of the proposed Access Notification part of the interface. The researcher would make the point that even though the studies gathered the providers' impressions on the idea of Access Control, no question was asked about their views on Access Notification. (Tierney, et al., 2015)





A brief synthesis of the research proposal and the reason for the questionnaire.

How would Healthcare providers feel about patients being able to access audit log events from their patient portal?

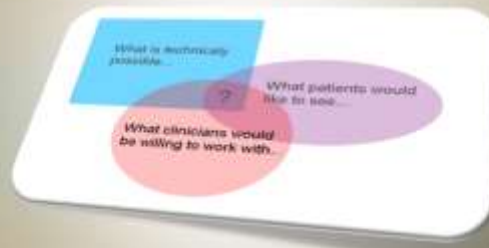


Table 3 Synthesis of the presentation

### 3.3 Questionnaire

After the discussion session, a questionnaire was handed out. The questionnaire was divided into four parts:

#### 3.3.1 Part 1

This section attempts to find out about the patients' stance regarding the "Need to know" principle and the different attitudes towards privacy between Doctors, Consultants, Nurses and non-clinical staff.

- Do you think your Health Records should only be accessed on a "Need to Know" basis?
- Do you trust that your Health Records are only accessed on a "Need to Know" basis?
- If you see a different doctor other than your usual, would you like for them to be able to access your Medical Records wherever it may be?
- If a consultant needs it, should they be able to access any part of your Health Records?
- If a nurse needs it, should they be able to access any part of your Health Records?
- If the administrative staff need it, should they be able to access any part of your Health Records?

#### 3.3.2 Part 2

This section attempts to find out about the patients' stance on Access Control and their perceived capability to manage their privacy.

- Do you think you should be able to decide exactly who accesses your Health Records?
- Do you consider yourself capable to decide what information Healthcare Professionals should have access to?

### 3.3.3 Part 3

This section was designed to aid the design of the demo app to be shown to Healthcare Professionals in the Second Study. Four questions were asked to determine how important it is to include certain elements of the app.

- Is it important that you know the name of whoever has accessed your health records?
- Is it important that you know exactly what information was made visible to anyone?
- Is it important that you know exactly the date and time when anyone accesses your records?
- Is it important that you are able to report inappropriate activity directly from your Patient Portal?

### 3.3.4 Part 4

This section was designed to allow the patients to add their comments on what information and functionalities they would like to add that was not specified in the questionnaire and the discussion.

- Is there any other information that you would like to see in your future Patient Portal regarding your privacy?
- Are there any other things you would like to be able to do with your future Patient Portal regarding your privacy?
- Comments:

## 3.4 Personas

A total of 14 topics were identified during the discussions with the patients and the first two sections of the questionnaire. The below patient personas do not reflect on any particular case, but they are an amalgamation of the personality characteristics, capabilities and personal concerns regarding the topic.

### 3.4.1 Jane:

Jane is retired due to disability. Her former employer was an IT company in South Dublin. Coming from an IT background, she is familiar with the threat of data breaches and firmly believes that these are underreported and kept quiet. She strongly believes that administrative staff in her GP surgery should be restricted from access since she does not believe that medical records are only accessed on a "Need to know" basis. She also feels it would be unfair if her data were used for research purposes by large pharmacological corporations, resulting in the development of a treatment that is

unaffordable. In her opinion, governments are not capable to effectively regulate IT companies without slowing them down.

Due to her Fibromyalgia, she has feared in the past that her condition was misunderstood and misdiagnosed. She would like to have some control over clinical notes that she disagrees with in her EHR.

#### 3.4.2 Tom:

Tom works as a clerk in a bank. Although he understands that in large, organisations can be trusted with his privacy, he has occasionally seen colleagues accessing bank records for purposes that aren't strictly professional. He is more inclined to believe that doctors are not likely to breach his privacy but is not sure that nurses should have the same access entitlements as doctors. He has found himself in the past in conflict with one of the doctors in his local GP surgery and would like to make sure that this particular doctor does not add notes to his record.

In the day to day, he manages to keep his chronic condition from interfering with his work but is concerned that an EHR could be shared with his employer causing him to lose progression opportunities in the bank.

#### 3.4.3 Sandra:

Sandra teaches Math class in a secondary school in a small town. She does not know precisely what the risks are when it comes to IT, but she heard recently in the news about confidentiality breaches in Social Media sites. Her health insurance premiums have recently gone up, and she would dread to think what these companies would do if they could access her medical records, looking for an excuse to raise her premium even further.

In her profession, she feels her privacy can sometimes be challenged. She hates the idea of one of her former classmates who works as a nurse going through her EHR without her knowing it.

Her attitude towards her healthcare is that of an engaged patient. She likes to keep up with her treatments and to be involved in decisions regarding her care. She would like to be able to see the notes her doctor adds to her EHR as well as being able to track referrals etc. without having to call the surgery.

### 3.5 Demonstration app

#### 3.5.1 Overview

To proceed with the description of the process in which this research developed the Demo App, it becomes necessary to point out that the app created does not constitute a working application. For

the purpose of clarity, this dissertation will differentiate between what will be called Reference App and what will be called Demo App. The Reference App is fictional, and the description of its requirements is only theoretical, while the Demo App which is an actual mobile application. The Demo App was developed for demonstration purposes only, to emulate what the Reference App would look like.

### 3.5.2 Reference App:

The Second Study requires the interviewer to demonstrate how a Patient Portal would look like if the concept of Access Notification is applied to it. This would be an app that allows patients to see their Audit Trails. The app that the interviewer would show in the Second Study interviews would emulate what this dissertation calls "The reference app". After analysing the results of the first study, the conversations with its participants and the reviewed in the Literature, the researcher determined some parameters to be emulated. These specifications are described below:

This app would hypothetically be part of, or ancillary to a patient portal for the Irish Healthcare System. The primary objective of the Reference App would be to display audit events related to the patient's data. This would be carried out in a way that is relevant, easy to understand and easy to access.

In order to display relevant information, the menus need to be relevant as well. Ideally, the main options would be created dynamically and programmatically, according to the events available to each patient. For example, if a patient's health record does not contain any information from the obstetrician, then the menu should not display "Obstetrics" in the list of Services. However, if the activity on a patient's data is highly concentrated on GP notes, then "General Practice" should appear at the top of the menu.

To maintain relevance and in order to achieve a user interface that is easy to use, development would endeavour to minimise the number of clicks the user would require to see the events list. Ideally, the user would select one option from the main menu, which would generate a sub-menu. Upon selection, in this sub-menu, the events list should be displayed. Further processing of the results would be carried out employing filters, sorting options etc.

An easy to navigate, clear and intuitive design could be produced to reduce the amount of effort required on behalf of the user. The layout and structure of the Reference App would follow, where possible the structure of the main patient portal. This would also reduce the amount of effort and provide a sense of transparency. In order to avoid confusions, the

Reference App would have a different colour scheme to that of the main portal, while following the same logic of patterns. For example, if the menu of the patient portal is displayed on a darker tone than that of the query results, the Reference App would use the same logic, but applied to a different colour scheme.

### 3.5.3 Demo App

#### 3.5.3.1 Objectives

It could not be expected that Healthcare Professionals take too much time off to participate in the interview, which meant that the interviews should not take more than 15 minutes. The objectives to achieve when designing the Demo App were that the app could be viewed and understood in no more than 4 minutes. As a result, this limited the number of points to highlight, and therefore the number of topics the interview could tackle, but given that Healthcare professionals usually are too busy, the researcher could not ask for a larger slot in their schedule.

The app would need to reflect the characteristics and stories of the personas created while provoking the interviewee to respond not only from a professional point of view but also to provide their impressions. Each example of the data showed in the app was inspired by either the results of the Questionnaire, the literature or the personas created.

The app needed to show very clearly and in a simple way what patients would get from it when using it. It was necessary that the interviewee would see that in the event of an app of this nature goes online, patients would have access to the fundamental fields of an Audit Trail. These are "Date", "File accessed" and "Username". The app would also demonstrate an example of an "easy click" report button, where the user would be able to flag as inappropriate any event with a single click.

Other fields to include were considered. Full timestamp with the time of the event or an expandable "file accessed" link.

Also, it was considered showing examples of events created by software queries. These would be perhaps examples of crawler software gathering anonymous data for public health reporting, for example. These last examples would take too much time to explain in a short interview, so they were left out.

#### 3.5.3.2 Initial Stages

The first option considered for designing the app was to use Xamarin, which is a developing cross-platform software, embedded in MS Visual Studio. However, since the app was simple and unlikely

to change once developed it was decided that the use of this technology would introduce initial complexities that would be difficult to justify.

Since the objectives of the app could be achieved with a simple screen navigation app, the less complicated option resulted to be MIT App Inventor. This online application can be extremely robust when creating apps that require no connectivity and limited code in the background.

Another option considered would have been using HTML and CSS to create the illusion of a web application. Due to the nature of the interviews, the most natural option would have been to produce an offline smartphone that would double as a voice recorder and a random number generator. Although an HTML and CSS web application was the easiest way to create the app, it would have brought unnecessary practical complications at the time to demonstrate the app on an interview.

### 3.5.3.3 Logic mapping

The app would have two levels of menus and two sets of results lists. The app would also have a set of screens emulating an external source of professional profiles for the healthcare staff. It would be made evident that when clicking to view the username in the list of results, the app would navigate to an external source (See Figure 5).

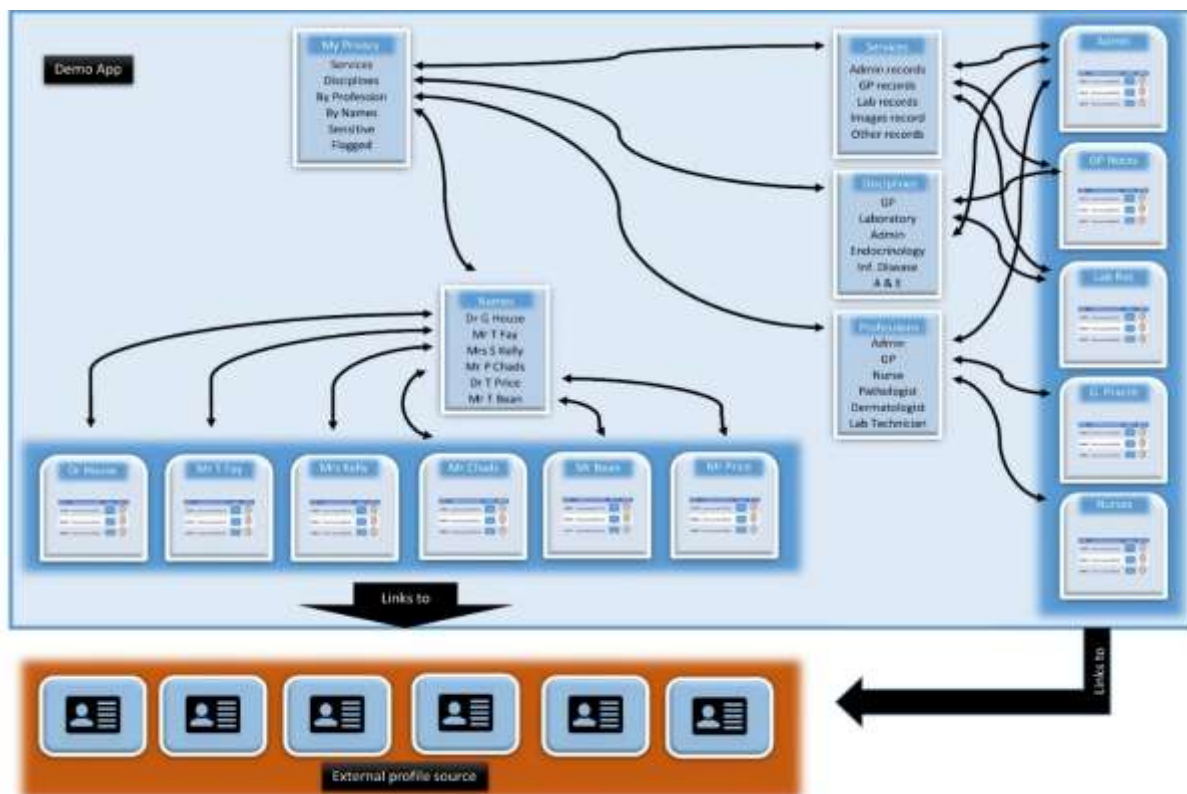
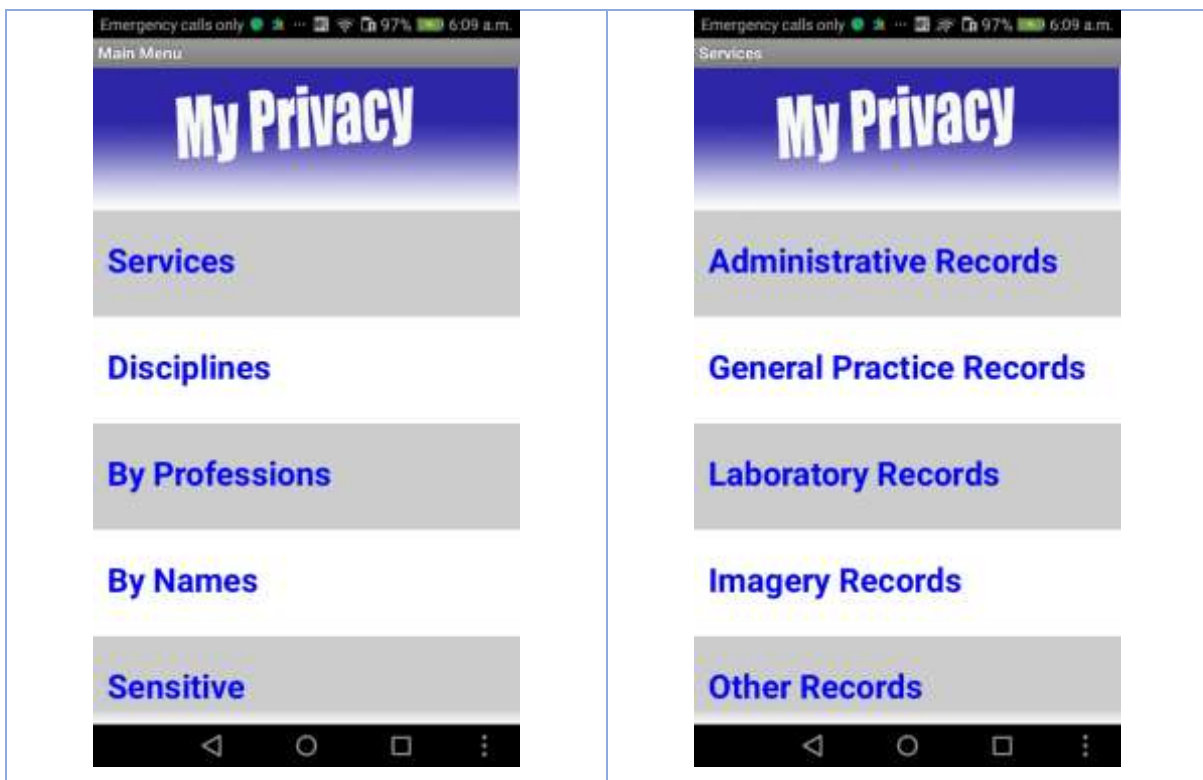


Figure 5 Diagram of the logic path of the Demo App

### 3.5.3.4 Menu screens

The menu screens were designed to emulate a dynamically created menu, to tailor each user's audit trail information as per Table 4. Upon selection of an option in the main menu, a sub-menu would appear. For the Demo App, only the three first options will link to an events list page. There is an exception to this on the sub-menu "By Names", where all the options lead to events list page. The reason for this is that it is expected that interviewees might have more of an interest in seeing how their names could be displayed.



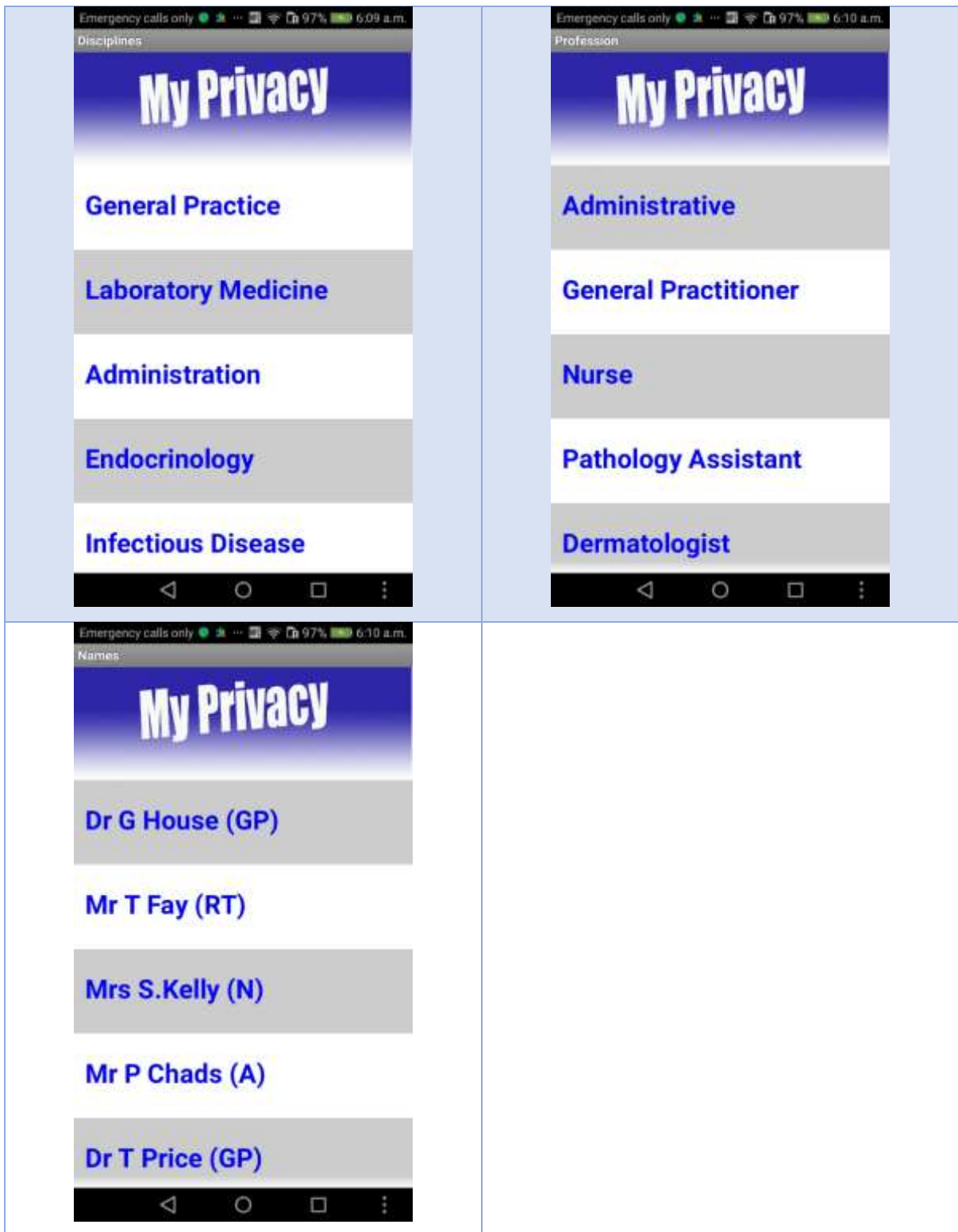


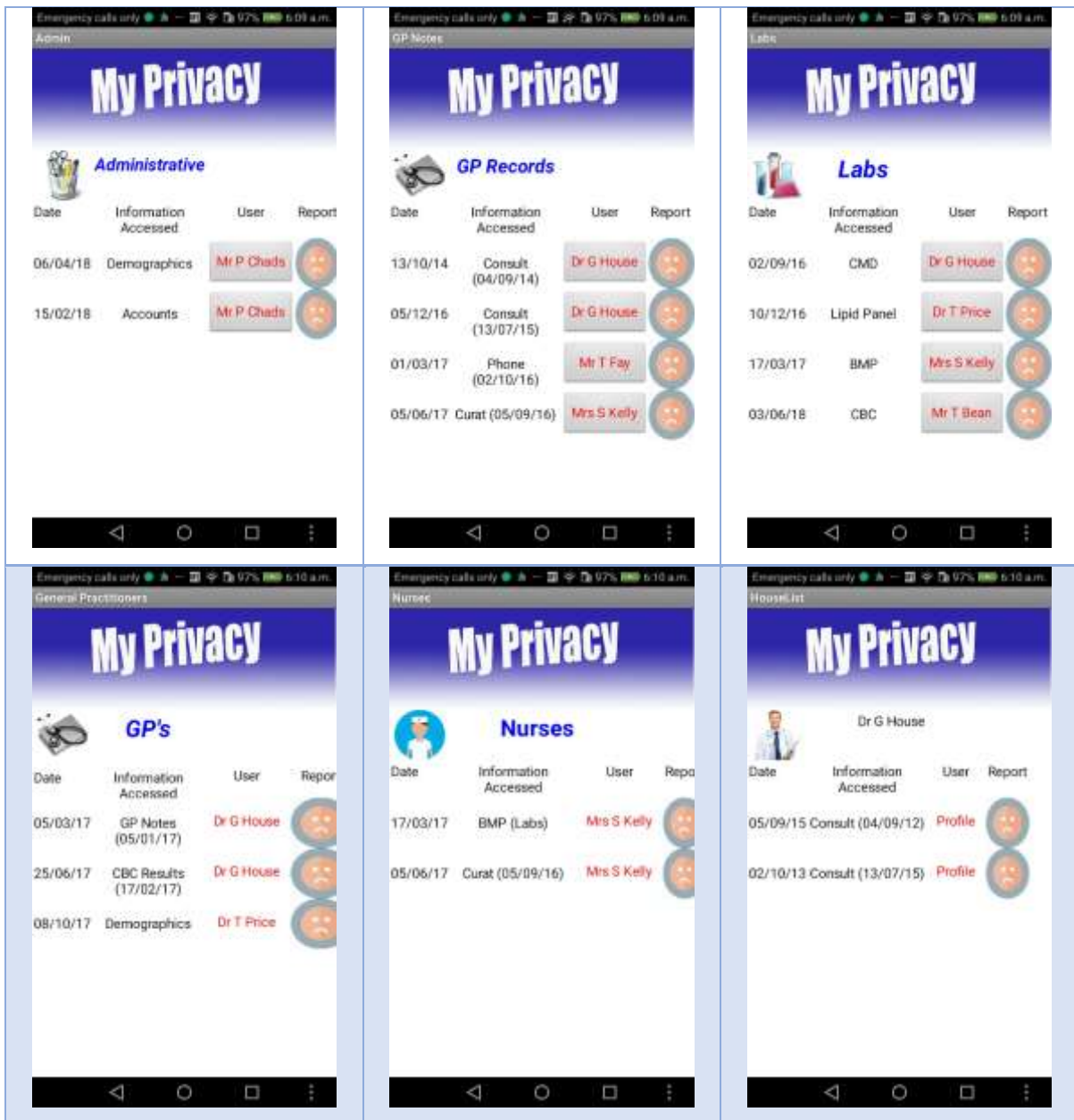
Table 4 Examples of the dynamic menus

### 3.5.3.5 Events list screens

The events list screens were designed to emulate a query based results page (list of events returned by the query) that displays the activity logged in the Audit Trail (See Table 5). The fields to display are Date, File Accessed, User and a "Click to report" button. As mentioned before, all the information is



hard coded. The script behind the user buttons to the profile pages. The script behind the "Click to report" button merely change the button image from a faded warning triangle to a strongly coloured version of it.







		
		

Table 5 Examples of events list pages

### 3.5.3.6 Profile screens

The buttons in the column "User" led to what would be an external source with the providers' professional profile. The design is deliberately different from that of the rest of the app to create the effect of the app navigating to an external site or application. Navigating back into the privacy context was made deliberately unintuitive to emulate the effects of the app opening a web browser.

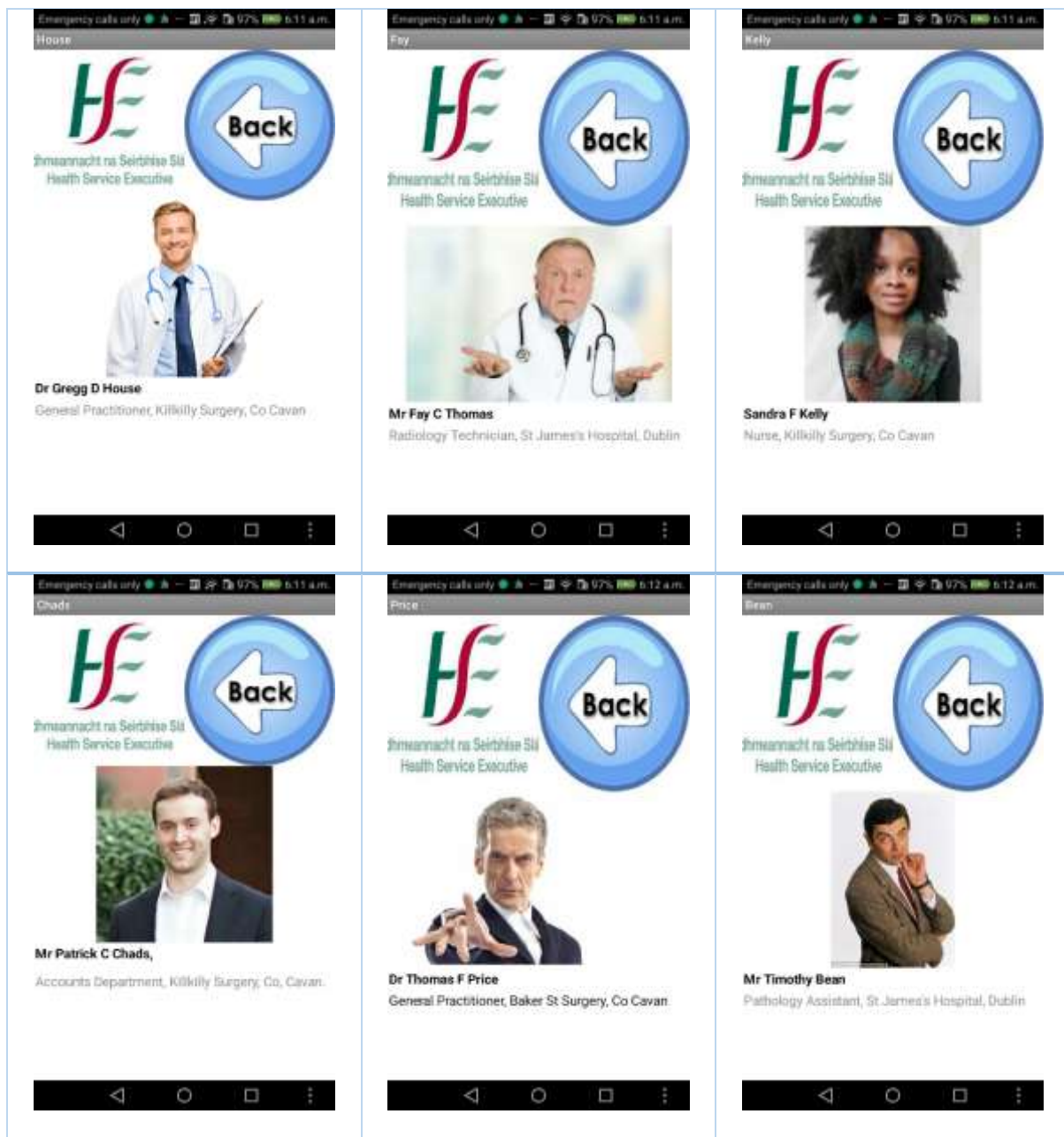


Table 6 Examples of Profile screens

### 3.6 Provider Interviews

#### 3.6.1 Overview

In order to record the impressions of Healthcare providers on the possible introduction of Access Notification, a series of semi-structured interviews were carried out. The interviewer would first explain the nature of the interview and show the Demo App to the participant. From the very beginning, it would be made clear that the app is not a working piece of software. Instead, it would be explained that there are good reasons to believe that an app or interface of this nature would be introduced in future stages of the development of a patient portal pilot in Ireland.

Time would also be allocated to provide an overview of the research process and the reasons for looking to record their opinion. A brief reminder of the assurances of anonymity would also take place before the start of the interview as well as an opportunity to ask questions. These questions would be noted immediately after each interview in the absence of the participant. At the end of the session, the interviewer would use a simple app that generates a random six digit number for reference.

### 3.6.2 Preparation

Preparing for the interview various guides and qualitative research books were consulted. Many online tutorials, videos were taken as initial references, but most of the techniques used in the interviews were based on Creswell (2014) and Mc Namara (2009).

Each question was formulated to keep participants' attention to the topic of Access Notification. It had been noted during the first study that it is very easy for participants to get carried away and find themselves talking about the concept and possible consequences of Patient Portals and the discussions about Access Control.

As a technique to mitigate with eventual deviations from the topic a number of follow up questions had been pre-scripted. In the event of finding interviewees that not necessarily answer the question asked, these follow-up questions would reformulate the enquiries and try to capture the right information.

### 3.6.3 During the interview

During the interview, one question would be asked at the time. Encouragement would be provided through body language, for example with occasional nods of the head. Eye contact would be maintained where possible, and no notes would be taken during the interview.

### 3.6.4 Interview cheat sheet

As an aid to the interviewer, the below memory aid would be kept in view. Figure 6 and Figure 7 would be printed and attached to the interviewer's clipboard during the interviews. Above the questions and possible follow-ups, the following reminders were printed.

- I guarantee the anonymity of participation
  - I only have access to the recording
  - Transcripts will be only available to my supervisor and examiners
- You can stop the interview at any point.
- I will discard all your information if you ask.

- You will get a six digit random number that you can quote if you want to delete your info in the future.
- I will hold on to the recording until the thesis is graded and they are not needed anymore.
- I will keep the recordings and the transcripts in an encrypted USB drive.
- The thesis will be published on the TCD intranet for students only.

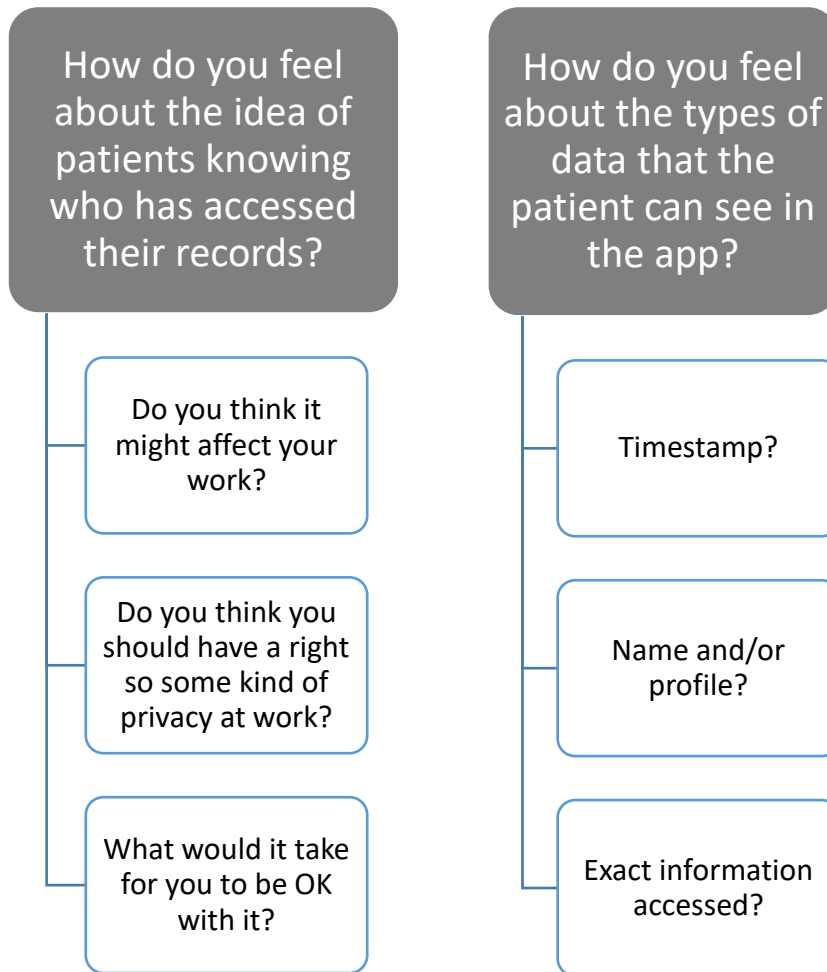


Figure 6 First page of the Cheat Sheet

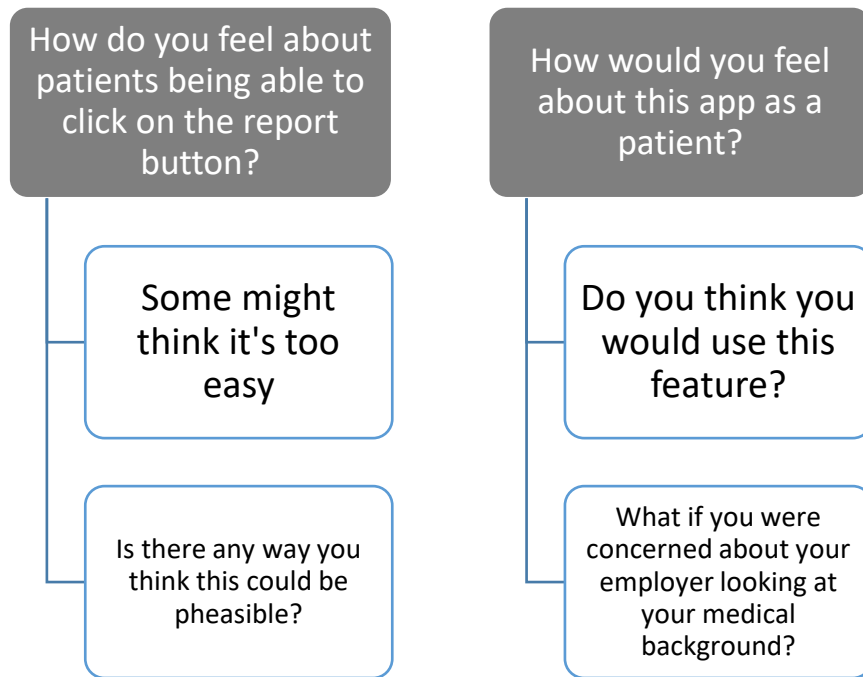


Figure 7 Second page of the Cheat Sheet

### 3.6.5 Topics

Four questions would be asked with further follow-up questions where responses are limited or off-topic:

- How do you feel about the idea of patients knowing who has accessed their records?

This question aims at getting a general idea of their stand on the matter. Another purpose of this question is to initiate the conversation in the most natural way possible.

The possible follow up questions would aim a rephrasing the question or incur deeper in what the participant meant. It is expected that participants take a stand on the matter. Whether it is viewed as positive or negative, the interviewer will ensure further elaboration from the participant. If the general feeling was positive, a follow-up question could be "Do you think it might affect your work?" Where participants demonstrate a reluctance to accept the concept, a mitigating follow-up question could be presented, for example, "What would it take for you to be OK with it?"
- How do you feel about the types of data that the patient can see in the app?

This question asks the participant to reflect on the details and nature of the information to be displayed in the app. It may be expected that some participants might not show interest in the particular data fields displayed. Where participants show signs of deference or little interest in the topic the interviewer can point out examples that put the participant in the

situation “Are you OK with patients knowing exactly the time and date or exactly the file you’ve been looking at?” or “What about patients seeing your name and perhaps your professional profile?”

- How do you feel about patients being able to click on the report button?

This question enquires about the idea of having the functionality on the app that allows patients to just click to flag as inappropriate any access event they might consider not to follow the "Need to know" principle. It is expected that participants may find it positive or might be against such functionality. A follow-up question for an interviewee that shows a positive attitude to the "Inappropriate" button could be "Some think it is too easy". In the case where the participant shows reluctance in accepting the functionality a follow-up question could be "Is there any way you think this could be acceptable?"

- How would you feel about this app from the patient’s point of view?

The purpose of this question is to further encourage reflection on the topic from a different point of view. Determining the possible responses and attitudes from participants to this question is quite challenging and more complex than the previous questions. The participant could manifest positive or negative feelings about the app, but depending on their stand on the previous questions, the interviewer could further enquire about multiple scenarios. The participant could feel positive about the app in previous questions, but indifferent to it as a patient. They could show resistance to the idea of Access Notification as a provider but could see the benefits of it as a patient who is also a provider. Their opinion may or may not change depending on the perspective from which they contemplate the question, and they may be for or against the app at this point. In the case of receiving a short answer possible follow up questions could be "Do you think you would use this feature?" Where the participant shows deference to the app, the interviewer could place their interests in the example "What if you were concerned about your employer/future employer looking at your medical history?"

### 3.6.6 Random number generator

The researcher used the MIT app inventor to create a simple six digit random number generator. The participant would tap on the screen, and a six digit number would appear. The number assigned could be used as a reference in case the participant wanted their data to be eliminated.

## 4 Results

### 4.1 Introduction

The first part of this chapter presents the findings of the first study in two tables, one for the first and second section, and one for the third section. The chapter later includes a short analysis of each question answered and its significance.

The second part presents the results of the second study, with a description of the participant outreach process and details about the responses received. The section later provides with a breakdown of positive and negative impressions, as well as an analysis of the topics that were mentioned in the interviews with any recurrence.

### 4.2 First Study

The questionnaire was handed out to patients the group meeting following the presentation and discussion. A total of fourteen questionnaires were returned. Eleven participants fully completed the multiple choice questions (Q1 to Q12), while only six made any comments in questions 13, 14 and the comments section.

#### 4.2.1 Results

Table 7 provides the details of the participants' answers in parts 1 and part 2 of the questionnaire.



Part 1 Questions	Total	Strongly agree	Agree	Not sure	Disagree	Strongly disagree
Do you <u>think</u> your Health Records should only be accessed on a "Need to know" basis?	13	46%	38%	8%	0%	8%
Do you <u>trust</u> that your Health Records are only accessed on a "Need to know" basis?	12	17%	25%	42%	17%	0%
If you see a different doctor other than your usual, would you like for them to be able to access your Medical Records wherever it may be?	11	9%	55%	27%	9%	0%
If a <u>consultant</u> needs it, should they be able to access any part of your Health Records?	12	33%	58%	0%	8%	0%
If a nurse needs it, should they be able to access any part of your Health Records?	12	17%	17%	25%	42%	0%
If the administrative staff need it, should they be able to access any part of your Health Records?	13	8%	15%	8%	69%	0%
Part 2 Questions	Total	Strongly agree	Agree	Not sure	Disagree	Strongly disagree
Do you think you should be able to decide exactly who accesses your Health Records?	14	50%	43%	7%	0%	0%
Do you consider yourself capable to decide what information Healthcare Professionals should have access to?	14	50%	43%	7%	0%	0%

Table 7 Results of the first and second sections of the questionnaire in percentages

Table 8 provides the details of the participants' answers in the third section of the questionnaire.

Part 3 Questions	Total	Extremely important	Very important	Important	Less important	Not important at all
Is it important that you know the name of whoever has accessed your health records?	14	86%	7%	7%	0%	0%
Is it important that you know exactly what information was made visible to anyone?	14	79%	14%	0%	7%	0%
Is it important that you know exactly the date and time when anyone accesses your records?	14	57%	29%	0%	14%	0%
Is it important that you are able to report inappropriate activity directly from your Patient Portal?	14	77%	15%	8%	0%	0%

Table 8 Results of the third section of the questionnaire

## 4.2.2 Analysis

### 4.2.2.1 Answers to Part 1

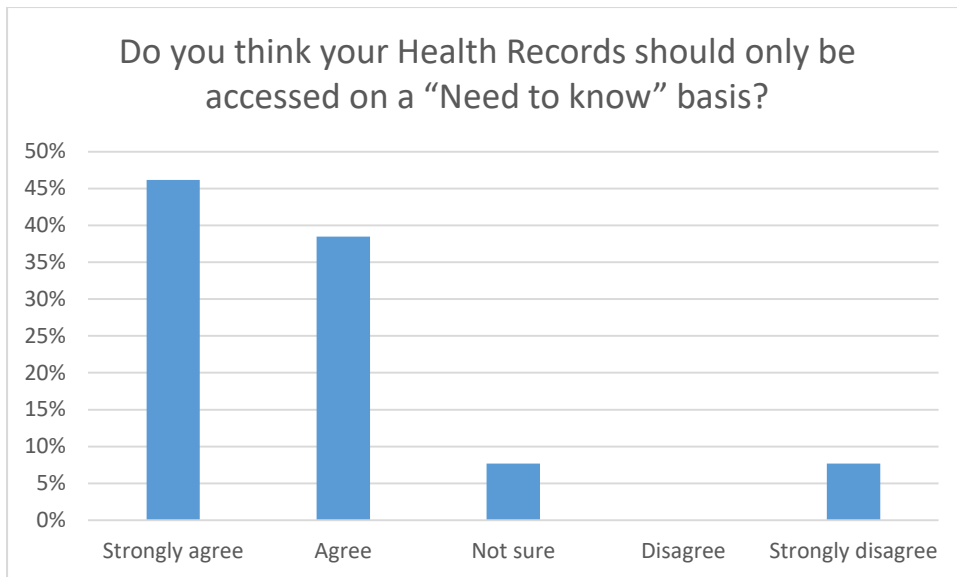


Figure 8 Results of question 1

The results of Q1 (“Do you think your Health Records should only be accessed on a “Need to know” basis?”) unsurprisingly revealed that 46% strongly agreed and 38% agreed. Only one participant (8%) selected “Strongly Disagree”, and the remaining one remained “Not Sure” (See Figure 8). This strong response coincides with the interviews in Caine, et al. (2015) where 25 out of 30 interviewees made spontaneous mentions of the “Need-to-know” principle. Healthcare providers also understand the importance of following this. A guide to Healthcare Organizations by the Data Protection Commission states that “The patient is entitled to an assurance that their medical information will be treated on a need-to-know basis” (Data Protection Commission, 2018) when answering the question whether secretaries should be able to access patients’ records.

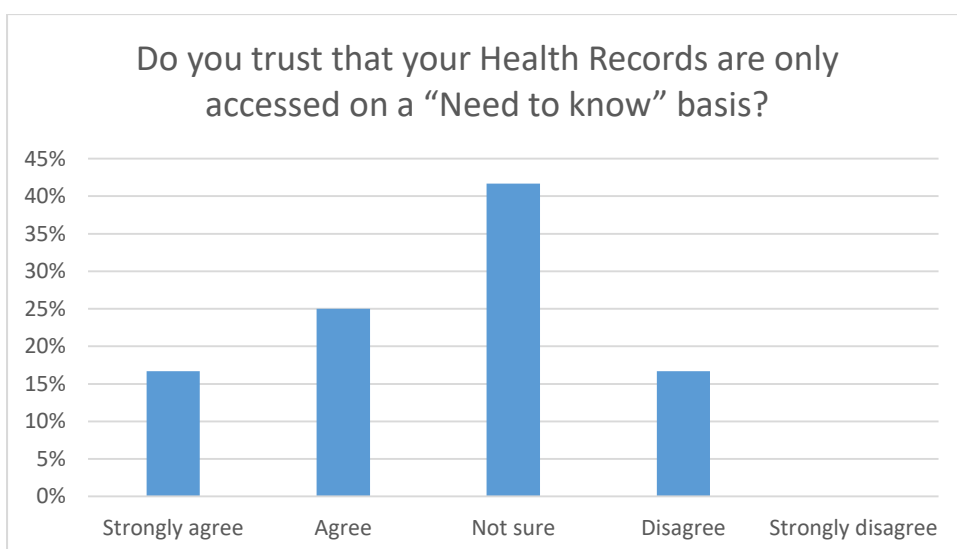


Figure 9 Results of question 2

The results of Q2 (“Do you trust that your Health Records are only accessed on a “Need to know” basis?”) reveals a much more reserved attitude towards trusting the Healthcare System. From a total of 12 answers, only two chose "Strongly Agree" and three selected "Agree". As many participants demonstrated uncertainty (42% selected "Not Sure") and the remaining selected "Disagree" (See Figure 9). Perhaps the prevalence of participants that responded “Not Sure” reveals a similarity with the findings of the study by the Cyber Dialogue (Cyber Dialogue & Institute for the Future, 2000) and the urgent need to reassure patients of the extent of measures the Healthcare System takes to ensure patient privacy and confidentiality (Civan, et al., 2006).

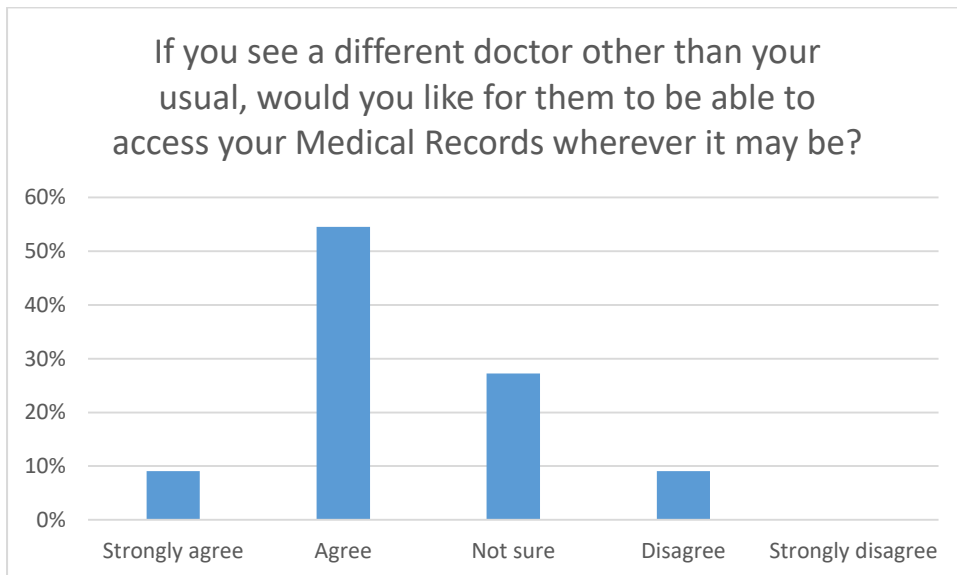


Figure 10 Results of question 3

The results of Q3 (“If you see a different doctor other than your usual, would you like for them to be able to access your Medical Records wherever it may be?”) revealed that patients could be considered to desire data portability (See Figure 10). Out of 11 participants, six agreed with the question, two strongly agreed, and another two selected "Disagree". The remaining 3 (27%) participants remained uncertain, selecting "Not Sure".

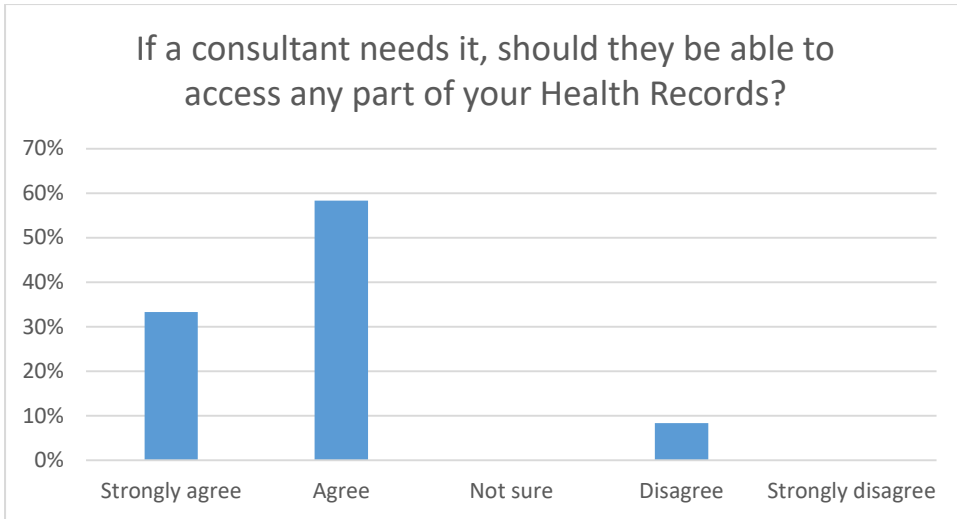


Figure 11 Results of question 4

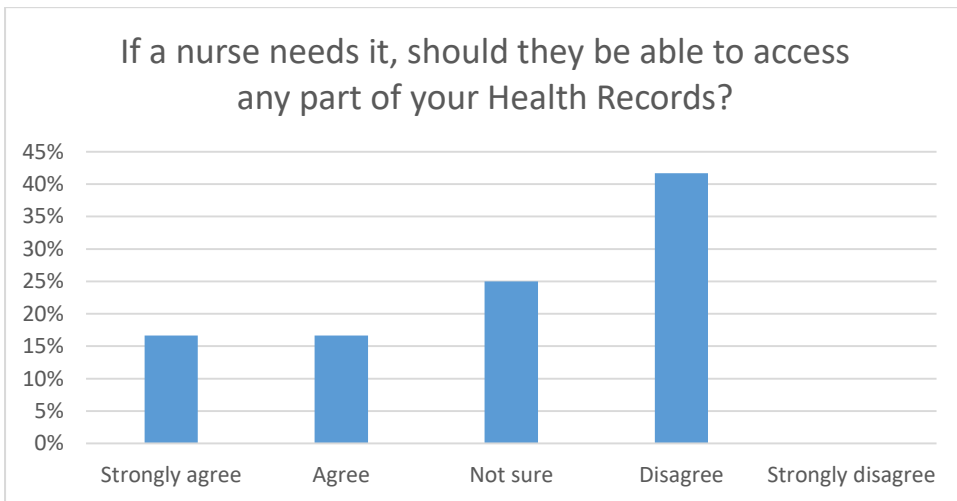


Figure 12 Results of question 5

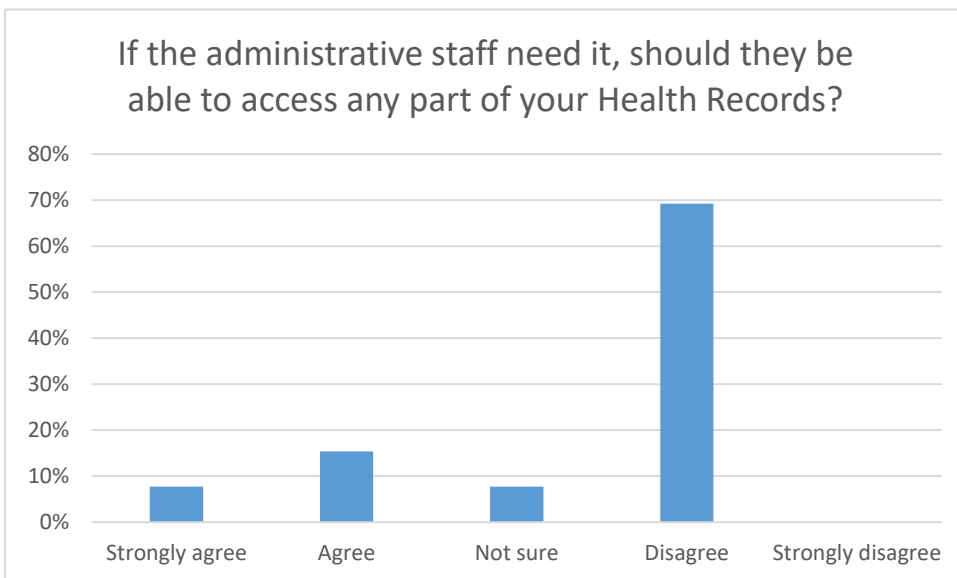


Figure 13 Results of question 6

The results of questions 4, 5 and 6 reveal a clear difference between the willingness of patients to share their information, based on the occupation of the provider. While most patients responded that they were in favour of consultants to have full access to their records, 4 (33%) strongly agree, and 7 (58%) agreed, the number of participants in favour of full access by nurses substantially decreased. More participants disagreed with this (5 patients or 42%), than those who trusted Nurses with full access to their records. The disparity between occupations becomes evident when asked if administrative staff should have access to any part of their Health Records. Only three patients strongly agreed or agreed, one selected not sure, and nine (69%) disagreed with it (See Figure 11, Figure 12 and Figure 13).

The answers to these questions also suggest a lack of knowledge and understanding of the confidentiality principles registered nurses are bound by and coincides with the results of surveys that state the same (Cyber Dialogue & Institute for the Future, 2000) (Vodicka, et al., 2013). Principle 4 of the Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives entitles patients to confidentiality and to being protected from the inappropriate use of their data (Nursing and Midwifery Board of Ireland, 2014).

These results also may suggest a limited understanding of the confidentiality agreements held with Secretarial, Managerial and administrative staff in GP Practices. According to the GPIT group's guideline for processing of patient personal data (GPIT, 2018) "All persons in the practice (not already covered by a professional confidentiality code) should sign a confidentiality agreement that explicitly makes clear their duties in relation to personal health information and the consequences of breaching that duty". Furthermore, to ensure that staff maintain data hygiene GP Practice Software systems are expected to provide an Audit Trail capabilities, and data controllers are expected to hold a register of regular Information Security audits.

#### 4.2.2.2 Answers to Part 2

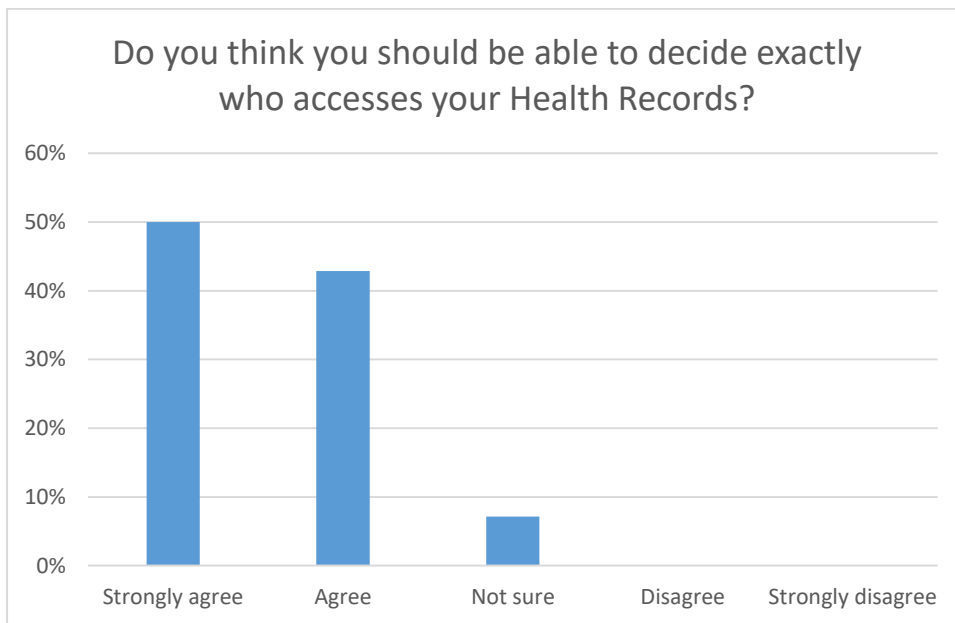


Figure 14 Results of question 7

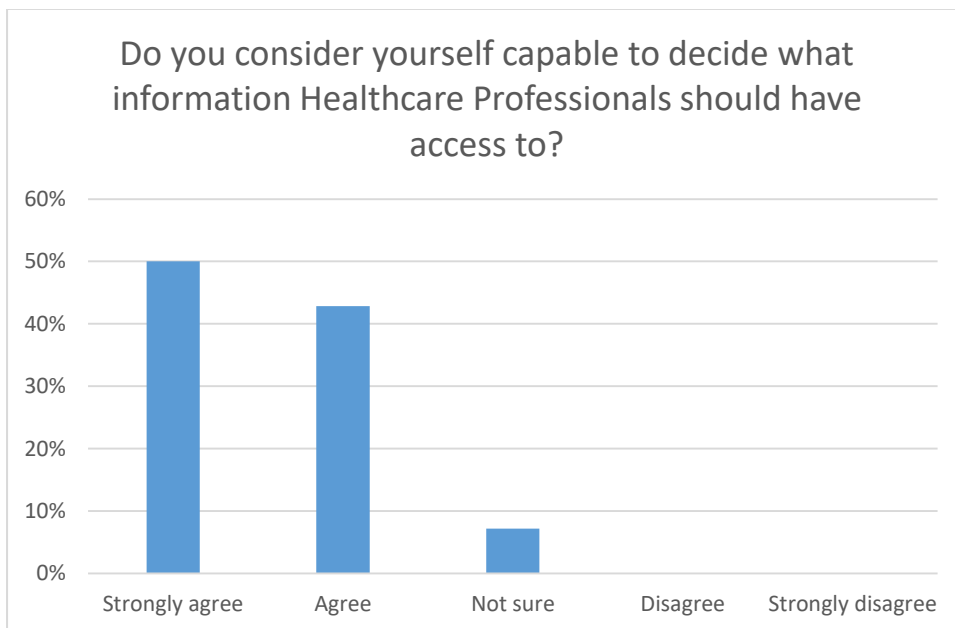


Figure 15 Results of question 8

The results of Questions 7 and 8 (See Figure 14 and Figure 15) show that patients not only want to have Access Control but also consider themselves capable of making decisions on who should access their information and what. Out of 14 responses, 7 (50%) strongly agree, and 6 (43%) agree with both questions. The remaining one vote remained undecided about this (7% Not Sure). This largely coincides with the findings in an article (Caine & Hanania, 2013) prior to the Regenstrief studies. It

also agrees with some of the points made by Caine in Point and Counterpoint (Caine & Tierney, 2015).

#### 4.2.2.3 Answers to Part 3

All 14 participants answered all of the questions in this section except for Question 12, where one question remained unanswered. The results reveal a keen interest in including the minimum data fields of an Audit Trail in an eventual app that provides Access Notification.

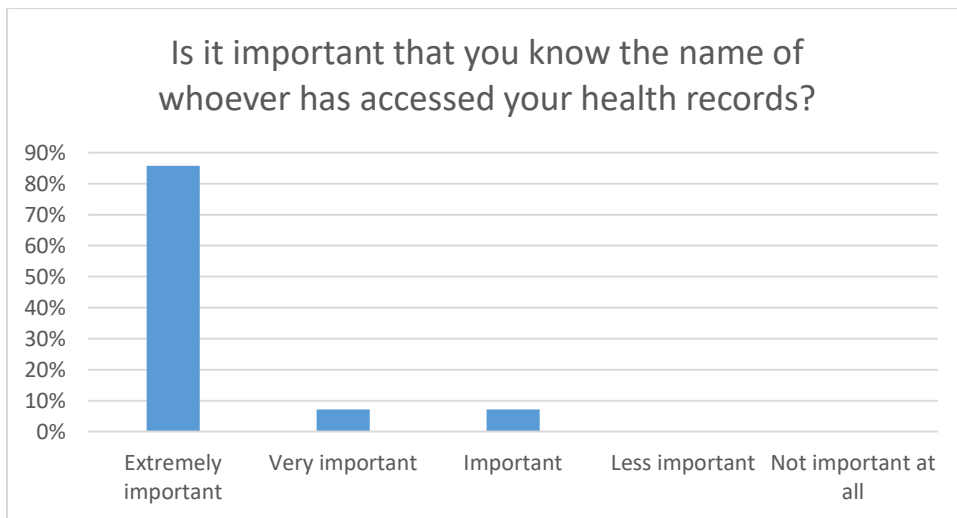


Figure 16 Results of question 9

12 participants (86%) considered extremely important that they know the name of the person interacting with their health records (See Figure 16). The other 2 participants considered very important and important respectively. No participant chose "Less important" or "Not important at all".

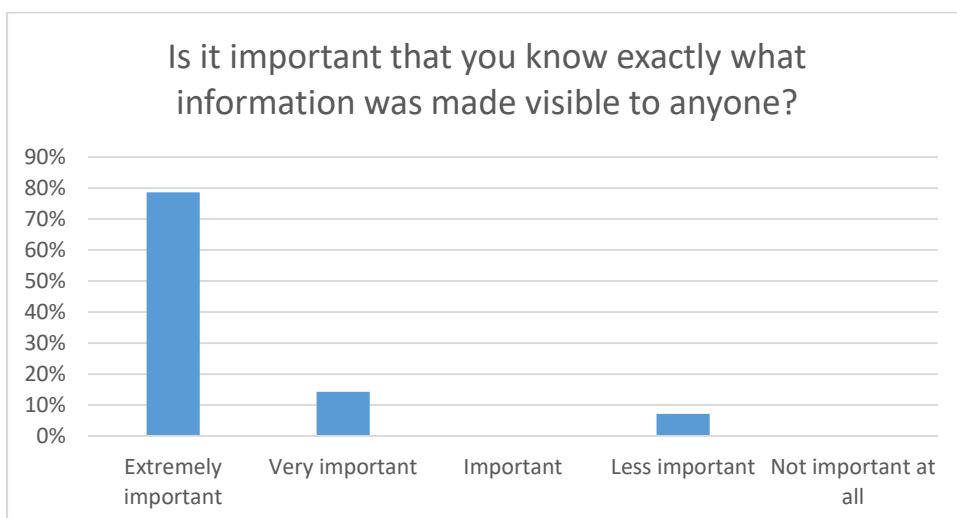


Figure 17 Results of question 10

When asked in Question 10 about the importance to know the exact information accessed, rather than a description of the type of information accessed, participants also demonstrated high interest in it. Eleven participants (79%) considered it Extremely Important; another two chose "Very Important" (14%) and only one participant considered it less important. No participant selected "Important" or "Not important at all" (See Figure 17).

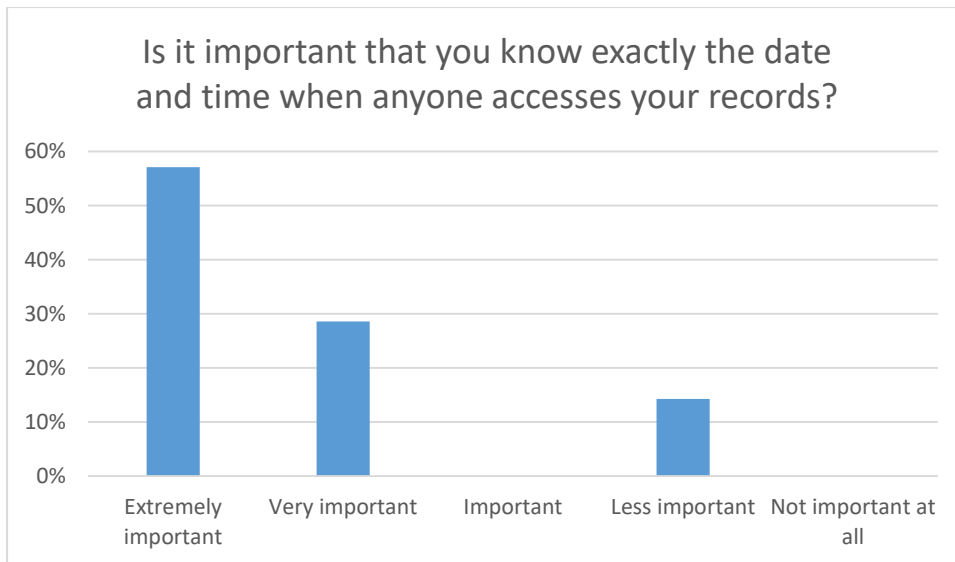


Figure 18 Results of question 11

The results for Q11 ("Is it important that you know exactly the date and time when anyone accessed your records?") revealed that 8 participants (57%) considered it extremely important, four chose "Very important" (29%) and two selected "Less important" (14%). No participant selected the options of "Important" or "Not important at all" (See Figure 18).

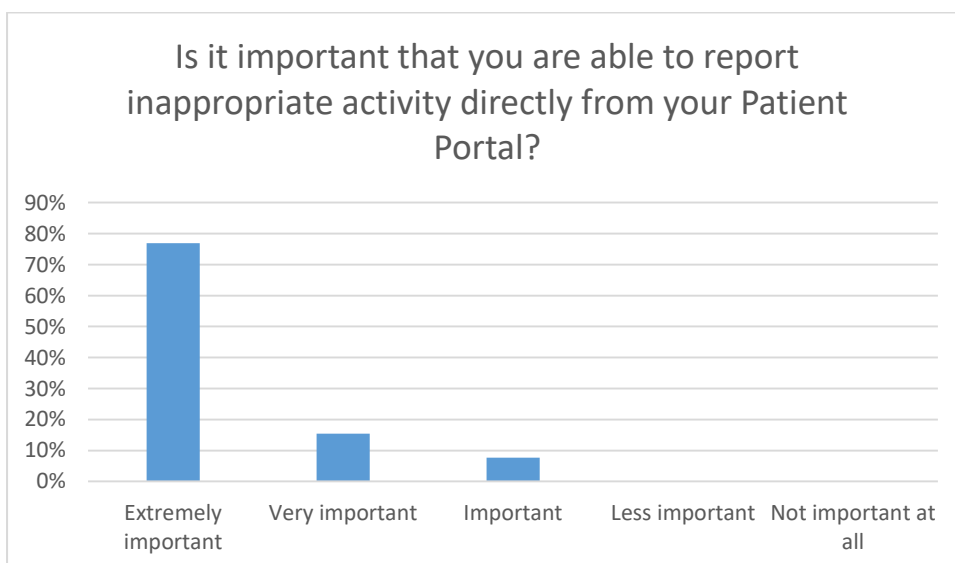


Figure 19 Results of question 12



Concerning the inclusion of a capability for reporting inappropriate activity directly from the Patient Portal, participants demonstrated a clear interest in the functionality. 10 participants (77%) considered it extremely important, 2 chose "Very important" (15%) and 1 selected "Important" (8%). None of the participants considered this to be less important or not important at all (See Figure 19).

#### 4.2.2.4 Answers to Part 4

The responses to the fourth section were scarce. Only 6 participants chose to answer open questions 13 and 14. No participant added any comments in the final comments section.

From the comments made one participant mentioned that they would like to be able to correct inaccurate and conflicting information. The prospect of including this functionality, although significant perhaps is more suitable to be included in the main body of the Patient Portal, rather than the Access Notification section.

Another comment which was placed under question 13, but perhaps is more suitable to the comments section, stated that in the event of being incapable of making decisions about Access Control, they would agree to grant full access to Healthcare providers. Although interesting, the comment exceeds the scope of this research.

### 4.3 Second Study

#### 4.3.1 Reaching out

Contacting providers was carried out in three approaches.

- An email was sent to the person responsible for the North Eastern GP Training Programme, part of the HSE's Primary Care services. The recipient forwarded the invitation to participate in 36 GP Training Practices and Practice Managers.
- An email was sent to the Research Administrator in the Irish College of General Practitioners requesting the recipient to forward the invitation to possible suitable participants.
- Once an appointment was made for an interview, the researcher used Google Maps for a search of "GP's nearby" and "Doctors nearby", based on the location agreed. The closest results would be cold called by phone, to later forward an introductory email and invitation.

Phone calls were used mostly to request a reliable email address and portend the introductory email. The introduction email provided a short message to the first contact and a further text with the message inviting to participate. This message would contain a brief background and state of the art, the purpose of the interview and a short explanation of the interview process (SEE APPENDIX). The email would also carry attached the respective participant's information sheet (SEE APPENDIX).

### 4.3.2 Responses

Six interviews resulted from the contact with GP training and one was the result of 15 cold calls. No respondents resulted from the contact with ICGP.

The time and location of the meetings were set at the participants' convenience. Four interviews took place at the GP surgery where participants worked. One interview took place at the private residence of the participant.

Another three participants were interviewed, also at their place of work. However, due to time constraints, the interview had to be carried out as a conference with all three participants in the room, instead of the desired one to one interactions. In this occasion, there was a General Practitioner, a Primary Care nurse and the receptionist. Unfortunately, this meant that most of the opinions recorded were that of the GP and the Nurse. The receptionist's participation was too limited to take into account, therefore for the purposes of this dissertation, it was not counted.

### 4.3.3 Positive or negative feelings?

The questions required providers to manifest whether they find the app or a specific part of the app Positive or Negative. Table 9 provides a summary of the positions taken by the participants.

Provider's Opinion	Question 2					
	Question 1	Date	Information accessed	Username	Question 3	Question 4
Positive	5	4	3	6	1	3
Negative	0	1	0	0	4	0
Neutral/ Indifferent	0	0	0	0	0	4

Table 9 Breakdown of positive, negative and neutral opinions

Analysing the transcripts the researcher had to make some decisions whether a comment can be interpreted as a positive response or negative, even though there is no explicit mention of the terms. Examples of what has been interpreted as positive can be "I would not have a problem with that..." or "I think it's OK..." or "I think it's a good idea..." Phrases like "I have a problem with that..." or "I don't like that..." were reasons to consider a participant's answer as negative. In some cases, decisions had to be made based on the context and the notes on non-verbal clues taken after the interview. For example, if a participant stated "I'm not sure about that..." it could be considered neutral, but based on context and non-verbal communication the opinion is counted as negative. At

this point, it is necessary to clarify that the above are not direct quotations, just examples of the criteria used to determine whether to consider a participant's stance positive or negative.

#### *4.3.3.1 Question 1*

When asked about the overall opinion about the app, five participants had varying degrees of acceptance, but no participant responded to have negative feelings about the app. In two interviews the participants went off topic, and follow-up questions failed to extract the answer required.

#### *4.3.3.2 Question 2*

Participants were implicitly required to provide their opinion about the three different fields: Date, Information Accessed and the Username. 6 participants had positive feelings about having their name rendered on the app, 3 showed a positive attitude towards patients knowing the exact file accessed and 4 considered positive the idea of disclosing the date of the event. One participant emphatically elaborated about being against patients seeing the date or time of the events. The participant's stance was related to their right to privacy and to decide how to operate in their profession.

#### *4.3.3.3 Question 3*

Participants were asked about the "Report" button in the app. The button would allow users to flag as inappropriate any results they might find inappropriate. One participant felt positive about the button, clarifying that making it simple would benefit users who are not IT experienced. Three participants replied that the button would be "too easy", which raises questions about the consequences of patients clicking these reports. Participants were interested in knowing how the reports would be investigated, who would be responsible and suggested that it would be better to introduce some level of friction to the process, for example having to fill an online form or the button to link to a printable form. Under these circumstances, participants would agree with the complaint channel.

#### *4.3.3.4 Question 4*

This question required participants to provide their opinion as patients. 3 participants reported positive feelings about the app, while 4 showed indifference and claimed they would not use it.

#### *4.3.4 Spontaneous mentions of topics*

The interview was also an opportunity for participants to raise concerns that the researcher may not have considered or expected. As it was in the case of interpreting phrases into "Positive" or "Negative", the mentions were grouped according to the intended meaning as described in Table 10.

Spontaneous mentions	Criteria
Need to know principle	Healthcare providers should only access Healthcare information when needed.
Need for Transparency	The Healthcare System needs to continue to take steps towards creating a more transparent system.
Report button with frictions	Frictions like the requirement of filling an online form or printing a form should be introduced instead of the button
Consequences of the report button	Concerns about the process behind the report button. Who deals with the complaints? How are they dealt with?
Trust needs to be restored	As a consequence of the faults with cervical cancer screening, the Healthcare System needs to restore the patient's trust.
Concerns about extra workloads	Concerns regarding GP staff having to deal with extra workload as a result of complaints about Access Notification
Doctors need to access records	The importance for Doctors to have full access to the patient's medical records in the context of Access Control
Patient education and understanding of notes	The need for patients to understand the information in their EHR and the need for education programmes to this end.
Concerns with third-party data requests	Difficulties about the disclosure of patients' data to third parties, specifically to insurance companies and family members.
Patients need the reassurance of their privacy	The lack of understanding by patients of the privacy measures taken to protect their privacy and confidentiality
Doctors need to change writing habits	Patient Portals will force Doctors to be careful when writing notes and will require them to consider patients ability to understand them.
Exaggerated attitude towards privacy	Mentions of patients being disproportionately concerned about disclosing their information, for instance, their PPS number.
Patients with limited IT skills	Mentions of concerns that patients might not have the IT skills to handle the patient portal due to age or level of education.

Table 10 List of spontaneous mentions with the criteria they are based

The chart below (Figure 20) is a breakdown of the topics spontaneously mentioned more than once by different participants.

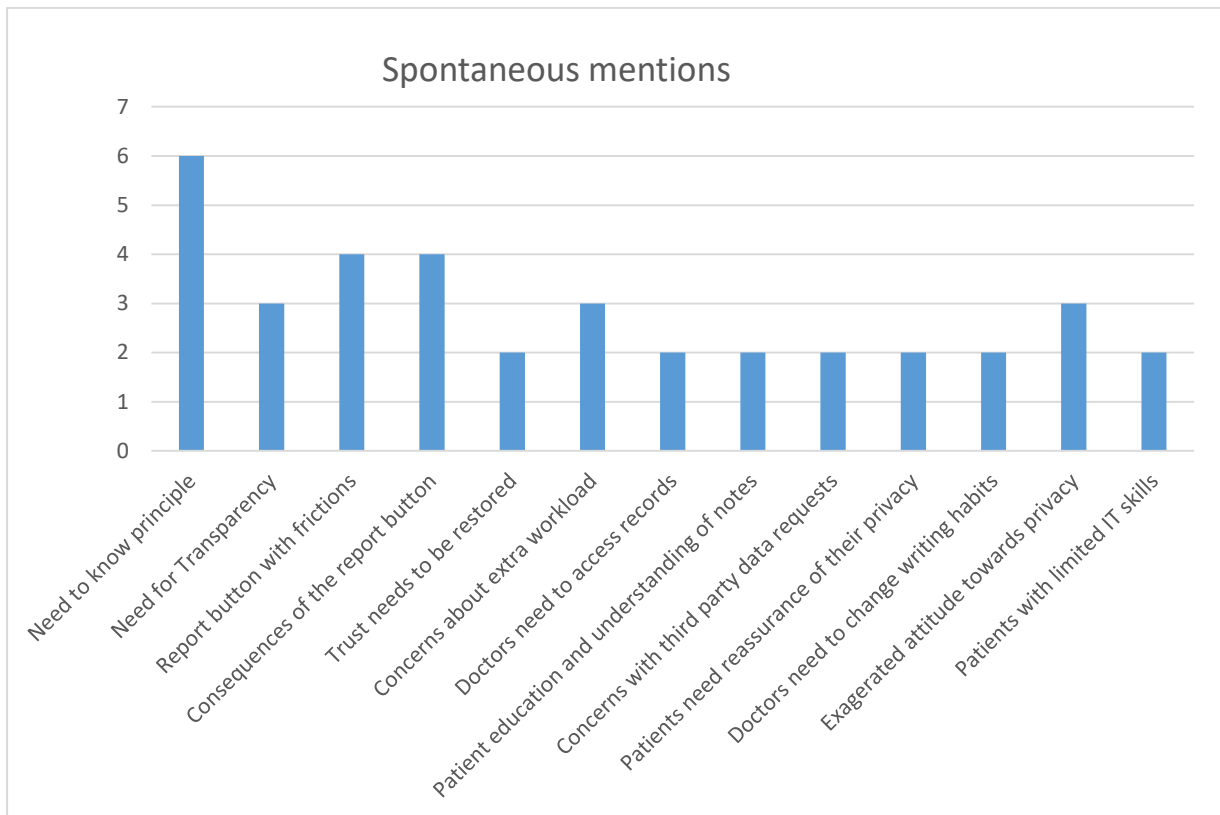


Figure 20 Graph of the frequency of spontaneous mentions

The need-to-know principle was the most brought up topic among the interviews. All but one participant mentioned the issue and the count of mentions raises to 9 when counting repeated mentions within the interviews but in another question.

It was the opinion of four participants that the report button was "Too easy" referring to a concern that patients might not take it seriously enough if they could report inappropriate activity by just one click. In all cases, participants suggested some level of friction introduced, for example having to fill in a form explaining their reasons to consider it inappropriate.

The need for transparency in primary care, concerns about possible extra workload and an exaggeratedly secluded attitude on behalf of patients were topics mentioned three times, with a strong correlation between participants linking the possibility of extra workload with an extremely protective attitude towards privacy on behalf of patients.

Less repeated topics, with two mentions, are:

- The need to restore trust in the healthcare system.

- The need for patients to be educated in the contents of their medical records.
- The need to reassure patients of the measures taken to protect their privacy and confidentiality.
- Concerns about the patient's level of IT skills.
- The need for doctors to change the way they enter notes to avail for patients to understand.
- How necessary it is that doctors have access to the full medical history.

Misunderstandings and misconceptions about third-party requests, for example from family members and insurance companies, was also mentioned by two participants, but both mentioned the topic twice while answering two different questions.

#### 4.4 Conclusion

The process of outreach, although time-consuming, proved effective. The generosity of Providers and patients allowed this research to carry out the studies according to plan. In general, the opinions on privacy and portals of the patients surveyed concurs with those of patients in other countries.

In general, providers showed a positive attitude towards the disclosure of Audit Trails in an eventual Patient Portal. They felt that every time they accessed a patient's record, there was a professional reason behind it and felt confident that they could justify any access. However, there were concerns with making it too easy to report inappropriate activity directly from the application. They felt that it could lead to abuses and cause extra workload.

## 5 Conclusions

Patients and Healthcare Providers adhere to the "Need to Know" principle. This principle needs to be reflected in the process of design of the nationwide Patient Portal since patients do not seem to trust that this principle is duly respected. Concerning professional confidentiality patients do not seem to be aware of the measures to protect their privacy taken by the Healthcare Industry. They also want to be able to control who accesses their data, and they feel competent that they are capable of doing so.

If Ireland is to implement a national Patient Portal, it is worth exploring the possibility to provide Access Notification to patients instead of the controversial Access Control. Healthcare Providers seem receptive to the idea as long as their concerns are addressed. These concerns range from patient education and understanding of the data accessed, to fears of increased workload due to patients making excessive reports of privacy breaches. Should the functionality to report

inappropriate activity to be made available in the Patient Portal, it may be a good idea to introduce some interface frictions to the process to reduce unfounded privacy claims.

## 6 Discussion

In light of the paradigmatic shift towards Patient Engagement and Patient Empowerment both the world and the Irish Healthcare System agree that EHR's have the potential to better patient outcomes (Steward, et al., 2009) (Epstein & Street, 2011) (America, 2001) (Epstein & Street, 2011) (Rigby, et al., 2015).

It has been established during this dissertation that Patient Portals have this potential and the concerns raised can be mitigated through the use of empiric evidence and inclusion and consultation with the stakeholders in the process of design.

Patient Portals improve social accessibility through the application of Heuristic evaluation methods like the proposed by Nielsen and Molich (1990), where empirical tests are used to evaluate the usability of an interface.

Strong ethical arguments have been made for the use and implementation of Patient Portals, provided that every effort be made to mitigate its possible shortcomings. For example, as a tool of communication Portals can be highly efficient, but in some cases, some restriction, delay or release process could increase beneficence and nonmaleficence, while minimising compromises to the respect for patients' autonomy.

Privacy concerns should also be addressed, and in accordance with the findings of the studies in this dissertation, patients are undoubtedly concerned about their privacy. The causes that can be traced to:

- Patients' lack of understanding of the effectiveness common of access management practices. For example how effective user access credentials and profession based access entitlements prevent inappropriate uses of data.
- Patients' paucity of knowledge of standard security and confidentiality measures, particularly with administrative staff, who are in most cases required to sign a confidentiality agreement, or nurses who are bound by their professional codes of practice.
- The prevalence of patients whose computer literacy levels and skills fall short of being able to navigate complex interfaces.

Even patients who regularly use internet services like social media, utility applications, portals, etc. can have concerns. These patients are likely to feel suspicious of Patient Portals since in their experiences they would have almost certainly come across Dark Patterns.

Patients need to be educated, not only to understand the notes they will have access to but to comprehend the real risks and assurances associated with an online presence. An exciting approach to both, educate and learn from patients has been applied in a recent study to extend knowledge about Access Control (Tully, et al., 2018). In a citizens' jury method participants were asked to pass judgement over situations where data would be used for secondary purposes. As the participants gained knowledge of the concepts like data anonymisation and the risks and potential benefits of research, they became more inclined to information sharing.

It could be argued that evidence-based medicine

### 6.1 [Is Healthcare genuinely keeping up?](#)

The introduction of Electronic Health Records has been promising improvements to Healthcare Systems all over the globe. Countries around the world find themselves in various stages of adoption and utilisation of EHR's. Although Ireland has found itself far back in this trend, its eHealth Strategy continues to make progress. The creation of eHealth Ireland Committee in 2015 and its consistent progress has made a positive impact and facilitated companies to believe in a stronger business case to further develop solutions for the Healthcare market (eHealthIreland, 2018). This, however, does not mean that at an industry level Healthcare is at all keeping up with other industries.

The Irish advances in eHealth, although greatly welcomed, not only falls short of catching up but also could be argued that the ambitions of the industry are too modest. Compared with those of sectors like finance where the technological acceleration surpasses the most audacious of imaginations, Healthcare is still far from being at the cutting edge.

In order to understand the point of this section, it is necessary to view the Scientific Method as a tool for humanity to gain an understanding of the scheme of things. The Scientific Method is not an invention with a time and place of origin. It can be stated that it took generations to become a paradigm and permeate, whether a person believes or not, into homes, jobs language and culture. Roger Highfield (Highfield, 2018) proposes the Scientific Method as humanity's greatest invention.

Countless arguments have been made about Artificial Intelligence being "Humanity's last invention". Some of those arguments, made by the brightest minds in the world propose an apocalyptic view of the future of this technology. Professor Stephen Hawking warned about the dangers of AI in an interview with BBC (Cellan-Jones, 2014), Elon Musk warned in an interview with CNBC that Artificial



Superintelligence could lead to an “Immortal Dictator” (Browne, 2018). Other, less pessimistic views reason that once humans create an AI that surpasses human intelligence, human inventions could become obsolete (Gohd, 2017) (Price, et al., 2012) (van Oerle & van Lent, 2017). Whether the reality of the future of AI proves its best invention or its biggest mistake, what becomes apparent is that it will change humanity with at least the same significance as the Scientific Method did.

On 17th of May 2018, the multimedia website The Verge (Savov, 2018) published a leaked video created by Nick Foster, head of design at X [Formerly known as Google X] and David Murphy. The video, titled The Selfish Ledger had been in circulation internally at Google since 2016. Its purpose was to conceptualise possible future directions for the company and foster a discussion of a new approach to the way it uses the massive amount of data the company holds. The video has caused concerns about the most profound ethical and philosophical aspects of the future of technology by envisioning technologies that have the potential to modify or manipulate human behaviour at a species level. The video highlights the difference between a data ledger with a volitional purpose in direct opposition to the current paradigm of user centred design. It also states that these ledgers could be enriched by introducing more sources of information. By combining the notion of these ledgers that evolve by Lamarckian means with Richard Dawkins’ concept of “Selfish Genes” (Dawkins, 1976) the video proposes a Selfish Ledger. The authors propose to view the users as “custodians, transient carriers” of the ledger.

The question is whether Healthcare Systems are going to be ready to adapt when Artificial Super Intelligence begins to deliver better, faster, safer results than the current Scientific Method and Evidence-based Medicine.

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## Appendix

### INFORMED CONSENT FORM FOR IRISH FIBROMYALGIA SUPPORT GROUP RESPONSIBLE (First Study)

**Blackrock, Southside Co. Dublin**

Lead Researcher: Alfredo Ormazabal

#### Background

It is safe to say that in the future every patient in Ireland will have a single Electronic Health Record that could potentially be accessed from anywhere in the country. With all the obvious benefits this will bring, the new technology can also create problems. Any information, however sensitive, could potentially be accessed from anywhere, by anyone in the health sector. If access to these Electronic Health Records is left unrestricted, it might have a negative effect on the trust necessary in the patient-doctor relationship. There have been studies in the US looking into the possibility of granting patients the power to control their data. Patients could allow or disallow healthcare staff the ability to access their files. From the patient's point of view, this seems at first glance like a good idea. However, the answer to this question is more complicated than simple a yes or no. Healthcare staff often need the patient's complete medical information to provide professional healthcare. Furthermore, according to codes of practice, they actually have a right and duty to do so. Also, the patient often does not have the knowledge or expertise to identify parts of information that may be critical for their diagnosis and treatment.

In my dissertation for my MSc. in Health Informatics I'm attempting to side-step this impasse by proposing that patients relinquish their right to control access to their records. In exchange, they would be gaining the possibility to see who has accessed their data and report any activity that they might find inappropriate. This also requires a compromise on behalf of healthcare staff who would be partially relinquishing their own right to privacy at work.

#### Permission Request

I would like to request your permission to have contact with members of your FibroIreland support group during your one of your monthly meetings.

Your member's participation in this study is completely voluntary and anonymous. It is expected that their participation will not cause any risks to their safety in any way. The benefits of this study will not affect participants directly, however it is hoped that the study will inform the development of a patient-centred Electronic Health Record in Ireland. I'm looking to take note of their expectations and preferences for a hypothetical app that allows patients to see who's been reading, writing and interacting with their files.

First I will briefly present the topic to ensure that all participants understand the subject. Then there will be time allocated for a brief discussion followed by the attached questionnaire. The whole process should not take more than 15-20 minutes.

#### Data protection

The returned questionnaire will not be made publicly available and in order to further preserve anonymity, the returned sheets will be transcribed into electronic format. All the data collected will be safely kept in an offline storage device until my studies complete. Each questionnaire will contain a unique 6 digit random number which the participant can use to request their sheet to be discarded subsequently.

#### Conflict of interest

The researcher declares no conflict of interest for this study.

#### DECLARATION:

- I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
- I hereby grant my permission for the researcher to have contact with members of Irish Fibromyalgia, Blackrock, Southside Co. Dublin with the purpose of this research.

Organizer's Signature: \_\_\_\_\_

Organizer's Name: \_\_\_\_\_

Date: \_\_\_\_\_

### Statement of investigator's responsibility:

- I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

### RESEARCHERS CONTACT DETAILS:

Alfredo Ormazabal  
ormazaba@tcd.ie  
086-866 4748

### INVESTIGATOR'S SIGNATURE:

**Date:**



# INFORMED CONSENT FORM (First Study)

Lead Researcher: Alfredo Ormazabal

## Background

It is safe to say that in the future every patient in Ireland will have a single Electronic Health Record that could potentially be accessed from anywhere in the country. With all the obvious benefits this will bring, the new technology can also create problems. Any information, however sensitive, could potentially be accessed from anywhere, by anyone in the health sector. If access to these Electronic Health Records is left unrestricted, it might have a negative effect on the trust necessary in the patient-doctor relationship. There have been studies in the US looking into the possibility of granting patients the power to control their data. Patients could allow or disallow healthcare staff the ability to access their files. From the patient's point of view, this seems at first glance like a good idea. However, the answer to this question is more complicated than simple a yes or no. Healthcare staff often need the patient's complete medical information to provide professional healthcare. Furthermore, according to codes of practice, they actually have a right and duty to do so. Also, the patient often does not have the knowledge or expertise to identify parts of information that may be critical for their diagnosis and treatment.

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First I will briefly present the topic to ensure that all participants understand the subject. Then, there will be time allocated for a brief discussion followed by a very short questionnaire. The whole process should not take more than 15-20 minutes. Each questionnaire will contain a unique 6 digit random number which the participant can use to request their sheet to be discarded subsequently.

## Data protection

The returned questionnaire will not be made publicly available and in order to further preserve anonymity the returned sheets will be transcribed into electronic format. The transcribed questionnaires will only be made accessible to the researcher, supervisor and examiner. The data collected will be safely kept in an offline storage device until my studies complete.

## Conflict of interest

The researcher declares no conflict of interest for this study.

## DECLARATION:

- I am 18 years or older and am competent to provide consent.
- I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
- I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.
- I understand that if I make illicit activities known, these will be reported to appropriate authorities.
- I understand that I may withdraw my participation at any time, and that I may at any time, even subsequent to my participation have any data gathered safely destroyed.
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.

Participant's Signature: \_\_\_\_\_

Participant's Name: \_\_\_\_\_

Date: \_\_\_\_\_

Statement of investigator's responsibility:

- I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

RESEARCHERS CONTACT DETAILS:

Alfredo Ormazabal

ormazaba@tcd.ie

086-866 4748

**INVESTIGATOR'S SIGNATURE:**

**Date:**

# INFORMATION SHEET FOR IRISH FIBROMYALGIA SUPPORT GROUP RESPONSIBLE (First Study)

**Blackrock, Southside Co. Dublin**

Lead Researcher: Alfredo Ormazabal

## Background

It is safe to say that in the future every patient in Ireland will have a single Electronic Health Record that could potentially be accessed from anywhere in the country. With all the obvious benefits this will bring, the new technology can also create problems. Any information, however sensitive, could potentially be accessed from anywhere, by anyone in the health sector. If access to these Electronic Health Records is left unrestricted, it might have a negative effect on the trust necessary in the patient-doctor relationship. There have been studies in the US looking into the possibility of granting patients the power to control their data. Patients could allow or disallow healthcare staff the ability to access their files. From the patient's point of view, this seems at first glance like a good idea. However, the answer to this question is more complicated than simple a yes or no. Healthcare staff often need the patient's complete medical information to provide professional healthcare. Furthermore, according to codes of practice, they actually have a right and duty to do so. Also, the patient often does not have the knowledge or expertise to identify parts of information that may be critical for their diagnosis and treatment.

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First I will briefly present the topic to ensure that all participants understand the subject. Then there will be time allocated for a brief discussion followed by the attached questionnaire. The whole process should not take more than 15-20 minutes.

## Data protection

The returned questionnaire will not be made publicly available and in order to further preserve anonymity the returned sheets will be transcribed into electronic format. Each questionnaire will contain a unique 6 digit random number which the participant can use to request their sheet to be discarded subsequently.

## Conflict of interest

The researcher declares no conflict of interest for this study.

## Any questions?

Researcher Name: Alfredo Ormazabal  
Course: MSc in Health Informatics  
Email: [ormazaba@tcd.ie](mailto:ormazaba@tcd.ie)  
Mobile: 086-866 4748

# INFORMATION SHEET FOR PROSPECTIVE PARTICIPANTS (First Study)

Lead Researcher: Alfredo Ormazabal

## Background

It is safe to say that in the future every patient in Ireland will have a single Electronic Health Record that could potentially be accessed from anywhere in the country. With all the obvious benefits this will bring, the new technology can also create problems. Any information, however sensitive, could potentially be accessed from anywhere, by anyone in the health sector. If access to these Electronic Health Records is left unrestricted, it might have a negative effect on the trust necessary in the patient-doctor relationship. There have been studies in the US looking into the possibility of granting patients the power to control their data. Patients could allow or disallow healthcare staff the ability to access their files. From the patient's point of view, this seems at first glance like a good idea. However, the answer to this question is more complicated than simple a yes or no. Healthcare staff often need the patient's complete medical information to provide professional healthcare. Furthermore, according to codes of practice, they actually have a right and duty to do so. Also, the patient often does not have the knowledge or expertise to identify parts of information that may be critical for their diagnosis and treatment.

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## Participation

Your participation in this study is completely voluntary and anonymous. It is expected that your participation will not cause any risks to your safety in any way. The benefits of this study will not affect you directly, however it is hoped that the study will inform the development of a patient-centred Electronic Health Record in Ireland. Your identity will not be recorded. You must be 18 years of age or over. I'm looking to take note of your expectations and preferences for a hypothetical app that allows patients to see who's been reading, writing and interacting with their files.

First I will briefly present the topic to ensure that all participants understand the subject. Then, there will be time allocated for a brief discussion followed by a very short questionnaire. The whole process should not take more than 15-20 minutes. Each questionnaire will contain a unique 6 digit random number which the participant can use to request their sheet to be discarded subsequently.

## Data protection

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## Conflict of interest

The researcher declares no conflict of interest for this study.

## Any questions?

Researcher Name: Alfredo Ormazabal  
Course: MSc in Health Informatics  
Email: [ormazaba@tcd.ie](mailto:ormazaba@tcd.ie)  
Mobile: 086-866 4748

<p>Questions (First study)</p> <p>Each question is optional. Feel free to omit a response to any question, however the researcher would be grateful if all the questions are answered. <b>If you wish to have these records deleted quote the following number: 776976</b></p>	Strongly agree	Agree	Not Sure	Disagree	Strongly disagree
Do you <u>think</u> your Health Records should only be accessed on a “Need to know” basis?					
Do you <u>trust</u> that your Health Records are only accessed on a “Need to know” basis?					
If you see a different doctor other than your usual, would you like for them to be able to access your Medical Records wherever it may be?					
If a <u>consultant</u> needs it, should they be able to access any part of your Health Records?					
If a <u>nurse</u> needs it, should they be able to access any part of your Health Records?					
If the <u>administrative staff</u> need it, should they be able to access any part of your Health Records?					
Do you think you should be able to decide exactly who accesses your Health Records?					
Do you consider yourself capable to decide what information Healthcare Professionals should have access to?					
	Extremely important	Very important	Important	Less than important	Not important at all
Is it important that you know the name of whoever has accessed your health records?					
Is it important that you know exactly what information was made visible to anyone?					
Is it important that you know exactly the date and time when anyone accesses your records?					
Is it important that you are able to report inappropriate activity directly from your Patient Portal?					
<p>Is there any other information that you would like to see in your future Patient Portal regarding your privacy?  <i>(Please do not name third parties in any open text field of the questionnaire. Any such replies will be anonymised.)</i></p>					
<p>Are there any other things you would like to be able to do with your future Patient Portal regarding your privacy?  <i>(Please do not name third parties in any open text field of the questionnaire. Any such replies will be anonymised.)</i></p>					
<p>Comments: <i>(Please do not name third parties in any open text field of the questionnaire. Any such replies will be anonymised.)</i></p>					

## Second Study contact message

Trinity College Dublin,

Provider impressions on a system that allows patients to know who's accessed their medical records.

Patient Portals are being implemented by healthcare systems across the world. Countries like Australia and Estonia have made the bold movement to allow patients full control over their data (**Access Control**), making it their own decision whether to allow healthcare providers to see their medical records or not. This has sparked controversy within the healthcare sector without clear resolution.

Ireland is no exception, with a Patient Portal pilot deployed in Cork University Maternity Hospital. As it stands the HSE doesn't show any indications of intending to grant Access Control to patients, but it will introduce the capacity for patients to access their audit trails in future stages of the pilot.

As part of my MSc in Health Informatics dissertation I've already carried out a study to confirm the desires of patients regarding privacy and developed a mock app to demonstrate what it would look like. In this stage of the research I intend to demonstrate the app to healthcare staff, both clinical and non-clinical, and record their impressions through a semi-structured interview.

The interviews are designed to be short and to the point. A two minute demonstration of the app will be followed by four questions. The interviews will need to be recorded to maximize data collection in a short time. Only I will have access to the recordings and only my supervisor and evaluators will have access to the transcripts. Participation is completely anonymous and voluntary. This study has received ethical approval by the University's Research Ethics Committee. More details of the study can be found in the attached participant information sheet.

If you would like to participate or know anybody that would, please contact me to the below details.

Alfredo Ormazabal.

0868664748

[ormazaba@tcd.ie](mailto:ormazaba@tcd.ie)

# INFORMED CONSENT FORM (Second Study)

Lead Researcher: Alfredo Ormazabal

## Background

It is safe to say that in the future every patient in Ireland will have a single Electronic Health Record that could potentially be accessed from anywhere in the country. With all the obvious benefits this will bring, the new technology can also create problems. Any information, however sensitive, could potentially be accessed from anywhere, by anyone in the health sector. If access to these Electronic Health Records is left unrestricted, it might have a negative effect on the trust necessary in the patient-doctor relationship. There have been studies in the US looking into the possibility of granting patients the power to control their data. Patients could allow or disallow healthcare staff the ability to access their files. From the patient's point of view, this seems at first glance like a good idea. However, the answer to this question is more complicated than simple a yes or no. Healthcare staff often need the patient's complete medical information to provide professional healthcare. Furthermore, according to codes of practice, they actually have a right and duty to do so. Also, the patient often does not have the knowledge or expertise to identify parts of information that may be critical for their diagnosis and treatment.

In my dissertation for my MSc. in Health Informatics I'm attempting to side-step this impasse by proposing that patients relinquish their right to control access to their records. In exchange, they would be gaining the possibility to see who has accessed their data and report any activity that they might find inappropriate. This also requires a compromise on behalf of healthcare staff who would be partially relinquishing their own right to privacy at work.

## Participation

Since you are a staff member of this GP surgery, I would like to invite you to participate in a short interview at your most convenient time, perhaps at lunchtime if that is your best suit. You will be given the opportunity to interact with a prototype app that fictionally allows your patients to see who has accessed their Electronic Health Record. This will be followed by a short audio recorded interview to take note of your impressions, concerns, etc. The whole process shouldn't take more than 15 minutes. Your participation in this study is completely voluntary and anonymous. Your identity will not be collected, neither will your role or profession in this practice. A 6 random digit number will be issued to you should you wish to subsequently have your recordings, transcripts etc. discarded. You must be 18 years of age or over. At any time during the interview you may decide to stop and discard the recording and/or decline to answer any question. No risks to your person are anticipated in this study. The benefits of this study will not affect you directly, however it is hoped that our findings will inform the development of a patient-centred Electronic Health Record in Ireland.

## Audio recordings

The actual recording, as well as its transcription will not be made public. Access to the recordings will only be made available to the researcher. Transcriptions will only be made available to the researcher, supervisor and examiner. The recording will be carried out on an offline recording device. At any point during the interview consent can be withdrawn and all data gathered discarded. You may also decline to answer any question at any time. In order to further preserve anonymity no questions will be asked about your title or specifics of your daily tasks. All the data collected will be safely kept in an offline storage device until my studies complete.

## DECLARATION:

- I am 18 years or older and am competent to provide consent.
- I have read, or had read to me, a document providing information about this research and this consent form. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction and understand the description of the research that is being provided to me.
- I agree that my data is used for scientific purposes and I have no objection that my data is published in scientific publications in a way that does not reveal my identity.
- I understand that if I make illicit activities known, these will be reported to appropriate authorities.
- I understand that I may stop electronic recordings at any time, and that I may at any time, even subsequent to my participation have such recordings destroyed (except in situations such as above).
- I understand that, subject to the constraints above, no recordings will be replayed in any public forum or made available to any audience other than the current researchers/research team.
- I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights.

Participant's Signature: \_\_\_\_\_

Participant's Name: \_\_\_\_\_

Date: \_\_\_\_\_

Statement of investigator's responsibility:

- I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

6.1.1.1.1 RESEARCHERCONTACTDETAILS:

Alfredo Ormazabal

ormazaba@tcd.ie

086-866 4748

**INVESTIGATOR'S SIGNATURE:**

**Date:**



# INFORMATION SHEET FOR PROSPECTIVE PARTICIPANTS (Second Study)

Lead Researcher: Alfredo Ormazabal

## Background

It is safe to say that in the future every patient in Ireland will have a single Electronic Health Record that could potentially be accessed from anywhere in the country. With all the obvious benefits this will bring, the new technology can also create problems. Any information, however sensitive, could potentially be accessed from anywhere, by anyone in the health sector. If access to these Electronic Health Records is left unrestricted, it might have a negative effect on the trust necessary in the patient-doctor relationship. There have been studies in the US looking into the possibility of granting patients the power to control their data. Patients could allow or disallow healthcare staff the ability to access their files. From the patient's point of view, this seems at first glance like a good idea. However, the answer to this question is more complicated than simple a yes or no. Healthcare staff often need the patient's complete medical information to provide professional healthcare. Furthermore, according to codes of practice, they actually have a right and duty to do so. Also, the patient often does not have the knowledge or expertise to identify parts of information that may be critical for their diagnosis and treatment.

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## Conflict of interest

The researcher declares no conflict of interest for this study.

## Any questions?

Researcher Name: Alfredo Ormazabal  
Course: MSc in Health Informatics  
Email: [ormazaba@tcd.ie](mailto:ormazaba@tcd.ie)  
Mobile: 086-866 4748

## First Study Answers parts 1 and 2

Participant	Question 1	Question 2	Question 3	Question 4	Question 5	Question 6	Question 7	Question 8
775114	Strongly agree	Not sure	Agree	Strongly agree	Strongly agree	Agree	Strongly agree	Strongly agree
790845	Agree	Disagree	Not sure	Disagree	Disagree	Disagree	Strongly agree	Strongly agree
459941	Agree	Agree	Agree	Agree	Agree	Disagree	Agree	Agree
440235	Strongly agree	Strongly agree	Strongly agree	Strongly agree	Disagree	Disagree	Not sure	Agree
095288	Strongly agree	Not sure	Agree	Agree	Agree	Disagree	Agree	Agree
871202	Agree	Disagree	Disagree	Agree	Disagree	Disagree	Strongly agree	Strongly agree
919929	Strongly agree	Strongly agree	Not sure	Agree	Not sure	Not sure	Strongly agree	Strongly agree
622894	Agree	Not sure	Agree	Agree	Disagree	Disagree	Agree	Agree
370422	Strongly agree						Strongly agree	Strongly agree
430984	Strongly disagree	Not sure	Not sure	Agree	Not sure	Disagree	Agree	Not sure
746234						Disagree	Agree	Agree
1864441	Strongly agree	Agree	Agree	Strongly agree	Not sure	Agree	Strongly agree	Strongly agree
824920	Agree	Agree		Agree	Disagree	Disagree	Agree	Agree
776976	Not sure	Not sure	Agree	Strongly agree	Strongly agree	Strongly agree	Strongly agree	Strongly agree

## First Study answers part 3

Participant	Question 9	Question 10	Question 11	Question 12
775114	Extremely important	Extremely important	Extremely important	Extremely important
790845	Extremely important	Extremely important	Extremely important	Extremely important
459941	Extremely important	Extremely important	Less important	Extremely important
440235	Extremely important	Extremely important	Extremely important	Very important
095288	Very important	Very important	Very important	Very important
871202	Extremely important	Extremely important	Extremely important	Extremely important
919929	Extremely important	Extremely important	Extremely important	Extremely important
622894	Important	Less important	Less important	Important
370422	Extremely important	Extremely important	Extremely important	Extremely important
430984	Extremely important	Extremely important	Very important	Extremely important
746234	Extremely important	Extremely important	Extremely important	
1864441	Extremely important	Extremely important	Very important	Extremely important
824920	Extremely important	Very important	Very important	Extremely important
776976	Extremely important	Extremely important	Extremely important	Extremely important