Design and evaluation of a mobile application for pre-procedural safety checklists.

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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. I further declare that this research has been carried out in full compliance with the ethical research requirements of the School of Computer Science and Statistics.

Signed:_____

Debbie Wood

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Abstract

The purpose of this study was to explore the feasibility of using tablet computers and mobile applications within a clinical workflow. A patient safety checklist app was designed and built, and then used for a month in a clinical setting. The usability and acceptance of the app among clinicians, and the suitability of the tablet device for use in a clinical workflow was evaluated using a mixed methods approach. The app was used on two tablet computers in two departments in an academic teaching hospital. The aims of this study were to:

- Design and construct a mobile application for the capture of pre-procedural safety checklists in radiological procedures.
- Pilot the use of the application for a month in an academic training hospital within the Interventional Radiology (IR) room, and the breast care clinic.
- Evaluate the suitability of the tablet device, and the usability and acceptance of the mobile application among the clinicians involved.

The researcher used an agile software development methodology to develop the application, or 'app'. Usability engineering, in the form of usability testing, usability inspection and user training among the end user population of nurses was employed. The application was built iteratively with a focus on ensuring the usability of the user interface. The application checklist content was also adapted for the local hospital practice during the development of the app.

A mixed methods approach was then used to explore the suitability, usability and acceptance of the application when used by 6 IR nurses and 5 Specialist Registrars (SpRs) in IR during a month long pilot study. Two tablet computers were used, and 134 checklists were entered into the application. The time taken to complete checklists was under 1 minute in 68.2% (n=75), and under 5 minutes in 83.7% (n=102) of cases, with only 12 checklist items skipped out of a total of 1404 checklist items offered.

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I would like to dedicate this dissertation to my mom who gave me her love for medicine, and every opportunity to study. I miss you, and I think of you every day.

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Abbreviations

CIRSE	Cardiovascular and Interventional Radiological Society of Europe
EPR	Electronic Patient Record
HIS	Hospital Information System
IOM	Institute of Medicine
IR	Interventional Radiology
JC	Joint Commission
JCAHO	Joint Commission on Accreditation of Health Organisations
OR	Operating Room
SpR	Specialist Registrar
WHO	World Health Organisation
XP	Extreme Programming

Definitions

Circulating nurse:
Registered nurse responsible for preparing an operating room for an operation, who also monitors the patient during the operation and works in the operating room outside the sterile field.

Embolisation:
A minimally invasive procedure performed by interventional radiologists which selectively blocks blood vessels.

Lumbar Puncture:
A diagnostic or therapeutic procedure performed to collect cerebrospinal fluid.

Mammography:
An X-ray image of the breast used as a diagnostic tool.

Outpatient:
A patient who is not hospitalized overnight but who visits is treated at a hospital.

PICC line:
Peripherally Inserted Central Catheter. A flexible tube inserted into a peripheral vein and advanced until the catheter tip terminates in a vein in the chest close to the heart for intravenous access.

Sterile Field:
The area prepared for a surgical procedure immediately around a patient, which includes the scrubbed team members and all tools in the area.

TIPS:
Transjugular Intrahepatic Portosystemic Shunt. The artificial creation of a channel in the liver allowing communication between the portal vein and the hepatic vein.

Ultrasound:
A diagnostic imaging technique used to visualise body structures such as tendons, muscles, joints, vessels and internal organs below the skin.

Chapter 1 Introduction

This chapter will give a brief outline of the study site involved in the research, the background to the proposed study, the proposed research question, an overview of the study design and the significance of the study. The author will describe the current paper-based nursing documentation and safety procedures, and will highlight the potential advantages to introducing an electronic checklist application on a tablet computer. The app was developed in an effort to focus attention on the necessary checks and facilitate easy collaborative safety checking which documents the timeout. For the purpose of this dissertation the words application and app will be used interchangeably. The words tablet, tablet device and tablet computer are also used interchangeably. Distinction was made between the hardware and software components by referring to the 'tablet device or 'app' respectively.

1.1 Introduction

> *"However, despite the benefits of the WHO checklist for patient safety in some cases the practical implementation of the checklist has been found to be less than universal, and to decay over time." (O'Connor et al. 2013, p.1).*

Medicine, like aviation, is facing a crisis of ever increasing and extreme complexity (Gawande 2011). Consequence of this complexity in the high-stress, life-critical field of surgery are the occurrences of avoidable medical errors and deviation from known best practice. A checklist is an itemised list of actions or instructions and is used in aviation as a memory aid. Safety checklists were famously developed by pilots in the United States Air Force during World War II when the Boeing B-17 was found to be 'too much airplane for one man to fly' (Gawande 2011).

The World Health Organisation (WHO) issued the '*Safe Surgery Saves Lives Challenge'* in 2009, which was the introduction of a safety checklist for use in surgery. The three-phase checklist was based on the aviation model, with each phase to be completed at a particular stage in surgery i.e. before the induction of anaesthesia, before incision, and before the patient leaves the operating room (WHO 2009b). While the introduction of these checklists resulted in a dramatic drop in post-surgical complication, morbidity and

mortality, the adoption and utilisation of the checklist has been problematic and has met with resistance (O'Connor *et al.* 2013).

In 2011 the *Quality and Patient Safety Audit, Final Audit Report* by the Health Service Executive (HSE) of Ireland recommended that all HSE acute hospitals implement a standardised correct site surgery (CSS) policy based on the WHO '*Safe surgery saves lives'* guidelines within the next twelve month period, and that regular audits of the policy's implementation should be completed, the results of which should be published as key quality indicators for patient safety (Keane and McHale 2011).

Following the publication of the WHO *'Safe surgery saves lives'* challenge, electronic versions of the checklists have been developed in an attempt to support the practice and its documentation, in line with the health sector's movement toward Electronic Patient Records (EPR). Some of the implementations discussed in this study's review of the state of the art are either prototypes which were not intended to be used in a working clinical environment, or are specialised systems which depend on expensive hardware.

Several clinical areas are adapting safety checklists, among them is the Cardiovascular and Interventional Society of Europe (CIRSE) Interventional Radiology (IR) checklist (Lee *et al.* 2012).

The study site is an academic medical centre with over 1085 beds which provided treatment for 26 000 inpatients, 94 000 day care patients and 225 000 outpatients in 2011. The Diagnostic Imaging Department (DID) provides an IR service which performed over 3400 procedures in 2011. The study site also offers a Breast Service which provides a breast care clinic to the community. The Breast Service completed over 12600 procedures in 2011. The hospital is open 24 hours a day, 365 days per year. (*Money Follows the Patient Policy Paper on Hospital Financing* 2013)

The Clinical Director (CD) of IR at the study site has chosen to pilot the use of the CIRSE IR checklist in the IR department, and breast clinic in order to increase patient safety. The suitability of tablet devices for use within a clinical environment is also of interest. Tablet devices can collect electronic data which could potentially be stored in the EPR

and be used to audit adherence to checklist use, and to report on the validity of checklist item content, while minimising the amount of paper generated in the patient paper file (Bates and Gawande 2003). The checklist app should be usable, the checklist content appropriate, and the tablet device suitable to the clinical environment in order to be acceptable among clinicians and to be an effective tool to improve patient safety.

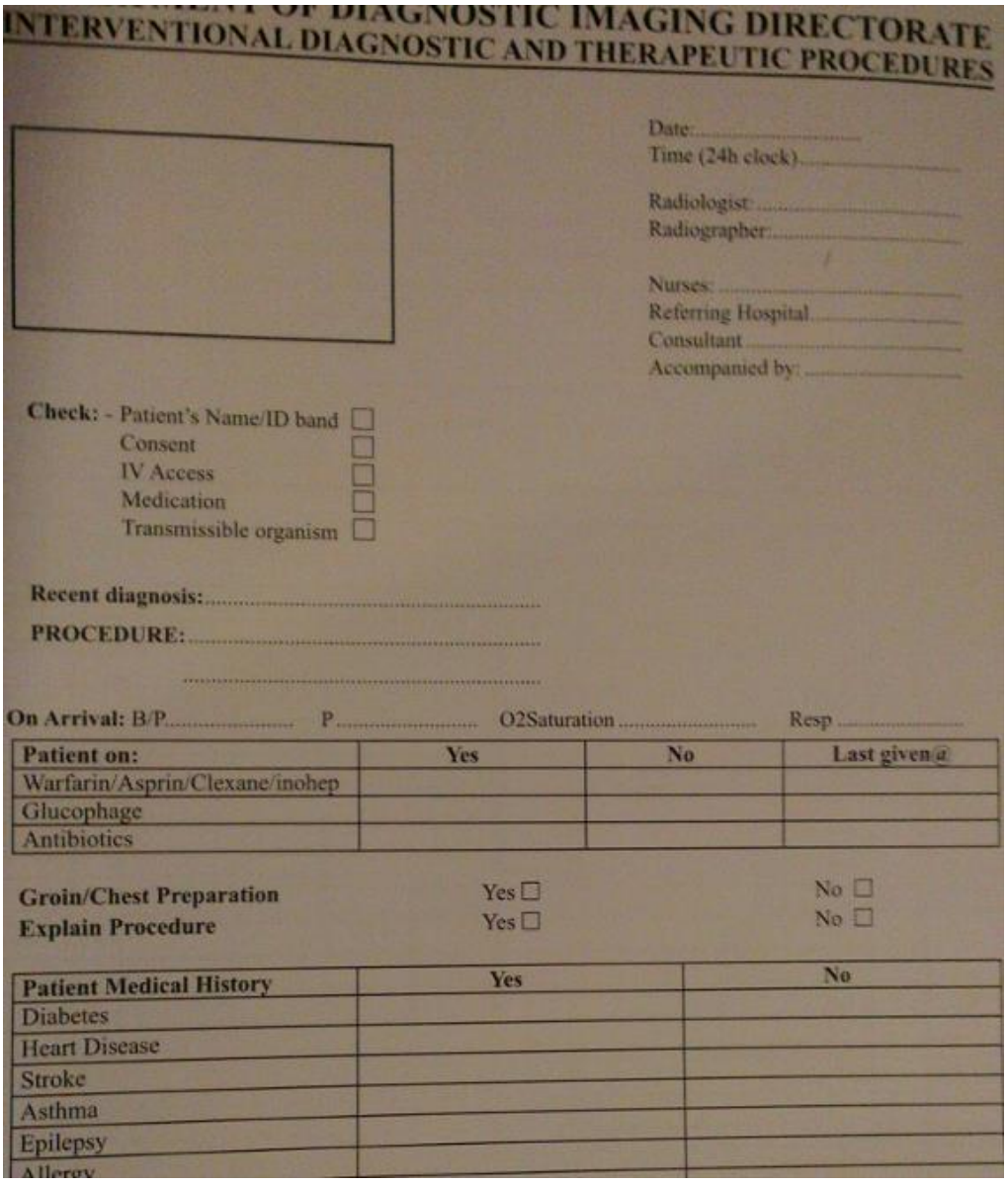
The research will briefly describe the current workflow and paper documentation which contains elements of safety checking. The process of refining and adapting the checklist content for local practice will be also described. Thereafter the design and construction of the software application will be discussed in terms of the requirements elicitation and the software development methodology, including prototyping, wireframes, deliberate usability engineering, and usability testing. Finally the pilot study and study findings concerning the evaluation of the app's usability, acceptance among clinicians, and the tablet's suitability to the clinical environment will be discussed.

1.2 Background

Safety checks are routinely completed before procedures start in the IR room, and the breast clinic. In IR safety checks are documented on a paper form upon the patient's arrival in the IR room together with their paper chart. The breast clinic serves the outpatient community, and safety checks are completed verbally from memory with walk-in patients and are not documented. Breast clinic procedures are not as complex or invasive as those completed in IR. Most cases involve diagnostic procedures using mammography and ultrasound and tissue biopsies that are taken under local anaesthetic with a biopsy needle. Safety checks in the breast clinic are not documented as the patient's paper chart is not brought down from the chart room. Consent forms are scanned in and saved on the EPR.

The procedures performed in IR range in size and complexity. Bigger procedures take longer and are more complex but rarely require general anaesthetic. Upon the arrival of the patient and the patient's paper chart in the IR room, the patient is routinely asked to repeat their date of birth before they are placed on the theatre bed. In every case the most recent laboratory blood test results are sourced from the EPR using a desktop computer in the post procedure recovery room – this is sometimes done in advance of

the patient's arrival. These laboratory results are hand written onto the Interventional Diagnostic and Therapeutic Procedures form as shown in Figure 1.1. A nurse asks the patient about each item on the 'Patient Medical History' section. Other safety checks present on the form such as whether consent has been given, and whether they have taken anti-coagulant medication within the last 24 hours are discussed with the patient and written in by the nurse.



DIAGNOSTIC IMAGING DIRECTORATE
INTERVENTIONAL DIAGNOSTIC AND THERAPEUTIC PROCEDURES

Date:
Time (24h clock):
Radiologist:
Radiographer:
Nurses:
Referring Hospital:
Consultant:
Accompanied by:

Check: - Patient's Name/ID band ☐
Consent ☐
IV Access ☐
Medication ☐
Transmissible organism ☐

Recent diagnosis:
PROCEDURE:

On Arrival: B/P..... P..... O2Saturation ..... Resp .....

Patient on:	Yes	No	Last given@
Warfarin/Asprin/Clexane/inohep			
Glucophage			
Antibiotics			

Groin/Chest Preparation Yes ☐ No ☐
Explain Procedure Yes ☐ No ☐

Patient Medical History	Yes	No
Diabetes		
Heart Disease		
Stroke		
Asthma		
Epilepsy		
Allergy		

Figure 1.1: Study Site - Interventional Diagnostic and Therapeutic Procedures Paper Form

During the procedure nursing observations are captured on the same form along with detail of all administered medications. Once the procedure is completed either the

Specialist Registrar (SpR) training with the consultant radiologist, or the consultant radiologist themselves will write in post procedure orders and sign any verbally prescribed medications required during the procedure. Upon completion all clinicians sign the form. This form then becomes part of the patient's paper chart.

Thus, while the safety checking is being done routinely

- It is done verbally from memory in breast service, and not documented.
- IR checklist content is dispersed through the documentation.
- The paper format requires the manual transcription of laboratory results from a screen which could lead to errors.
- Safety check items or questions are completed independently by various personnel in the team rather than together with everyone's attention.
- The paper format makes it difficult and expensive to analyse or report on the data of safety checks captured over a selection of patients or timeframe.
- The paper format means that it is not possible to easily update the list of the checklist items quickly or cheaply, as paper forms are purchased in bulk.
- Paper forms can only exist in one physical location, and may get lost.
- Finally it is not possible to easily complete audits on whether the checklists were completed as each form is filed away in the patient's paper chart in the chart room.

The WHO safety checklist was designed to be generic enough to be applicable to all types of surgery and requires the attention and participation of certain members of the clinical team during particular phases while it is being completed. The checklist was published together with an implementation manual which describes the recommended team interaction, and details the motivation for each task.(WHO 2009a)

A case of wrong site surgery in the Republic of Ireland in 2008 prompted the National Hospitals Office (NHO) of the HSE to instruct all HSE acute hospitals to implement a correct site surgery policy. The WHO checklist was provided for guidance. Further incidents of wrong site surgery were reported after this instruction suggesting that some hospitals may not have such polices, or were not adhering to them. The *Final Audit*

Report of the Quality & Patient Safety Audit competed in 2011 by the HSE noted that literature indicates that "many hospitals are already undertaking most of the processes on the checklist" in perioperative nursing documentation, "but may not be reviewing them as a team." (Keane and McHale 2011)

Areas of non-compliance with the hospital's correct site surgery policy discovered during the HSE audit included the completion of documentation. The audit also found that the responsibility for initiating and documenting the safety policies were seen as purely a nursing responsibility. Some surgeons interviewed during site audits considered the process to be too time consuming and excessive. The *Final Audit Report of the Quality & Patient Safety Audit* reported that international evidence indicates that correct site surgery policy effectiveness depends on teamwork, communication, resources, feedback and audit (Keane and McHale 2011). In response to the audit, the *National Policy for Patient Safety* was published in July of 2013 which enforces the use of surgical safety checklists in Ireland, (*National Policy and Procedure for Safe Surgery* 2013) and annual audits.

While the *Final Audit Report of the Quality & Patient Safety Audit* specifically discussed surgical safety checklists, the observation that pre-procedural safety checking is dispersed throughout perioperative nursing documentation rather than being a concise separate checklist holds true for the IR department at the study site. Also, as noted by the audit report, safety checks are being completed largely by nurses in IR and the breast clinic at the study site.

While the *National Policy for Patient Safety* explicitly excludes IR procedures, it states that IR will be addressed separately in a forthcoming policy. An audit of checklist completion would be time consuming and expensive when attempting to collect that data from multiple paper records. An electronic app may address some the limitations of paper checklists, i.e. that checklists are reported by clinicians as being too extensive and may contain undetected redundant information; that documentation is only attended to by nurses; that checklists are difficult or expensive to update, that adherence to policy is difficult to report on or audit; and that the paper form can only exist in one place, and may be lost.

1.3 Research Question and Study Aims

The research questions for this study are:

1. How might pre-procedural safety checks be supported by an app?
2. How acceptable and usable would such an app be to clinicians using it within a clinical workflow?
3. How suitable would a tablet device be within a clinical workflow?

The aims of this study are to:

1. Design and build a user-friendly checklist app that meets the requirements of the clinicians in IR and the breast clinic.
2. Evaluate the usability of the app and whether it was accepted by clinicians.
3. Evaluate the suitability of the tablet device for use in a clinical environment.

1.4 Overview of the Research

The research questions were addressed through a series of activities:

1. First a literature review was conducted to understand the origin and evolution of clinical safety checklists, and to establish the state of the art in electronic checklist applications and their usability and acceptance among clinicians.
2. The adaptation of the CIRSE checklist content to be more suitable to local practice by participant clinicians.
3. The requirements elicitation, design and construction of the app using an agile software methodology, prototyping and wireframes, and usability testing.
4. Training of study participants in the use of the app.
5. The quantitative evaluation of the use of the app during a month long pilot study in the IR room and breast clinic at the study site.
6. The quantitative and qualitative evaluation of the usability and acceptance of the app, and the suitability of the tablet device among clinicians after 21 days of use through semi structured exit interviews, usability surveys and a 2 week period of observation.

7. The quantitative evaluation of the target population's exposure to and habitual use of touch devices and their experience of using safety checklists, by means of a survey.

1.5 Overview of the Dissertation

This chapter has presented the motivation for the research, the research question and objectives and an overview of the research.

Chapter 2 provides the literature review. The chapter is laid out in two sections, the first section i.e. the checklist section, covers the literature concerned with checklists. The second section introduces literature concerned with the methodological aspects of the study: namely case study research methodology, the eXtreme Programming (XP) software development methodology and usability engineering. The checklist section first addresses the introduction of surgical safety checklists. It then looks at whether checklist use is enforced in international health legislation. This is followed by an overview of the development of electronic checklists implementations as present in the literature with attention being paid to the hardware and software used, the user interaction and design, the acceptance of the implementation among clinicians and the effectiveness of the implementation. A brief look is taken into the availability of checklist apps published in app stores, and the falling cost of tablet devices, particularly Android devices. The methodological section introduces the case study methodology and the XP software development methodology, and describes the motivation for choosing XP for this research project. Finally prototyping, wireframes, usability engineering and the Android platform design conventions are introduced.

Chapter 3 presents the design of the research study, which is an explorative case study using a mixed methods approach into the design and evaluation of an electronic checklist app used on a tablet device. It describes the study site and the design of the pilot study which trialled the app in clinical use for a month in two departments at the study site and explains how the resulting quantitative and qualitative data sets were collected. It then outlines the analysis, data triangulation, and validity procedures that were carried out. The chapter also explains the rationale for using this design to answer the research questions.

Chapter 4 presents the detailed results of the study, describing the rationale for selecting the hardware and software used to implement and use the app. It describes the checklist content adaption to local practice, and the results of the web survey sent to clinicians involved in radiological procedures nationally. It then discusses the design and iterative development of the app and the associated usability testing and inspections. Thereafter it describes the findings from the period of observation and the examination of the electronic data collected during use. The quantitative analysis of the SUS usability survey is then presented. The chapter goes on to discuss the themes that emerged from the semi structured exit interviews among the clinicians involved during the pilot study. Finally, the physical condition of the tablet devices is examined as at conclusion of the pilot study.

Chapter 5 discusses the results, how they address the research questions, and the significance of the results.

Chapter 6 concludes the dissertation, and identifies the strengths and limitations of the study. It then discusses the potential for the use of tablet devices and checklist apps within the clinical environment and makes recommendations for future research.

Chapter 2 State of the Art

2.1 Introduction

A literature review is the examination of existing and relevant literature concerning the research topic which helps to orientate the current study in terms of what is already known about the subject matter, and provides direction for future research by uncovering what is yet unknown ('Analyzing the Past to Prepare for the Future: Writing a Literature Review' 2002). It is the methodical thorough investigation of existing literature within the area of interest which produces the basis and motivation for the current research (Jesson and Lacey 2006).

A study of peer reviewed literature was conducted with the following goals in mind

1. to develop an understanding of a number of aspects to the area of clinical safety checklists, namely
    a. to understand the origin of surgical and other clinical safety checklists;
    b. to understand whether use of such checklists is mandatory in health policy both internationally and in Ireland;
    c. to review the advancements made in the development of electronic checklists in terms of the usability and acceptance among clinicians, and the hardware and software used;
    d. to review guidelines for designing checklists and implementing them within the clinical workflow; and
    e. to investigate whether checklist apps have been published in app stores
2. to gain understand the trends in the cost and market penetration of tablet devices
3. to understand how to successfully implement XP as a software development methodology, and effectively incorporate usability engineering, and
4. to investigate how to conduct a rigorous explorative case study within the Software Engineering domain

As stated above, a literature review familiarises the researcher with the most recent discoveries in the research area. Two general areas were explored. The first (Section 2.3 to Section 2.8) covers the area of safety checklists, and the second section (2.9 to 2.11) covers areas relating to methodological aspects such as the case study research methodology, the XP software development methodology; prototypes, wireframes, usability engineering and Android developer conventions.

Articles in relation electronic safety checklists in clinical settings were reviewed with a particular focus on usability, the reported acceptance among clinicians, the suitability of the device for use in working clinical environments, and the hardware and software used. Checklist effectiveness in preventing errors when compared to paper checklists was also of interest.

2.2 Search Strategy

The key words used in the literature search included *surgical, safety, implement, checklist, eXtreme programming, prototype, wireframe, usability engineering, case study.* The word *electronic* and its synonyms: *digital, computerized,* or *computerised,* were used together with a combination of the following key words; *implement*, *surgical, checklist, safety, tool* when researching the state of the art in electronic safety checklists. Publications were limited to those written in English and in some cases French where a translated abstract was available. A time frame was specified where possible from 2000 – 2013.

The following database searches were used*, Proquest, Sage Journal Online, ScienceDirect, SpringerLink and Trinity College Dublin's Library online Stella Search*. The following journals were used; *International Journal of Risk & Safety in Medicine, New England journal of medicine, American Association of Nurse Anaesthetists Journal, Surgical endoscopy, Annales Francaises d'Anesthesie & de Reanimation, BMJ quality & safety, Journal of Management Information Systems, Strategic Management Journal, Anesthesia & Analgesia, Pharmacy Education, Cardiovascular and interventional radiology, Quality and Safety in Health Care, Archives of Surgery, Surgery, Canadian Journal of Surgery, Patient Safety in Surgery, Canadian Medical Association journal, Critical care nursing quarterly, Journal of the Royal Society of Medicine (JRSM short*

reports), Administrative science quarterly, Engineering Letters, Empirical Software Engineering, MIS quarterly, MIS Quarterly & The Society for Information Management.

The following web search engines were used; *Google*, and *Google Scholar.* Relevant articles were also selected from citations and references from reviewed literature or articles. The total results of the table below (Table 2.1) refers to the total number of articles found for the checklist section of the literature review. The articles and resources used for the methodological section of the literature review are not listed in the table below due to the very high volume of articles concerning case study methodology, XP and usability engineering. The relevant articles as selected for the checklist and methodological section and will be described below.

Table 2.1 Summary of articles identified during the literature search

Database (s)	Keywords	Total Results
TCD Stella search	digital surgical checklist	2295
Google Scholar	digital surgical checklist	About 10000
TCD Stella search	surgical safety checklist AND electronic OR computerised OR computerized	324203
TCD Stella search	implement electronic surgical checklist	2462
Google Scholar	implement electronic surgical checklist	About 20100

For the checklist section, articles mentioning electronic patient safety checklists seemed very scarce. This could be due to the ambiguity around the meaning of the words "tool", and "implement" as understood in the information technology (IT) field as opposed to the medical field. In IT “tool” may refer to a software artefact rather than a cognitive artefacts. Inconsistent use of the terms "electronic", "digital", and "computerised" was also encountered. Within the clinical space there is also ambiguity around the concept of a “checklist” with electronic checklists being developed for various clinical objectives besides surgical safety.

The scarcity of articles about electronic safety checklists could also be due to the fact that the WHO promotion of checklist use in surgical settings is a recent development. The WHO surgical safety checklist pilot study ended late in 2008 and the first journal

articles describing the successes of this pilot, which used paper checklist documents and posters, were published early in 2009 (Haynes *et al.* 2009). Electronic implementations of surgical safety checklists would have been developed in response to these publications which could explain the limited number of published studies to date. It was interesting to discover that the United States Food and Drug Administration (FDA) Anaesthesia Apparatus Checkout Recommendations checklist was implemented in 2000, eight years before the WHO Surgical safety challenge, and featured a design based on aviation flight safety checklists (Blike and Biddle 2000).

Books on surgical safety were reviewed and selected if surgical safety checklists were mentioned. The Republic of Ireland's Department of Health and HSE websites were also reviewed for audits of patient safety or policies addressing the use of surgical safety checklists in Ireland. Searches continued on an ongoing basis in an effort to identify unpublished work. The searches of databases and journals continued using the selected keywords and continued up until the submission date in an attempt to expand the initial searches and literature review. Not all of the articles reviewed were deemed relevant or suitable for this dissertation. The inclusion criteria for selecting articles from the reviewed literature included current articles in relation to: electronic pre-procedural patient safety checklists and checklist implementation. A total of 29 articles, books, government policy publications and audit reports were deemed suitable for the study of electronic checklists for this dissertation.

For the methodology section which included articles and resources about case study research methodology, the XP software development methodology, usability engineering, quantitative statistical analysis and Android developer convention resources a further 26 resources were used.

The first section will discuss the origin and development of clinical patient safety checklists.

2.3 Origin of clinical patient safety checklists

The origin of clinical patient safety checklists section will give a brief introduction and background to the adoption of checklists to improve patient safety in clinical environments.

As stated in section 1.1 safety checklists are used in aviation as memory aids and were developed by pilots in the United States Air Force when the complexity of the prototype Boeing B-17's controls and the many flight checks required before take-off led to the death of one of the most highly trained and experienced flight instructors testing the aircraft during World War II. By forgetting to perform one small action of the complex series of actions required during take-off, he inadvertently caused the aircraft to crash killing all on board. His colleagues felt that the vastly superior Boeing aircraft could still be used and developed a checklist as a memory aid to remind themselves of the checks required on take-off. As a result the aircraft was successfully used to great effect in World War II bombing campaigns, and the checklist became a fundamental safety standard in aviation (Gawande 2011).

Gawande (2011) asserts that the problem of 'extreme complexity' is not particular to aviation and is increasingly problematic in the medical field. The consequence of this complexity in the high-stress, life-critical field of surgery is the occurrence of avoidable medical error, and deviations from known best practice. Errors and deviations that occur due to omission or commission – i.e. such as forgetting to administer an antibiotic 60 minutes prior to incision, or incorrectly identifying the patient, procedure or procedure site when performing an operation.

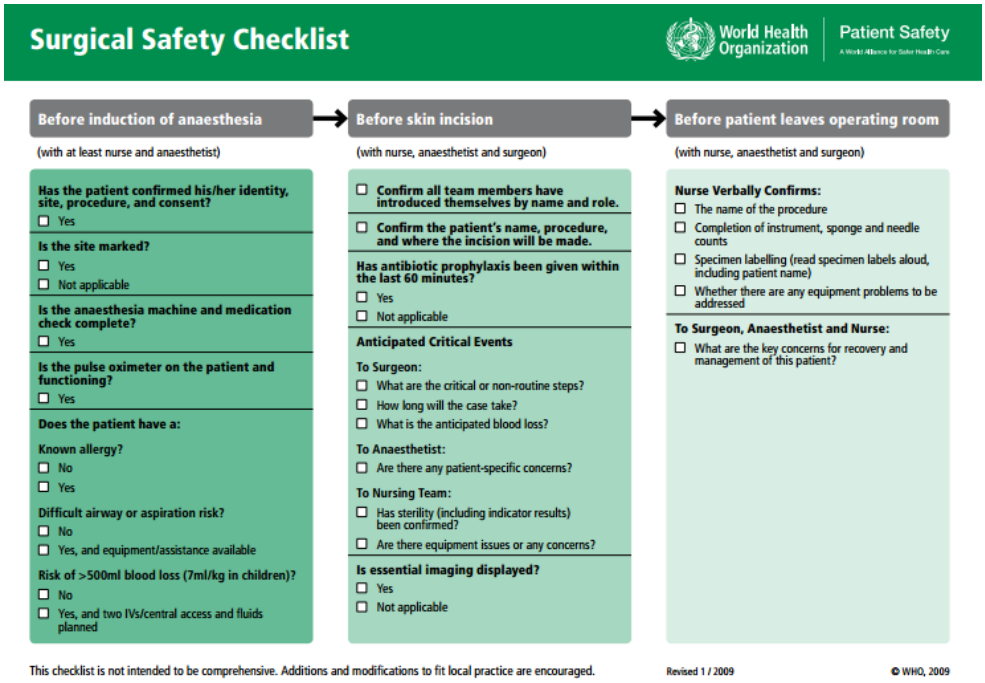
2.3.1 Joint commission

The Joint Commission (JC) – formerly known as the Joint Commission for the Accreditation of Health Organisations (JCAHO) - created the 'Universal Protocol' in 2004, which was a series of recommended checks which were to be performed before every surgical procedure in order to ensure that the correct procedure was being performed on the correct patient in the correct site or area of the patient's body. While the checks were effective, the Institute of Medicine (IOM) did not find the impact of the protocol

to have sufficient effect in lowering the rates of complication and death. (Eric Weiss and Corning 2012)

2.3.2. The WHO Checklist

The WHO extended the Universal Protocol in 2008 by introducing a checklist ('Safe Surgery Saves Lives: The Second Global Patient Safety Challenge: Safe Surgery Saves Lives Launch Event' 2008*)* which included antibiotic administration and team briefing as well as discussion around anticipated blood loss or known allergies. The checklist is intended to be brief, take no more than a few minutes to complete and was published together with an implementation manual which describes the recommended mechanism of use. The '*Safe Surgery Saves Lives Challenge*' aims to improve patient safety and reduce avoidable complications, morbidity and mortality. The checklist was designed to be generic enough to be applicable to all types of surgery, and was modelled on the deliberately concise checklists used in aviation. Extension or adaptation to the local hospital practice was encouraged (Weiss and Corning 2012). Evaluation of the effectiveness of the checklist in 8 hospitals of varying economic bands in 8 cities around the world found the rate of death fell from 1.5% before the checklist was introduced to 0.8% afterward (P=0.003). Inpatient complications which had occurred in 11.0% of patients only occurred in 7.0% after introduction of the checklist (P<0.001). *(Haynes et al.* 2009)



Surgical Safety Checklist

World Health Organization | Patient Safety

Before induction of anaesthesia → **Before skin incision** → **Before patient leaves operating room**

(with at least nurse and anaesthetist) | (with nurse, anaesthetist and surgeon) | (with nurse, anaesthetist and surgeon)

Has the patient confirmed his/her identity, site, procedure, and consent?
- ☐ Yes

Is the site marked?
- ☐ Yes
- ☐ Not applicable

Is the anaesthesia machine and medication check complete?
- ☐ Yes

Is the pulse oximeter on the patient and functioning?
- ☐ Yes

Does the patient have a:

Known allergy?
- ☐ No
- ☐ Yes

Difficult airway or aspiration risk?
- ☐ No
- ☐ Yes, and equipment/assistance available

Risk of >500ml blood loss (7ml/kg in children)?
- ☐ No
- ☐ Yes, and two IVs/central access and fluids planned

- ☐ **Confirm all team members have introduced themselves by name and role.**
- ☐ **Confirm the patient's name, procedure, and where the incision will be made.**

Has antibiotic prophylaxis been given within the last 60 minutes?
- ☐ Yes
- ☐ Not applicable

Anticipated Critical Events

To Surgeon:
- ☐ What are the critical or non-routine steps?
- ☐ How long will the case take?
- ☐ What is the anticipated blood loss?

To Anaesthetist:
- ☐ Are there any patient-specific concerns?

To Nursing Team:
- ☐ Has sterility (including indicator results) been confirmed?
- ☐ Are there equipment issues or any concerns?

Is essential imaging displayed?
- ☐ Yes
- ☐ Not applicable

Nurse Verbally Confirms:
- ☐ The name of the procedure
- ☐ Completion of instrument, sponge and needle counts
- ☐ Specimen labelling (read specimen labels aloud, including patient name)
- ☐ Whether there are any equipment problems to be addressed

To Surgeon, Anaesthetist and Nurse:
- ☐ What are the key concerns for recovery and management of this patient?

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged.

Revised 1 / 2009

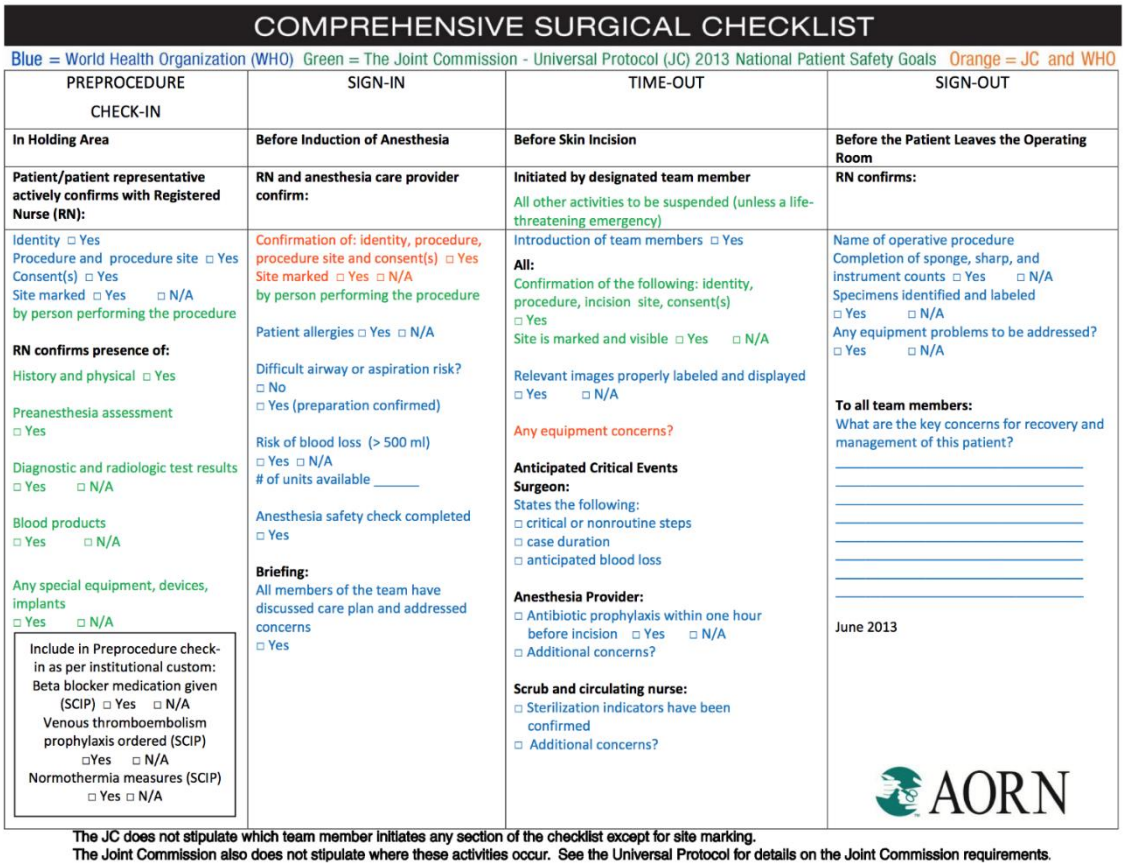
Figure 2.1: WHO Surgical safety checklist

Source: http://www.who.int/patientsafety/safesurgery/en/index.html

The WHO surgical safety checklist as shown in Figure 2.1 contains three phases of checks, each detailing the tasks to be performed before induction of anaesthesia ('Sign In'), before skin incision('Time Out'), and before the patient leaves the operating room ('Sign Out'), respectively.

2.3.3 The AORN comprehensive checklist

Figure 2.2 is published by the Association of perioperative Registered Nurses (AORN). The colour coded AORN checklist identifies the origin of each checklist item by means of the colour code: blue for the WHO checklist, green for JC Universal Protocol, and orange for items held in common. Note that this checklist has four phases. It introduces a 'Pre-procedure Check-in' phase prior to the 'Sign-in', 'Time-out' and 'Sign-out' phases of the WHO checklist in Figure 2.1.



COMPREHENSIVE SURGICAL CHECKLIST

Blue = World Health Organization (WHO) Green = The Joint Commission - Universal Protocol (JC) 2013 National Patient Safety Goals Orange = JC and WHO

PREPROCEDURE CHECK-IN	SIGN-IN	TIME-OUT	SIGN-OUT
In Holding Area	**Before Induction of Anesthesia**	**Before Skin Incision**	**Before the Patient Leaves the Operating Room**
Patient/patient representative actively confirms with Registered Nurse (RN):	**RN and anesthesia care provider confirm:**	**Initiated by designated team member** All other activities to be suspended (unless a life-threatening emergency)	**RN confirms:**
Identity □ Yes Procedure and procedure site □ Yes Consent(s) □ Yes Site marked □ Yes □ N/A by person performing the procedure **RN confirms presence of:** History and physical □ Yes Preanesthesia assessment □ Yes Diagnostic and radiologic test results □ Yes □ N/A Blood products □ Yes □ N/A Any special equipment, devices, implants □ Yes □ N/A Include in Preprocedure check-in as per institutional custom: Beta blocker medication given (SCIP) □ Yes □ N/A Venous thromboembolism prophylaxis ordered (SCIP) □Yes □ N/A Normothermia measures (SCIP) □ Yes □ N/A	Confirmation of: identity, procedure, procedure site and consent(s) □ Yes Site marked □ Yes □ N/A by person performing the procedure Patient allergies □ Yes □ N/A Difficult airway or aspiration risk? □ No □ Yes (preparation confirmed) Risk of blood loss (> 500 ml) □ Yes □ N/A # of units available _____ Anesthesia safety check completed □ Yes **Briefing:** All members of the team have discussed care plan and addressed concerns □ Yes	Introduction of team members □ Yes **All:** Confirmation of the following: identity, procedure, incision site, consent(s) □ Yes Site is marked and visible □ Yes □ N/A Relevant images properly labeled and displayed □ Yes □ N/A Any equipment concerns? **Anticipated Critical Events** **Surgeon:** States the following: □ critical or nonroutine steps □ case duration □ anticipated blood loss **Anesthesia Provider:** □ Antibiotic prophylaxis within one hour before incision □ Yes □ N/A □ Additional concerns? **Scrub and circulating nurse:** □ Sterilization indicators have been confirmed □ Additional concerns?	Name of operative procedure Completion of sponge, sharp, and instrument counts □ Yes □ N/A Specimens identified and labeled □ Yes □ N/A Any equipment problems to be addressed? □ Yes □ N/A **To all team members:** What are the key concerns for recovery and management of this patient? _____ _____ _____ _____ _____ _____ _____ _____ June 2013 AORN

The JC does not stipulate which team member initiates any section of the checklist except for site marking.
The Joint Commission also does not stipulate where these activities occur. See the Universal Protocol for details on the Joint Commission requirements.

Figure 2.2: AORN Comprehensive surgical checklist

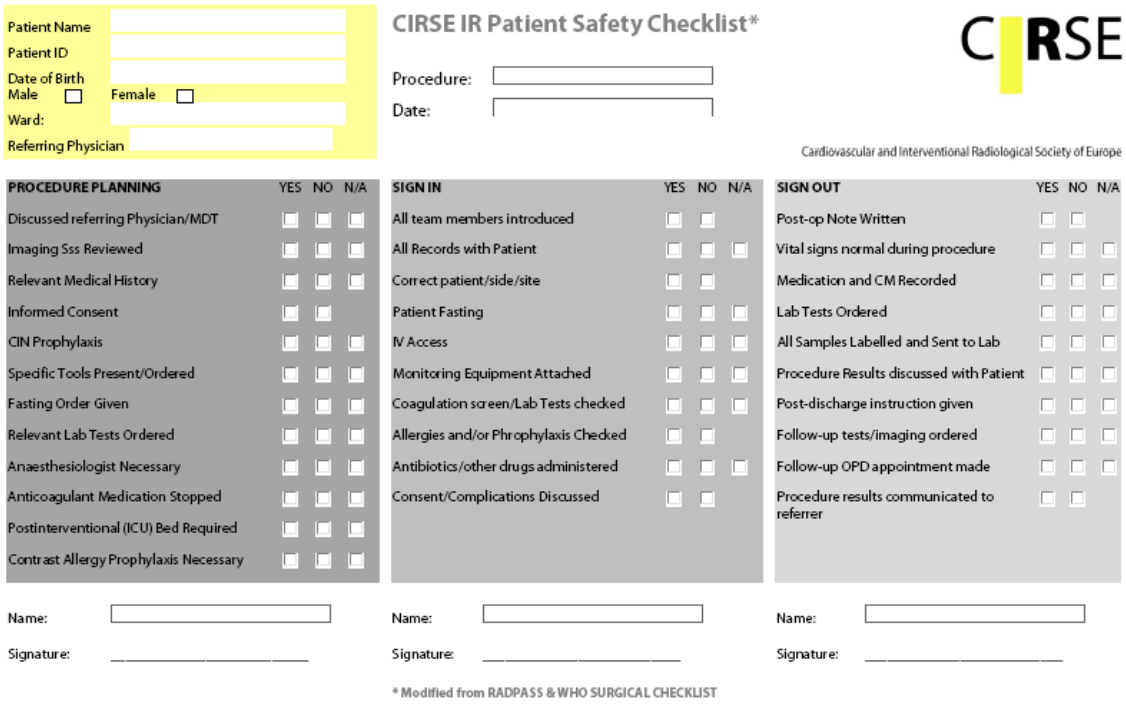
Source:

http://www.aorn.org/Clinical_Practice/ToolKits/Correct_Site_Surgery_Tool_Kit/Comprehensive_checklist.aspx

2.3.4 The CIRSE Checklist

(Lee *et al.* 2012) have published the checklist designed by the Cardiovascular and Interventional Society of Europe (CIRSE) for IR procedures as seen in Figure 2.3 below. Notice that like the WHO checklist in Figure 2.1, this checklist also has 3 phases, but that the phases begin with the phase 'Procedure planning' which is typically completed by the referring clinical team before the patient enters the room. 'Sign In', and 'Sign Out' are completed once the patient is in the room. This is in contrast to the 'Sign In', 'Sign Out', and 'Time Out' phases of the WHO checklist which all take place once the patient has arrived in the theatre for surgery. In effect the completion of the CIRSE checklist begins at the 'Procedure Planning' phase the day before the procedure rather than upon the patient's

arrival in theatre. This subtle difference became significant during the course of this research.



Patient Name
Patient ID
Date of Birth
Male ☐ Female ☐
Ward:
Referring Physician

CIRSE IR Patient Safety Checklist*

Procedure:
Date:

CIRSE

Cardiovascular and Interventional Radiological Society of Europe

PROCEDURE PLANNING	YES	NO	N/A
Discussed referring Physician/MDT	☐	☐	☐
Imaging Sss Reviewed	☐	☐	☐
Relevant Medical History	☐	☐	☐
Informed Consent	☐	☐	
CIN Prophylaxis	☐	☐	☐
Specific Tools Present/Ordered	☐	☐	☐
Fasting Order Given	☐	☐	☐
Relevant Lab Tests Ordered	☐	☐	☐
Anaesthesiologist Necessary	☐	☐	☐
Anticoagulant Medication Stopped	☐	☐	☐
Postinterventional (ICU) Bed Required	☐	☐	☐
Contrast Allergy Prophylaxis Necessary	☐	☐	☐

SIGN IN	YES	NO	N/A
All team members introduced	☐	☐	
All Records with Patient	☐	☐	☐
Correct patient/side/site	☐	☐	
Patient Fasting	☐	☐	☐
IV Access	☐	☐	☐
Monitoring Equipment Attached	☐	☐	☐
Coagulation screen/Lab Tests checked	☐	☐	☐
Allergies and/or Phrophylaxis Checked	☐	☐	
Antibiotics/other drugs administered	☐	☐	☐
Consent/Complications Discussed	☐	☐	

SIGN OUT	YES	NO	N/A
Post-op Note Written	☐	☐	
Vital signs normal during procedure	☐	☐	☐
Medication and CM Recorded	☐	☐	☐
Lab Tests Ordered	☐	☐	☐
All Samples Labelled and Sent to Lab	☐	☐	☐
Procedure Results discussed with Patient	☐	☐	☐
Post-discharge instruction given	☐	☐	☐
Follow-up tests/imaging ordered	☐	☐	☐
Follow-up OPD appointment made	☐	☐	☐
Procedure results communicated to referrer	☐	☐	

Name: Signature:

Name: Signature:

Name: Signature:

* Modified from RADPASS & WHO SURGICAL CHECKLIST

Figure 2.3: The CIRSE IR procedure checklist

Source: CIRSE http://www.cirse.org/index.php?pid=690

Thus the second phase, 'Sign In' of the CIRSE checklist was implemented in the research effort, as the app was intended to be completed in the room immediately before the procedure began.

This concludes the study of the origin and development of clinical patient safety checklists. The next section will discuss the legality of safety checklist use internationally.

2.4 Safety checklist use within the national and international context

The safety checklist use within the national and international context section will give a brief overview on whether checklist use is mandatory in the Irish and international contexts. When evaluating the usability and acceptance of the app in this study it is important to also know whether the use of checklists is optional or mandatory in clinical practice.

The WHO describes its goal when creating the surgical safety checklist as the improvement of patient safety when undergoing surgical or invasive procedures by reinforcing the consistent commitment to proven standards of care (WHO 2009b).

The use of checklists was originally a recommendation, or in the terminology of the WHO, a 'challenge.' In some countries it remains an optional tool available to surgical teams who would like to improve patient safety outcomes e.g. the United States of America (Weiss and Corning 2012). In other countries e.g. the United Kingdom (Sivathasan *et al.* 2010), France (Cabarrot *et al.* 2011), parts of Canada (*Patient Safety Indicator Public Reporting*, (2012), it has become a legal requirement either to complete certain parts of the checklist before commencing with procedures or that hospitals publish compliance statistics and audit the compliance with safety checklist policy. Surgical safety checklists became compulsory in Ireland in 2013 (*National Policy and Procedure for Safe Surgery* 2013).

2.4.1 United States of America

The JC hospital accreditation serves as a quality measure of the hospital's efforts to ensure safety for patients and staff, and most state governments in the United States require that hospitals be accredited by the commission as a condition for licensing and reimbursement by the state Medicaid (Patterson 1995) and (Jost 1994).

Weiss and Corning (2012) note that the use of WHO surgical safety checklists is not yet a requirement for hospitals seeking this JC accreditation, nor WHO surgical safety checklist use a legal requirement before surgery in the United States.

2.4.2 Canada

While the use of surgical safety checklists is not mandatory in Canada, it is mandatory that hospitals in the province of Ontario publically report on surgical safety checklist compliance. As of 28th May 2008 there is a plan to make this information publically available on a continuous basis. The *Public Hospitals Act* (PHA) regulatory amendment of 28th July 2008, requires hospitals to publicly report on certain patient safety indicators, which includes Surgical Safety Checklist Compliance (SSCC) through the

'Health Quality Ontario' website at http://www.hqontario.ca/public-reporting/patient-safety as shown in Figure 2.4 (*Patient Safety Indicator Public Reporting*, (2012).

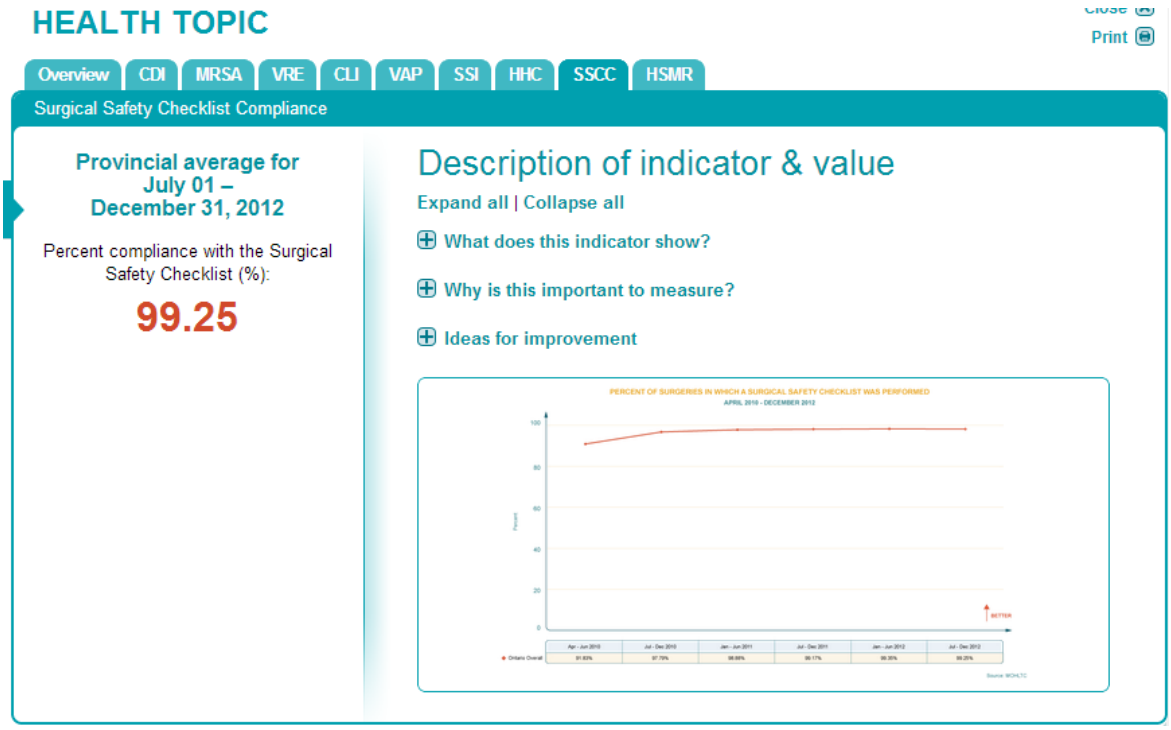


Figure 2.4: Health Quality Ontaio - Surgical Safety Checklist compliance

Source: http://www.hqontario.ca/public-reporting/patient-safety

2.4.3 United Kingdom

Mandatory preoperative safety checklist use is a legal requirement in all hospitals in the United Kingdom, as of February 2010 (Sivathasan *et al*. 2010).

2.4.4 France

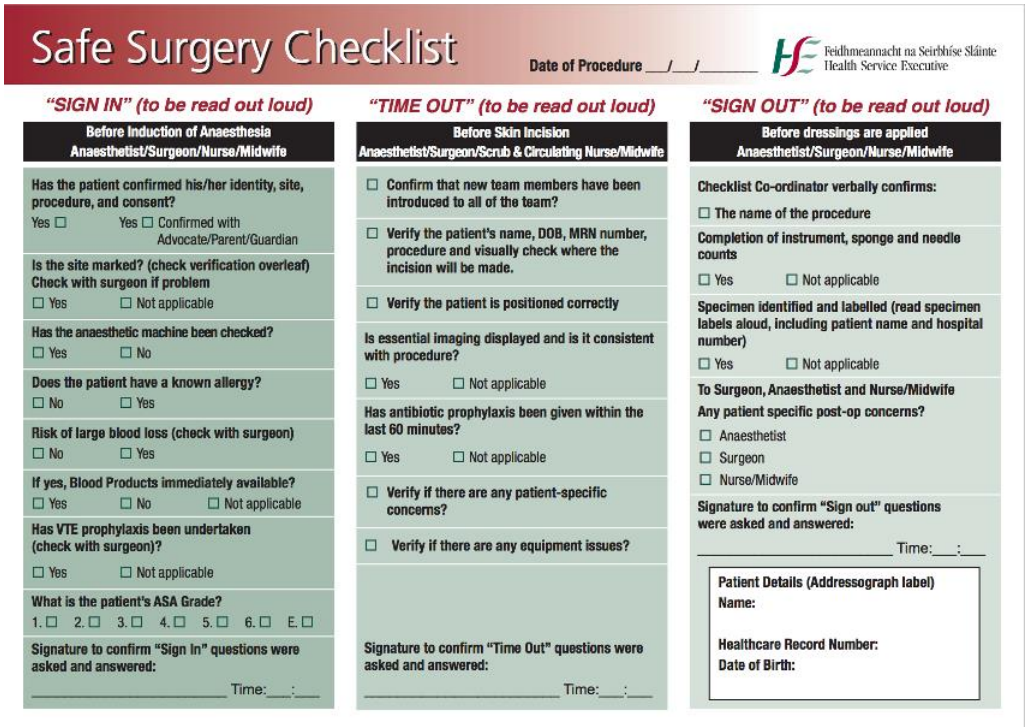
(Cabarrot *et al.* 2011) and (Fourcade *et al.* 2012) explain that the French National Authority for Health (Haute Autorité de santé, HAS) has integrated mandatory use of an adapted version of the WHO checklist into the framework of its certification process of health care organisations effective, January 1, 2010.

2.4.5 Republic of Ireland

As stated in section 1.2 repeated cases of wrong site surgery prompted the HSE to audit the adherence to correct site surgery policies (CSS) in HSE hospitals. The *Final Audit Report, of the Quality & Patient Safety Audit* of 2011 recommended that the Correct Site

Surgery guidelines be adopted and implemented nationally within twelve months at all HSE acute hospitals. The audit report concluded that "*A national approach is required in the development of a CSS policy and this should incorporate the introduction of the WHO surgical checklist as well as regular audit. Findings from local audits should be included as part of national key quality indicators for patient safety*" (Keane and McHale 2011).

In response to this audit report the *National Policy for Procedure and Safe Surgery* was published by the HSE and Royal College of Surgeons in Ireland in July 2013 which prescribes the use of a locally adapted version of the WHO Safe Surgery checklist as shown in Figure 2.5 for all patients having surgical procedures in operating theatres in Ireland. The policy applies to all staff involved in the surgical patient pathway. Details on the annual internal audit expected of hospitals (see Appendix A) to measure policy adherence are also provided. This policy excludes IR procedures, which are to be addressed in a separate policy (*National Policy and Procedure for Safe Surgery* 2013).



Safe Surgery Checklist

Date of Procedure ___/___/_____

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

"SIGN IN" (to be read out loud)

Before Induction of Anaesthesia
Anaesthetist/Surgeon/Nurse/Midwife

Has the patient confirmed his/her identity, site, procedure, and consent?
Yes ☐ Yes ☐ Confirmed with Advocate/Parent/Guardian

Is the site marked? (check verification overleaf) Check with surgeon if problem
☐ Yes ☐ Not applicable

Has the anaesthetic machine been checked?
☐ Yes ☐ No

Does the patient have a known allergy?
☐ No ☐ Yes

Risk of large blood loss (check with surgeon)
☐ No ☐ Yes

If yes, Blood Products immediately available?
☐ Yes ☐ No ☐ Not applicable

Has VTE prophylaxis been undertaken (check with surgeon)?
☐ Yes ☐ Not applicable

What is the patient's ASA Grade?
1. ☐ 2. ☐ 3. ☐ 4. ☐ 5. ☐ 6. ☐ E. ☐

Signature to confirm "Sign In" questions were asked and answered:
_____ Time:___:___

"TIME OUT" (to be read out loud)

Before Skin Incision
Anaesthetist/Surgeon/Scrub & Circulating Nurse/Midwife

☐ Confirm that new team members have been introduced to all of the team?

☐ Verify the patient's name, DOB, MRN number, procedure and visually check where the incision will be made.

☐ Verify the patient is positioned correctly

Is essential imaging displayed and is it consistent with procedure?
☐ Yes ☐ Not applicable

Has antibiotic prophylaxis been given within the last 60 minutes?
☐ Yes ☐ Not applicable

☐ Verify if there are any patient-specific concerns?

☐ Verify if there are any equipment issues?

Signature to confirm "Time Out" questions were asked and answered:
_____ Time:___:___

"SIGN OUT" (to be read out loud)

Before dressings are applied
Anaesthetist/Surgeon/Nurse/Midwife

Checklist Co-ordinator verbally confirms:
☐ The name of the procedure

Completion of instrument, sponge and needle counts
☐ Yes ☐ Not applicable

Specimen identified and labelled (read specimen labels aloud, including patient name and hospital number)
☐ Yes ☐ Not applicable

To Surgeon, Anaesthetist and Nurse/Midwife
Any patient specific post-op concerns?
☐ Anaesthetist
☐ Surgeon
☐ Nurse/Midwife

Signature to confirm "Sign out" questions were asked and answered:
_____ Time:___:___

Patient Details (Addressograph label)
Name:

Healthcare Record Number:
Date of Birth:

Figure 2.5: HSE Surgical Safety Checklist

Source:

http://www.hse.ie/eng/about/Who/qualityandpatientsafety/safepatientcare/safesurgerychecklist.pdf

This concludes the investigation into the legality of safety checklist use internationally. The next section will discuss the state of the art in electronic patient safety checklists.

2.5 The state of the art in electronic patient safety checklists

This section discusses the electronic implementations of clinical safety checklists as discovered in the literature review. The implementations reveal the progressive improvements in both the hardware and software used as well as the level of integration achieved with existing Hospital Information Systems (HIS).

2.5.1 Early implementations. Specialist hardware, specialist software, prototypes, not integrated

Blike and Biddle (2000) created an electronic safety checklist in their study, which precedes both the JC and WHO's formal introduction of clinical safety checklists as described in section 2.3 by 4 and 8 years respectively. Their creation and evaluation of the electronic FDA Anaesthesia Apparatus Checkout Recommendations checklist presented some valuable insights into the advantages of having an electronic implementation. Only 30% of prearranged machine faults were detected by users using a paper version of the checklist, where 95% of the easy and over 60% of the difficult errors were detected when using the electronic version of the checklist. Blike and Biddle (2000) acknowledge that irrespective of the format used (electronic or paper) that checklists are excellent memory aids, yet they noted that anaesthetists in the study had often relied on recall rather than referencing an actual list because they use the paper checklist repetitively.

Blike and Biddle (2000) argue that resorting to memory because of repetitive use defeats the purpose of having a check list as a memory aid, and once again allows items to be missed or forgotten. The electronic format they developed as shown in Figure 2.6 was therefore interactive, so that the check item needs to be touched or clicked to be acknowledged and thereby dismissed in order to advance to the next item. In so doing the electronic version prevents rote execution from memory, making it more resistant to human error.

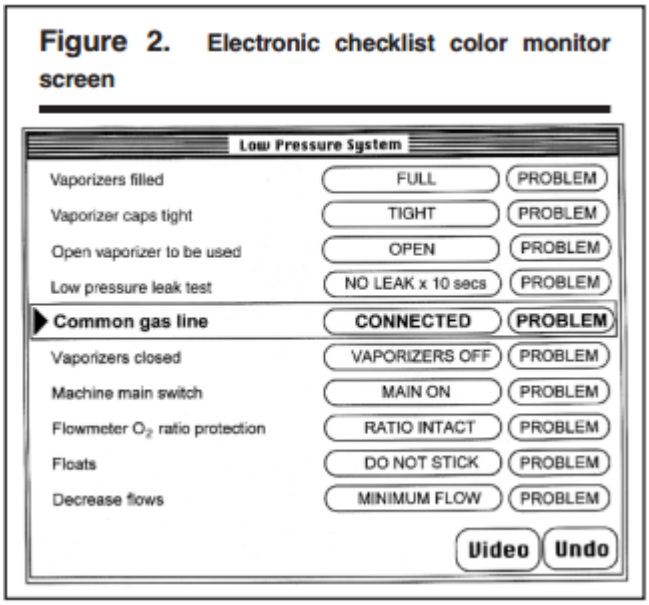


Figure 2.6: Anaesthesia apparatus checkout recommendations electronic checklist Source: (Blike and Biddle 2000)

In the checklist in Figure 2.6, progress is displayed on the screen through the use of colour or a pointer that contrasts completed and remaining steps, so that the clinician does not lose their place or skip items in the list should they need to look away momentarily. Video help features to explain checklist content were also possible in the electronic format and Blike and Biddle (2000) report they were referenced frequently.

Their study describes that the ideal mode of operation of their electronic checklist was two people would complete the checklist together, one seated at the screen reading out the items the other completing the checks and calling out an acknowledgement when done. One operator could use the checklist, but that would require that the operator walk back and forth between the checklist and the anaesthesia machine. The electronic checklist machine was not mobile and could not be carried around while completing the checks or operated remotely. The authors acknowledge that an electronic version like the one created would be expensive, and suggest that it would in time become more economical as the use of information systems became more prevalent in healthcare, or alternatively suggested that the system be integrated as a feature of the existing anaesthesia machine. The checklist was implemented using a Mactintosh Quadra 700 (Apple Computer, Inc) computer and the Prograph programming language, and was run on

a 19 inch monitor with a touch screen. It was created purely for use during the study, and it was not integrated with the existing anaesthesia machine. No information was offered as to the clinician's acceptance or experience of using the electronic checklist or whether the system would have been accepted by clinicians during actual procedures.

Hart and Owen (2005), 3 years ahead of the WHO Safe Surgery Saves Lives initiative, implemented an electronic anaesthesia checklist for the provision of general anaesthesia during caesarean delivery. This is rarely necessary due to the common use of epidural or spinal anaesthesia, and as a result there are few anaesthesiologists with experience in providing it. The checklist was built to investigate whether clinicians could be helped to prepare for such cases using a checklist as used by pilots. The device used was an EC-TS electronic programmable checklist (Aeronautical Electronics Corporation Pty. Ltd.) which has an optional voice synthesiser and a small screen which displays several lines of text as shown in Figure 2.7.

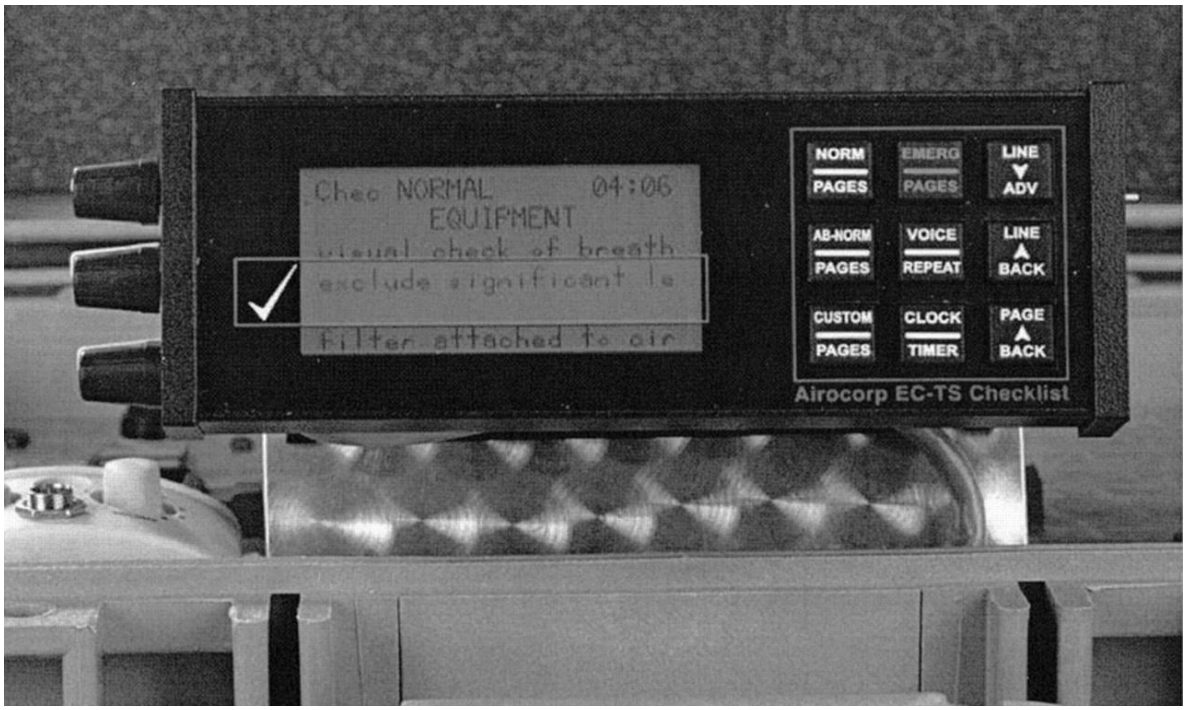


Figure 2.7: EC-TS Electronic Checklist Device

Source:(Hart and Owen 2005)

A button on the device was pressed to acknowledge the item and advance to the next item. Anaesthetic consultants and registrars were observed using a high-fidelity

anaesthesia simulator and a Laerdal SimMan 'patient' with and without the help of the checklist. The checklist was deemed useful by 95% of the participants, and 85% said they would like to use it for practicing simulated scenarios, but only 40% would have wanted to use it in real cases with many mentioning concern of it causing anxiety in patients.

The written instructions on the screen of the device were preferred over the voice play back in 60% of users, but the researchers felt that this might be due to the poor quality of speech synthesis on the device. A potential advantage to a verbal playback mechanism was that the operator need not be near the device or looking at it when the item was read out. Another interesting feature was that this device could be controlled remotely. The clinician could be free to walk around the theatre with a remote 'clicker' and advance down the list of items which were read back to him or her as the checks were completed. This would also minimise the amount of touching of the device and help with infection control. The clicker and device could be wrapped in disposable sealed containers for use in sterile environments.

2.5.2 Generic hardware, specialist software, prototypes, not integrated with HIS

The next step in the evolution of electronic surgical safety checklists was developed and tested by Buzink *et al*, (2010). Pro/cheQ was an electronic checklist that ran on a laptop computer, and was trialled in an operating room (OR). The laptop was placed on a surgical trolley in the theatre and operated by a circulating nurse.

The incidence of risk sensitive events– i.e. the events that could lead to an adverse clinical event - were counted when using 3 set ups.

Figure 2.8: The cart based OR set up

Source:

http://www.karolinska.se/upload/Innovationsplatsen/Symposium/Sonja%20Buzink%20OR%20integration%20symposium%20.pdf

a. A cart-based OR set up, as shown in Figure 2.8. The usual laparoscopic equipment was placed on a cart with a CRT monitor, and flat screen monitor attached to the side.

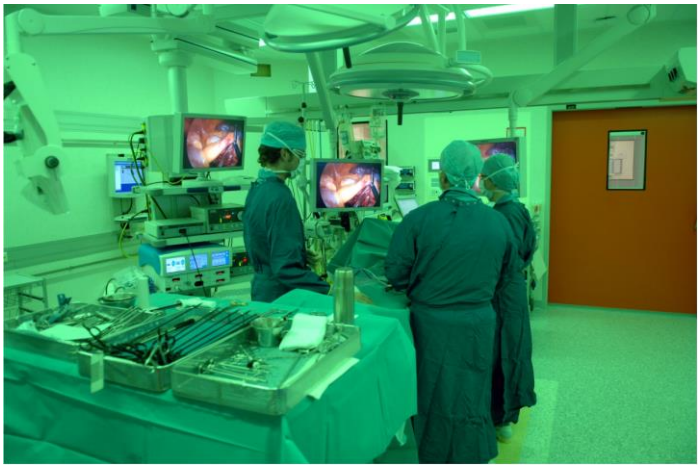


Figure 2.9: The integrated OR setting

Source:

http://www.karolinska.se/upload/Innovationsplatsen/Symposium/Sonja%20Buzink%20OR%20integration%20symposium%20.pdf

b. An integrated OR setting as shown in Figure 2.9 which featured several flat screen monitors and a Karl Storz OR touch screen.

Figure 2.10: Integrated OR setting with Pro/cheQ

Source: (Lier 2008)

c. The same integrated OR set up when used in conjunction with Pro/cheQ running on a laptop as shown in Figure 2.10

Pro/cheQ was a prototype of an electronic procedure-specific preoperative checklist running on a laptop, and did not integrate with the existing HIS. It was planned to integrate Pro/cheQ with the Integrated Operating Room software, in order to use it via the touch screen. It was operated by the circulating nurse but active participation by the entire surgical team was necessary to complete the Pro/cheQ steps. Extensive user engagement and usability testing was done when designing the Pro/cheQ user interface as seen in Figure 2.11 and training was supplied when introducing it into the workflow. It was felt that encouraging end user involvement during the development of the prototype created a sense of ownership and understanding of the value it would add to patient safety among clinicians, phenomena which Buzink *et al.* (2010) argue were crucial to the success of the project. Routine use of Pro/cheQ was proved to be feasible. It was found to support the clinical workflow in a natural way, and was found constructive by the entire surgical team.

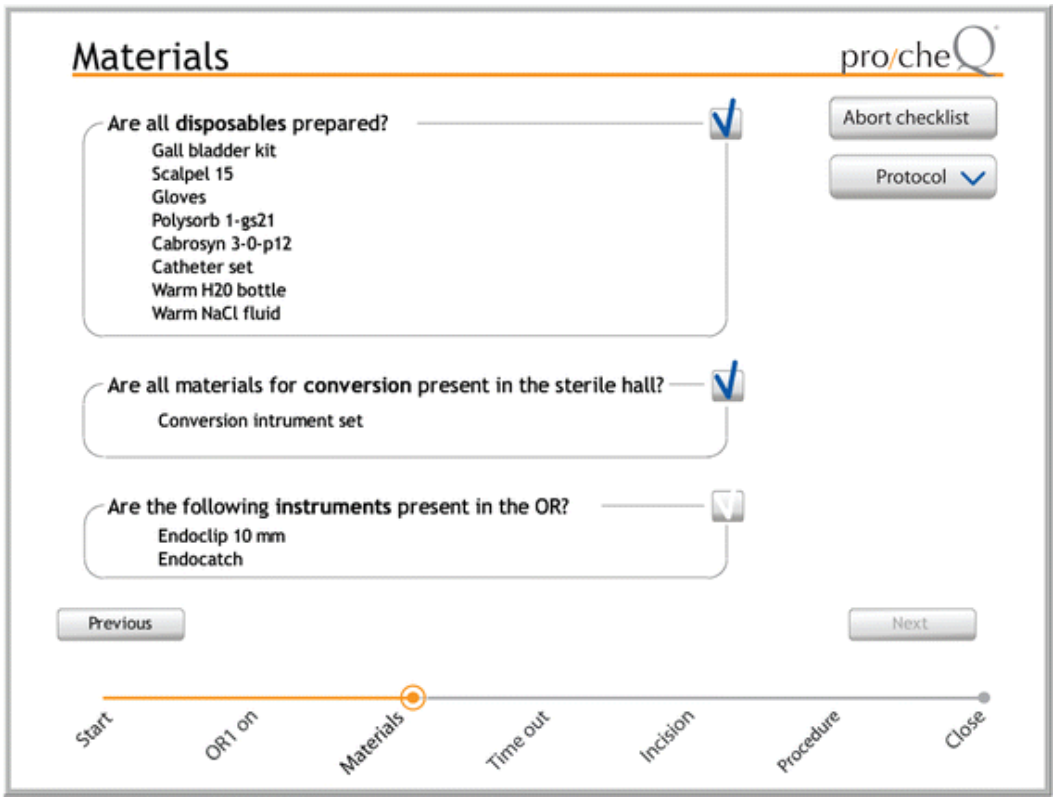


Figure 2.11: Pro/cheQ user interface

Source: http://link.springer.com/article/10.1007/s00464-010-0892-6/fulltext.html

Not only was the Pro/cheQ checklist accepted by users and found to be useful, it was also effective at reducing risk sensitive events. In the cart based OR setting and the integrated OR setting without Pro/cheQ, at least one risk sensitive event occurred in 87% of the procedures. This was reduced to 47% when using the integrated OR in conjunction with Pro/cheQ.

SURPASS using FLOWer

The most ambitious electronic implementation found in terms of scope was the initiative taken to implement a prototype of the full Surgical Patient Safety System (SURPASS) checklist using a workflow engine. SURPASS is an end-to-end multidisciplinary surgical safety checklist, beginning at preadmission and accompanying the patient all the way through to after discharge.

The objective of the (Burghouts 2010) study at the Academic Medical Centre of the University Of Amsterdam, was to explore whether an electronic version of the SURPASS

checklist which was already in use in paper format, would improve the adherence to the checklist by introducing validation rules and 'stopping rules.' In the study SURPASS was implemented in FLOWer, a workflow management system. Stopping rules were implemented as visual warnings in the system, rather than blocking errors which would prevent progression beyond the error, as requested by the clinical users.

The study found that during the testing of the prototype in a laboratory setting that the clinicians testing the system did not comply with the stopping rules, and Burghouts concluded that development of an electronic SURPASS checklist system, particularly the implementation of the stopping rules would be difficult in a live system due to the conflicting requirements of stringent controls for patient safety, and having a workable system (Burghouts 2010). Norton (2012) a registered nurse, however observes that electronic checklists can improve patient safety by prohibiting teams from skipping items, so the level of control enforced by an interactive system is an issue that should be carefully considered.

Burghouts (2010) also stresses the importance of involving end users in the development process, and the necessity for appropriate training. When the system was evaluated using the SUS Usability score it was interesting to note that managerial staff rated the system better in terms of usability than the clinical staff did (83 and 71 out of a possible 100, respectively). This highlights the importance of testing the system with a representative sample of the end users when evaluating usability. All participants saw the potential of the system and while participants did not struggle with the learnability of the system, they noted that the differing levels of technical skill among clinicians needs to be taken into account when developing a system and providing training, as well as the fact that sufficient workstations would need to be installed to make such a system workable throughout the hospital highlighting the financial implications of using electronic checklists.

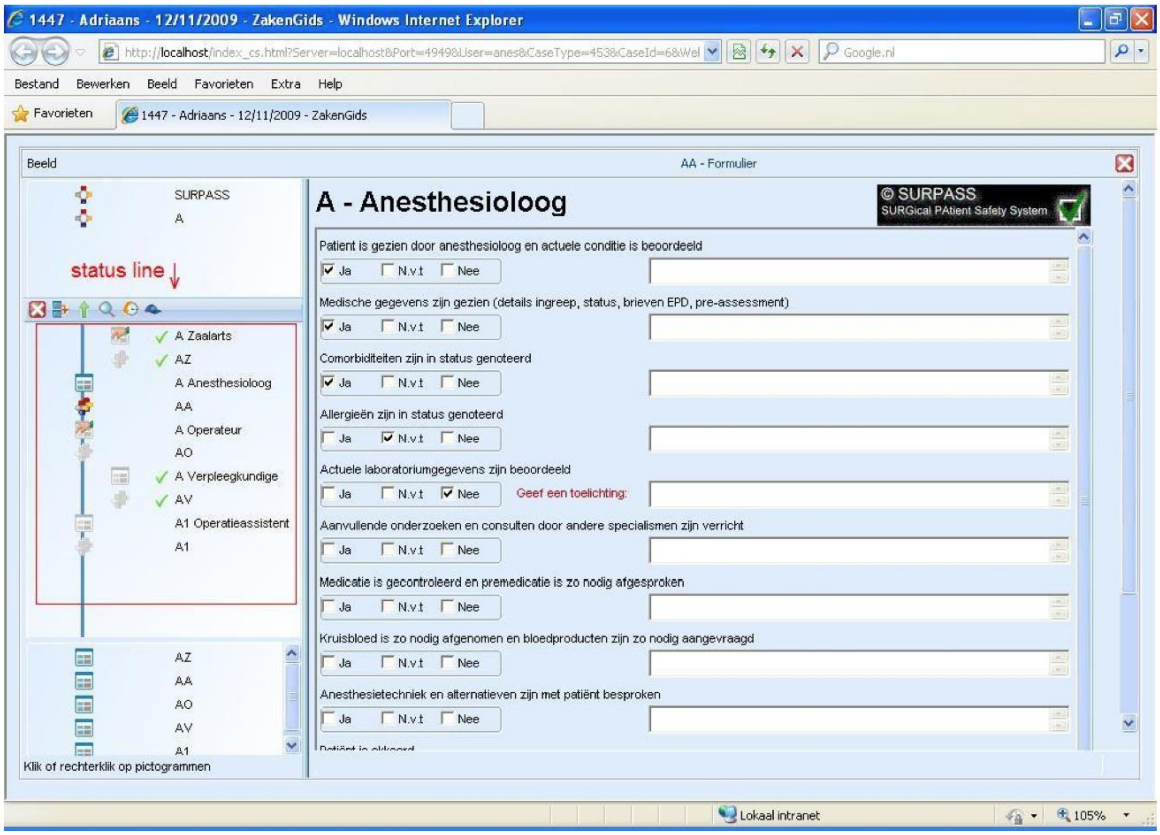


Figure 2.12: SURPASS implemented in the FLOWer workflow engine
source: (Burghouts 2010)

Also of interest was the fact that the SURPASS workflow implementation executed in a web browser as shown in Figure 2.12 and could thus be operated without specialist hardware – any device with network access and a web browser would be able to use this implementation.

2.5.3 Specialist hardware, specialist software, commercial product integrated with HIS

(Mainthia *et al.* 2012) report on the introduction of an interactive electronic checklist system (iECS) which was introduced into all surgical theatres in the study institution. All ORs were already equipped with a 40 inch LCD panel which serves as an electronic whiteboard which is visible to the entire team. The board was originally used to project static patient information throughout the procedure. Implementation of the new iECS software introduced an electronic timeout checklist with checkboxes onto this display, and as every item was completed a nurse ticked off the appropriate check item on the

operating room computer workstation. This action updated the display on the whiteboard display as shown in Figure 2.13.

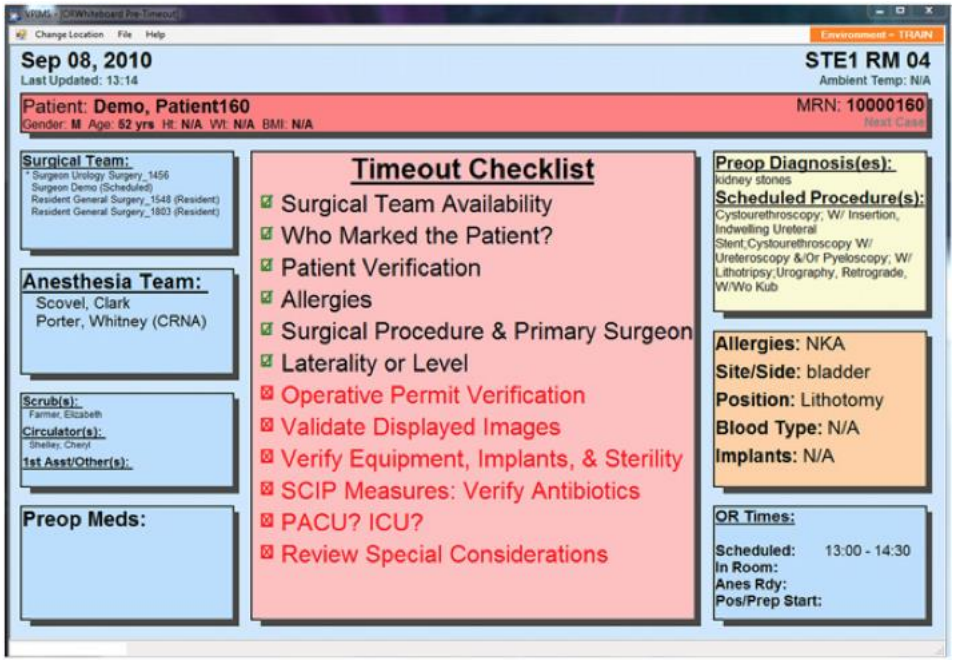


Figure 2.13: Interactive Electronic Checklist System – Whiteboard display

Source: (Mainthia et al. 2012)

Permission to conduct blinded direct observational analyses – i.e. observation of the surgical team without their knowledge by an observer who would be understood to be a student only observing the surgery - was granted by the ethics board of the hospital. 80 surgical cases were observed and scored one month before implementation, and then 160 surgical cases were similarly observed and scored after implementation at one month, and again at 9 month intervals post introduction. The study found that implementation of the iECs increased timeout compliance by 36.1%, Mean compliance with timeout items was at 85.8 +- 6.8% compliance at 9 months as compared to 81.6 +- 11.4% at one month after implementation. Mainthia *et al.* (2012) conclude that the sustained increase in timeout compliance after the iECS introduction suggests that lasting change occurred within the OR. Clinicians accepted and used the system consistently without knowledge that they were being observed, which avoided the Hawthorne effect i.e. that behaviour may change when a subject is aware that it is being observed.

The LiveData OR Dashboard discussed by Robbins (2011) extended the use of an OR dashboard display with the introduction of a remote clicker, and specialist software as shown in Figure 2.14. The clicker freed the circulating nurse from being bound to a computer work station and items could be marked as checked from anywhere within the OR.

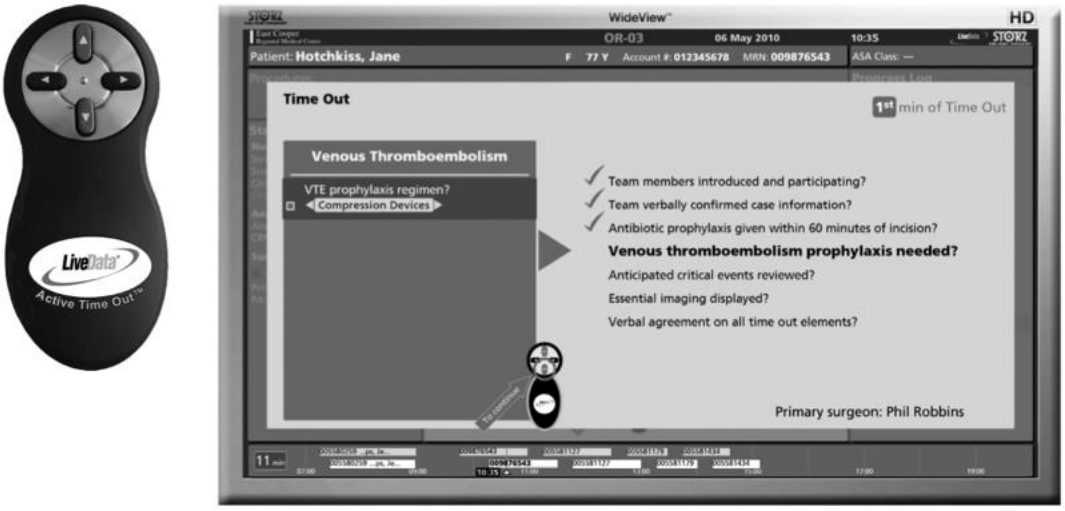


Figure 2.14: LiveData OR dashboard with 'Active Timeout'
Source: (Robbins 2011)

Staff at a hospital that had been using the LiveData OR dashboard for 4years indicated great appreciation for several of the features of the dashboard including the display of staff names and roles of everyone in the OR. This in part addressed the issues of socio or political hierarchy in the surgical theatre. The WHO Surgical safety checklist includes team introduction in order to create a better sense of teamwork and open lines of communication and to encourage team participation and a sense of responsibility among all team members during the procedure. Another valuable insight offered by Robbins is, when quoting Manoj Jain, that 'only what is measured can be improved' (Robbins 2011). Robbins notes that measuring checklist efficiency in order to improve checklist content is an essential aspect to acceptance. The ability to review and report on a series of checklists and the validity of their checklist content is possible when capturing the data electronically.

2.5.4 Conclusion

This concludes the state of the art in electronic checklist implementations discussed in the literature. The next section will discuss guidelines for the physical design of electronic patient safety checklists.

2.6 Guidelines for the physical design and successful implementation of electronic checklists

Verdaarsdonk *et al*, (2009) provide general guidelines for the design and implementation of electronic surgical checklists. Citing guidelines from the Civil Aviation Authority (CAA) and the Federal Aviation Administration (FAA), consistency, clarity and straightforwardness are identified as the most important requirements in the design, which is echoed by Gawande (2011) and the WHO implementation manual (WHO 2009a). A comparison of paper and electronic formats identifies that advantages to the electronic format include automatic update after checklist revision, the possibility to integrate with the HIS to retrieve patient demographic information and known allergies, etc. Verdaasdonk *et al* (2009) also note that multiple checklists could be created and run on a single device with the device being shared. The automatic capture of data for research purposes is also cited as a valuable feature. Guidelines from this paper will be referred to when describing the user interface design in Chapter 4.

The next section will discuss electronic checklist apps available on the Google Play and iTunes app stores.

2.7 Commercial electronic checklist apps

Applications for surgical safety checklists are already available on the Google Play store for Android devices and on the Apple iTunes app store for iOS devices. The *Surgery Safety CheckList Free* application on the Google Play store is listed as having between 1000 and 5000 installations with 5 reviews in total, with the average review score being 4.2 out of 5 and was last updated on the 27th of March 2013. (Warnock 2012) mentions the *Safe Surgery* app on iTunes, but it appears to not have been updated since 2010 and does not seem to have much activity in terms of reviews.

2.8 The affordability of tablet computers

When deciding on the type of mobile device to use for this study, the options were smaller smart phone touch devices, or larger tablet sized touch devices. Tablets were considered by the researcher to be more usable when shared by a team due to the larger screen sizes. It is also worth noting that the shipments of tablet computers is growing, see the blue line in Figure 2.15 (IDC 2013). The red line in Figure 2.15 denotes the total shipments of portable and desktop PCs. The average selling price (ASP) of tablet devices fell by 21 percent in 2012 to 386 USD (including iPad), and low end tablet devices are sold at prices below 200 USD, see Figure 2.16 (Xu 2012).

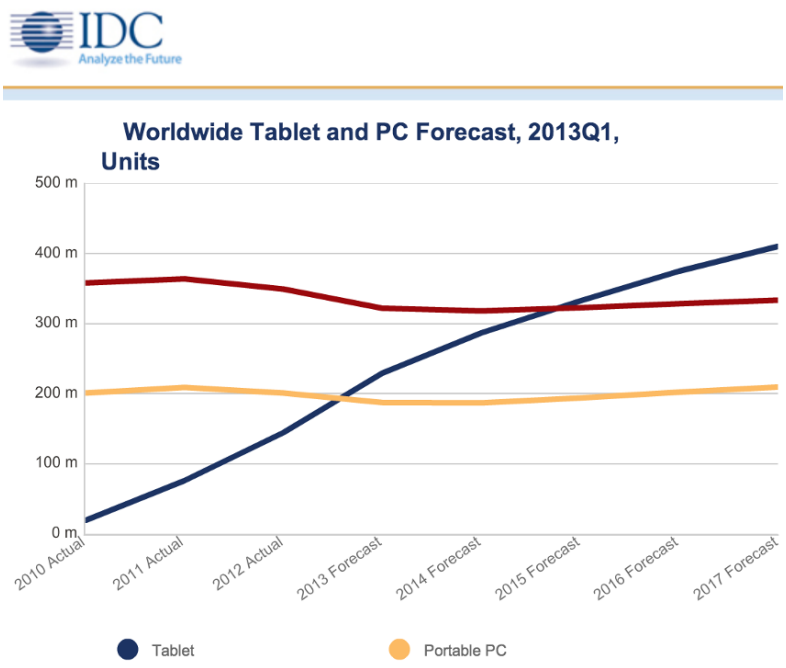


Figure 2.15: Tablet and PC sales forecast

Source: (IDC 2013)

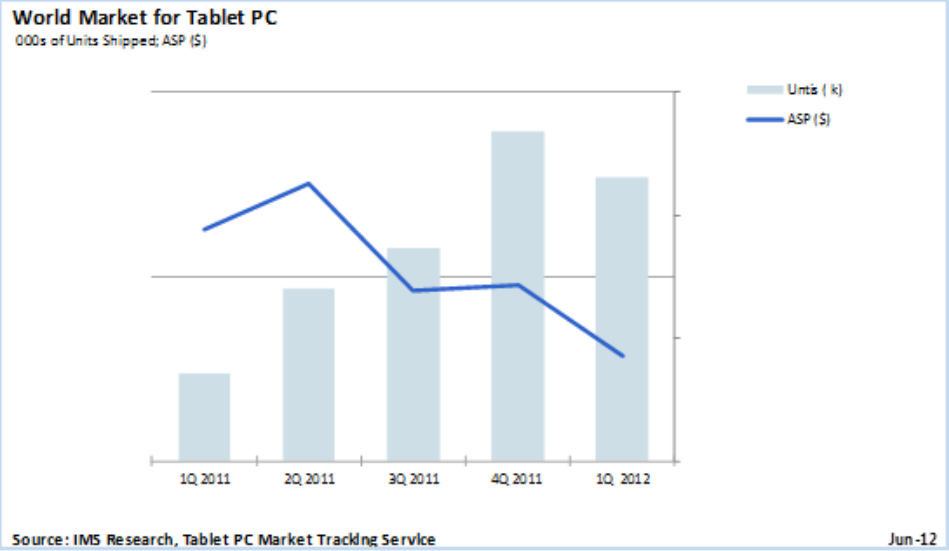


Figure 2.16: World market and sales of tablet PC

Source:(Xu 2012)

Android tablet devices are typically less expensive than iOS devices, and the Google Nexus 7 tablet released in 2013 has a 1080P High Definition display and sells for 230 USD at the time of writing. It is small enough to be held in one hand, while large enough to be shared between users in a team. The ASP of a personal computer, which is a subcomponent of Computer on wheels (COW) devices is nearly triple that at 635 USD (IDC 2013). COWs have been used in hospitals to provide a means of shareable portable computing and cost about 2000 EURO in total per device which effectively means that 10 tablets can be bought for the cost of one COW.

In summary, this section of the literature review (section 2.3 to section 2.8) discussed the origin and development of clinical checklists, and described the advances made electronic clinical checklists in terms of the hardware, software and the level of integration achieved. It was shown that pre-procedural safety checklists are legally required in France, the UK and Ireland, and that reporting on checklist compliance is required in the Canadian province of Ontario. Guidelines for checklist implementations were then introduced. Checklist apps currently available on the Google Play and iTunes stores were identified. Finally evidence for the falling cost of tablet devices and the growing forecast of tablet sales was shown.

The next three sections (2.9 to 2.11) will introduce various methodological aspects of the study, such as the XP software development methodology, wireframes, prototypes and usability engineering. Case study research will also be introduced and discussed as the research methodology used during this study.

2.9 Software development methodology and Usability engineering

2.9.1 Selected Software Development Methodology

There are many different schools of thought or development methodologies, which describe the different approaches to designing and building software products. Fruhling and De Vreede (2006) describe these in broad terms as either the traditional plan-driven methodologies, such as the Waterfall approach, or the newer development models such as the various agile approaches which include eXtreme Programming (XP).

Fruhling and Vreede (2006) describe the traditional plan-driven approaches as involving extensive upfront planning (including scheduling and time lines), codified processes (including system design and documentation), and rigorous code reuse, with system architecture and design usually completed in advance, documented and contractually agreed on prior to the commencement of the project. This approach is effective in projects where all functional requirements are known in advance, and are stable. Plan driven projects are methodical and structured and largely used in practice, but make no provision to effectively handle changing requirements and frequently overrun the project budget and schedule.

Agile approaches attempt to better manage changing requirements by scheduling the frequent production of interim software releases within the duration of the project, and explicitly manage changing requirements during development. The XP process focusses on fast iteration over multiple development cycles and makes production-ready functionality available in increments per development-cycle release-artefact see Figure 2.17. The cycle would begin by gathering scenarios or user requirements, test plans are then written, and programmers are assigned to sets of requirements, the functionality is implemented in software source code, after which acceptance testing is done which depending on the outcomes may update the test plans. If acceptance testing fails new

requirements are established and the cycle is repeated. If acceptance tests pass an interim release is made available, and the process loops around again to implement further functionality. Once the full release is available, the process concludes with final delivery and documentation.

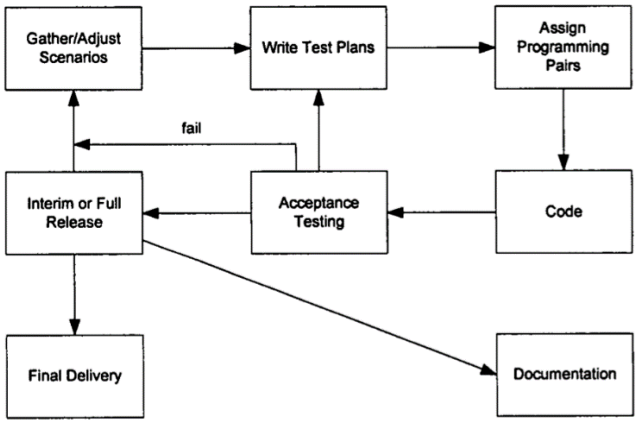


Figure 2.17: the eXtreme Programming Process

Source: (Fruhling and Vreede 2006)

Fruhling lists the four essential ideas behind agile as being the prioritisation of:

1. Individuals and interactions, over processes and tools
2. Working software, over comprehensive documentation
3. Customer collaboration, over contract negotiation, and
4. Responding to change, over following a plan.

Fruhling recommends the examination of the essential characteristics of a project when selecting an effective software methodology.

Table 2.2 Software development methodology selection

Agile versus plan driven project attributes		
Project parameters	Agile attributes	Plan driven attributes
Developers	Agile, knowledgeable, collocated and collaborative	Plan-oriented, adequate skills, access to external knowledge
Customers	Dedicated, knowledgeable, collocated, collaborative, representative and empowered	Access to knowledgeable, collaborative, representative, and empowered customers

Requirements	Largely emergent, rapid change	Knowable early, largely stable
Architecture	Designed for current requirements	Designed for current and foreseeable requirements
Size	Smaller teams and products	Larger teams and products
refactoring	Inexpensive	Expensive
primary objective	Rapid value	High assurance

Source: (Fruhling and Vreede 2006)

Factors that were taken into account when selecting the eXtreme Programming agile approach as the methodology for this study's software development portion were that:

1. The author is experienced with agile methods when developing software, knowledgeable about the process and is in collaboration with the Clinical Director, and nurses in IR in the study site.
2. Agile methodologies suit the development of smaller, non-complex information systems and smaller teams. The checklist application was developed by the author, so one developer was involved in building a simple application. No integration was attempted with the study sites HIS, so it was a largely self-contained piece of software.
3. Agile methodologies accommodate users altering their requirements once they see and test the system, which was expected.
4. Given the time constraints of the project, the lower overhead of reduced documentation was necessary and the absence of bureaucracy when making decisions about functionality was also preferred.
5. The highest priority of agile methods is to provide customer value by delivering key features early in the project. This was of paramount importance to the objectives of this research study.

2.9.2 Wireframes and Prototypes

Vitols et al. (2011) describe a wireframe as a simplified mock-up of the visual design of the system user interface which is expressed without colour, images or any styling including the font style. A wireframe is a blueprint, used to identify and solve issues in navigation, interaction and layout design before actual construction begins. The quality of design directly affects the system's usability and the end-user's user experience,

which in turn directly impacts the user's acceptance of the system (Nielsen 1994). Wireframes are used to plan ahead and detect design problems including aspects of layout and navigation in the early stages of development in order to pre-empt them, and to improve the usability of the design, and consequently improve the user experience. Wireframes form the basis for prototypes, which are more sophisticated visually and functionally and better represent the design and behaviour of the intended system, but are not fully functional. Both wireframes and prototypes are used to test the design of a system before final implementation.

A prototype is a scaled down simplified version of a system, and may be built to varying levels of sophistication. Yu (2008) describes a prototype a means to test the function of a new design before development of the full product, to avoid rework and wasted effort. In software engineering, prototyping is also used as a tool in system functional requirements elicitation (Yu 2008).

Yu (2008) refers to two approaches when using prototypes. They are either built in order to eventually be discarded, or to be converted into the final product. The convert approach builds the full functionality into the prototype once it has been approved, converting it into the final product. This study used the convert approach to prototyping.

2.9.3 Usability Engineering

"Usability is most often defined as the ease-of-use and acceptability of a system for a particular class of users carrying out specific tasks in a specific environment. Ease-of-use affects the users' performance and their satisfaction, while acceptability affects whether the product is used."(Holzinger 2005, p.1)

Madan and Kumar Dubey (2012) note that while the demand for quality software is on the increase that much of that software is rejected by users. This they attribute to failure of the system to fulfil its original tasks and the lack of usability which leads to user dissatisfaction and time wastage. Madan and Kumar Dubey (2012) quote the IEEE as defining usability as 'the ease with which a user can learn to operate, prepare inputs for, and interpret outputs of a system or component' (IEEE Std.1061, 1992).

The usability of a system is expressed in terms of its

1. Learnability – whether the system is easy to learn and understand to a new user
2. Efficiency of use – whether a user who is familiar with the system is able to work productively with it
3. Memorability - infrequent users of the system need not relearn everything on next opportunity for use
4. Low error rate –catastrophic errors are prevented by the system, errors which do occur can be recovered from, and
5. User satisfaction – whether the system is pleasant to use, is liked, and has been accepted (Madan and Kumar Dubey 2012) this is also referred to as the Attractiveness of the system.

Usability is refined using inspection and test methods. Inspection is done without the presence of end users, and is based on heuristics, or experiential knowledge (Nielsen 1994). Usability testing is done with the end users and can involve think aloud protocols, where the user describes what they are thinking while attempting to use the system, as well as indirect and direct observation, and usability questionnaires (Holzinger 2005).

Mobile applications can be created using either native platform technologies, or by building responsive web sites that resize to appropriately fit the device screen size and both approaches have advantages and disadvantages (Boudreaux 2013). As will be explained in section 4.2, it was chosen to build a native Android application, and follow the Android design conventions as recommended by Google (Google 2013).

2.10 Case study research in Software Engineering

Runeson and Höst (2009) provide guidelines for conducting and reporting on rigorous case study research in the field of software engineering. They note that case studies have been criticized for being of less value than controlled or analytical studies and have been considered biased. Case studies offer a view on a contemporary phenomenon in its natural context, and allow insight into understanding the interaction between the object and its environment. Benbasat *et al.* (1987) declare that case research is appropriate when studying certain types of problems where the experience of the actors are important and the context of the action is critical. Usability and acceptance are phenomena embedded in the interaction between a particular cohort of users and a

specific system within its intended environment and domain of use. Case study allows the researcher to understand the nature and complexity of the processes taking place. Bias and subjectivity can be addressed by using both quantitative and qualitative data sources where possible, triangulation, transparency, and reliance on multiple sources of evidence (Yin 2003), and the use of strategies employed throughout the study to address validity threats. These strategies could include maintaining a detailed case study protocol, having collected data reviewed by case subjects, spending sufficient time with the case and actively using negative case analysis to look for theories that contradict the initial findings (Runeson and Höst 2009).

2.11 Conclusion to State of the Art

As stated by ('Analyzing the Past to Prepare for the Future: Writing a Literature Review' 2002) a literature review establishes what is known about a topic, in order to identify what is not yet known, and where further investigation is needed. The objective of this review was to discover the origin and purpose of checklist use in a clinical domain. The legal context of their use was then examined nationally and internationally to understand whether use is optional or mandatory. Evidence of existing electronic checklist implementation was sought in the literature to explore the characteristics, usability, acceptance and implementation detail of these examples. The literature was also studied to identify the advantages discovered when using an electronic format. Finally evidence was sought for the existence of published safety checklist apps.

The literature review identifies that checklists were created to increase patient safety, , and have proven to do so. There are difficulties in implementing them routinely for various reasons such as checklist fatigue, inaccurate checklist content, non-standard implementation and lack of fidelity to the original implementation model (O'Connor et al. 2013) the need for documentation and irrelevant checklist content also detract from the effort.(Keane and McHale 2011)

The literature review also identifies the growing trend internationally and in Ireland of the legal stipulation to complete pre-procedure safety checklists, and the need to be able to audit and report on checklist completion.

The implementations of electronic checklists discovered in the literature review were either prototypes built on specialist hardware and not used within a working environment, (Blike and Biddle 2000, Burghouts 2010, Hart and Owen 2005), or were built using generic software and hardware, but were still in a prototype form (Buzink et al. 2010). In the case of the two most recent implementations found, checklists were integrated into pre-existing specialist hardware in the OR setups (Robbins 2011, Mainthia *et al.* 2012). In all cases the software was built either into a prototype device not intended for production use, or into 'non mobile' hardware systems: implementations on physical devices that are fixed in place and not designed to be portable. Where implemented in working clinical environments (Robbins 2011, Mainthia et al. 2012) electronic checklists were effective, were used and accepted, but it was noted by clinicians that the adoption of an electronic checklist system would require more availability of computer hardware if implemented throughout a hospital (Burghouts 2010) thus the cost of the hardware is a factor. (IDC 2013, Xu 2012) demonstrate that tablet computers are becoming significantly more affordable, and that more devices are being shipped as a result mostly fuelled by low-cost Android devices.

In the electronic checklist examples above the need to increase the mobility of the users operating the checklist has been identified and effort has been made by the introduction of remote controls and clickers(Robbins 2011, Hart and Owen 2005), or voice synthesis to varying degrees of success. While there does seem to be interest in the apps published in app stores (Warnock 2012) there are no studies to support or investigate the usability, suitability and acceptance of such applications.

This study is to explore both how an app can support the process of completing checklists electronically, and to then evaluate the usability and acceptance of such an app when used on a tablet device within a clinical environment for a month. Using the correct software development and research methodologies it would be possible to both design construct, and evaluate such an app and the tablet devices within its intended environment among its intended user class (Runeson and Höst 2009). It is also important that the system be deliberately designed to be supportive, user-friendly and acceptable to users within the realities of a clinical workflow (Verdaasdonk *et al.* 2009).

Electronic checklists that are captured on applications that run on tablet computers could enable the provision of electronically captured checklists that are

a) more affordable in terms of the hardware required (Xu 2012)
b) introduced in a minimally disruptive technology
c) enable easy and inexpensive audit and reporting
d) integrate with existing hospital information systems
e) automatically document the act of checking
f) facilitate content refinement over time and
g) flexibly integrate into the existing clinical workflow.

Chapter 3 Research Design / Methodology

3.1 Introduction

This chapter will describe the research design and detail how the data sets will be sourced. The procedures of analysis of both the quantitative and qualitative data will be described, as well as their significance in terms of the research questions. The following aspects of the study will be described: the study site, the research methodology, the study population and sampling techniques, data collection, analysis and ethical considerations. The research design explores how to support electronic checklist capture by means of an app, and then evaluates its usability and acceptance among clinicians, as well as the suitability of the tablet device to the clinical environment.

3.2 The Study Site

As stated in section 1.1 the study site is a major acute and academic teaching hospital, which handles over 14,000 surgically invasive procedures, and over 3400 procedures in IR per year. The study site has 1085 beds and in 2011 provided treatment for 26,000 inpatients, 94,000 day care patients and 225,000 outpatients.

The IR Department is headed by the Clinical Director who is assisted by a number of professional staff, including 9 nurses that assist in IR procedures, 18 consultant radiologists and several Specialist Registrars (SpR) training in IR.

Pre-procedural checks are currently being captured prior to procedures on paper forms that document the detail about the entire procedure, or verbally. The Clinical Director approached the researcher with the plan to pilot the use of the CIRSE IR safety checklist, implemented as an app on a tablet device in order to explore the viability of using tablet computers in the clinical workflow.

3.3 Methodology

The value of empirical research methodology in software engineering is gaining credibility. As described in section 2.10 case study offers a view on the interaction between an object and its environment (Runeson and Höst 2009). In this study the objects under study are the usability and acceptance of a checklist app, and the

suitability of a tablet device in a clinical environment. Case study research is flexible and adaptive due to the unpredictability of real-world settings and interactions.

Runeson and Höst (2009) classify research as having either a descriptive, explanatory, improving or exploratory purpose. According to that classification the purpose of this study is exploratory i.e. to discover what is happening, to seek new insights, generate ideas and hypotheses for new research.

Case studies may contain elements of other research methods for example surveys, literature search and archival analyses as part of its data collection, with interviews and observation being the most frequently used methods. Data collected in empirical research is either qualitative or quantitative. Quantitative data involves numbers and classes while qualitative data involves descriptions, pictures, subjective opinion, and diagrams. Quantitative data is analysed using statistics while qualitative data is analysed using categorisation and sorting. Runeson and Höst (2009) suggests using a combination of both quantitative and qualitative data to reach better understanding of the studied phenomenon.

Triangulation is the strategy of using a combination of different views, or approaches when studying the object (Runeson and Höst 2009). Multiple sources of evidence reinforce, confirm or refute findings. In terms of the different types of triangulation identified listed by Runeson and Höst (2009) this study will use data source and methodical triangulation. Data source triangulation is the use of more than one data source or collecting the same data at different stages - in this case: we will conduct usability testing before the use and then survey the usability experience again after the use. The methodological triangulation used was the combination of different types of data collection methods i.e. both quantitative and qualitative.

The validity procedures implemented during this study included the transcription of interviews with participant clinicians, which were given the opportunity to review the transcribed interview in order to make corrections before analysis took place.

3.3.1 Pilot Study

In this study an electronic checklist tablet application was developed in collaboration with the clinical users at the study site, and populated with checklist content adapted to best suit local practice by the clinicians using the CIRSE IR checklist as a starting point. The Clinical Director of IR at the study site invited 6 of the IR nurses to participate. The application was loaded onto two Google Nexus 7 tablet devices and used for a month in two clinical departments at the study site after user training on the tablets. 6 nurses and 3 SpRs in IR agreed to participate in the study. Checklist use was optional, and nurses were allowed to use their own discretion on when to complete an electronic checklist. The first tablet was available every day in the IR Room for use by the participant nurses assisting the three SpRs when performing procedures. During the first two weeks of the pilot the nurses were unobserved. The researcher observed the use in IR during the last two weeks of the pilot. The breast clinic nurse was one of the 6 nurse participants and she had sole use of the second tablet during the pilot study.

3.3.2 Data Collection and Study Aims

Qualitative data was collected using semi structured interviews with the SpRs and nurses (see interview questions in Appendix B and C respectively) and observation. Quantitative data was collected by the app during use, and by means of two surveys, namely the Brookes SUS Usability scale (see Appendix D), and a web survey sent to all radiologists and SpRs in Ireland, radiographers and radiography nurses please see Appendix E for the survey questions. Ethical approval was granted by the Trinity College Dublin School of Computer Science and Statistics Ethics board to distribute the survey.

The aim of the study was to design and construct a checklist app, and evaluate whether the app would be usable and accepted, and whether the tablet device running the app would be suitable for use in a clinical environment. The researcher used the XP software development methodology and wireframes, in combination with usability testing, usability inspection, and consultation with senior android developers to iteratively refine a prototype which was then converted into the final application. The CIRSE checklist content was iteratively adapted to better suit local hospital practice using the (Verdaasdonk *et al.* 2009) checklist implementation model with the aid of the Clinical

Director of IR and the staff nurses in IR as will be described in section 4.3. The researcher then used a mixed methods approach to evaluate the application's usability, acceptability and the tablet device's suitability within the clinical workflow at the study site after a month of use in two departments during the pilot study.

Usability testing and inspection was used to improve the design during development.

Initially a Survey Monkey questionnaire was distributed to radiologists, SpRs in IR, radiographers and radiology nurses in Ireland to survey their familiarity with touch devices, their attitudes toward and knowledge of safety checklists, whether they had a preference between electronic or paper format, their experience of team dynamics and their opinion on the efficacy of checklist use in terms of patient safety.

The usability of the final application was evaluated by using the following data sources:

1. Quantitative sources
    a. Brookes SUS simple usability score,
    b. Data captured by the application
2. Qualitative sources
    a. Exit interviews with SpRs
    b. Exit interviews with nurses

Acceptability of the final application was evaluated by using the following data sources:

1. Quantitative sources:
    a. Data captured by the application
    b. Observation
2. Qualitative sources:
    a. Exit interviews with SpRs
    b. Exit interviews with nurses

The suitability of the tablet device and application was evaluated using the following data sources:

1. Quantitative:

a. Findings from the web survey relating to familiarity, ownership and use of touch devices
b. The physical condition of the tablets after the month long study

2. Qualitative sources:
    a. Exit interviews with SpRs
    b. Exit interviews with nurses

The results and findings will be discussed in terms of the themes that emerge from the interviews, the survey findings, the condition of the tablet devices after the study and the display of graphs and charts for the quantitative data analysis of the electronic checklist data.

3.4 Quantitative data: Sources, Population and Sampling

When used in inferential statistics the term 'target population' is used to describe the full dataset available and 'sample', refers to a subset of that data selected from the population and which is used during analysis. The population may be comprised of people, events, or data records and the sample is a representative subset from which findings may be generalised. The sample can be obtained by using various sampling methods the aim being to select a sample that is representative of the target population. The methods of sampling used in this this study are purposive i.e. non-random. Volunteers who agreed to participate formed the sample of the nursing staff involved in the study, and a convenient sample of the Specialist Registrars that were performing procedures in IR were selected. Both methods are non-random and will thus not be representative of the entire population, but the findings are not intended to be generalized due to the explorative nature of this study. The results of this study will be valid for the sample which is termed internal validity. This study hopes to provide hypotheses and generate theories for further studies (Banerjee and Chaudhury 2010).

3.4.1 Survey Monkey Web survey

The web survey containing the questions listed in Appendix E was emailed to all consultant radiologists in Ireland. Of the approximately 300 recipients, 40 responded. Of the 75 Specialist Registrars training in IR, 5 responded. Of the 40 radiology nurses, 15 responded, and of the 700 radiographers 9 responded, for a total of 69 respondents.

3.4.2 Usability test during development

As per (Nielsen 1994) 5 end users testing a user interface, irrespective of the intended end-user population size will discover over 75 % of the usability issues. Thus of the 9 nurses on staff at the study site, 6 were invited to participate in the usability testing, and all 6 did. The test instructions are listed in Appendix F.

3.4.3 Brookes SUS usability score survey during exit interviews

All nurses (n=5) participating in the semi structured exit interviews completed a SUS usability survey. 1 SpR also completed the usability survey.

3.4.4 Electronic checklist data collected by application

All checklists captured on the two tablets were stored in the app database on the device, and provided data on all user interactions when capturing checklists during the duration of the pilot study. Details on the database and the type of data captured follows in Section 3.5.2.

3.5 Quantitative Data: Collection and Analysis

Quantitative data involves the precise measurement of quantifiable aspects of the studied phenomenon. It is the attempt to find answers to the questions "how much, how often, how many, when and who" in a way that can be evaluated statistically, and provides information in the form of facts and detail.(Blumberg et al. 2008)

3.5.1 Survey Monkey Web survey Analysis

As stated in section 3.4.1 35 survey questions were distributed to all radiologists and SpRs in IR in Ireland, all radiographers that are members of the Irish Institute of Radiography and Radiation Therapy and an opportunistic sample of radiology nurses at several hospitals in Ireland. Participant response data was collected online by Survey Monkey and analysed and expressed in terms of graphs.

Initially it was intended to use the Safety Attitudes Questionnaire from the University of Texas Health Science Centre by (Sexton *et al.* 2006), but as the case study progressed it was found that not all of the topics addressed by the questionnaire were relevant to the study aims as stated in section 1.3, as a result part of the question set was changed.

Survey questions were updated after the literature review to better examine subjects pertinent to the research questions i.e. the design, suitability, usability and acceptance of the tablet device and app. The following areas of interest were covered by the survey:

- Information on the clinical area, role, and level of experience of the participant
- The frequency and nature of use of touch screen devices including tablets and smart phones by the participant
- The level of familiarity and experience with pre-procedure checklists
- Their subjective opinion on the efficacy and usefulness of checklists
- Personal experience of the facilitators and blockers to checklist use
- Reflection on team dynamics within the multi-disciplinary clinical teams

3.5.2 Usability Test Analysis

The usability testing was based on the testing described by (Lier 2008) when developing the Pro/cheQ interface. The usability test was completed during application development to detect and fix design issues before the pilot study. Nurses completed the usability test individually with the researcher and the tablet. The application would always be closed on the tablet before the participant entered the test room, and the tablet would be presented with the screen-locked and switched off facing the ceiling.

The researcher explained that the nurse's performance was not being tested, but the application's design was being evaluated: in effect that nothing attempted by the nurse would be in error, but that the researcher was making sure that the interface itself was self-explanatory and easy to use. The Nielsen (1994) think aloud usability test method was explained, and nurses were encouraged to verbalise their thoughts as they attempted to complete the instructions (see Appendix F). Notes were made by the researcher of the observed actions, and the verbally expressed comments.

Before starting the test the researcher asked what device the participant used as their personal mobile phone as a very quick gauge of their familiarity with smart devices and touch screens. Based on their response participants were divided into one of two groups: novice touch device users (those who did not own a smartphone) were placed

in Group 1 (n=2) and habitual touch device users (those who did own a smartphone) were placed into Group 2 (n=4).

The researcher offered different levels of guidance or assistance depending on the group the participant was placed in. Novice users would be allowed to try complete the given task without help. When they were blocked a note was made of the issue and they were assisted to help them proceed. The habitual users of Group 2 were further divided into those that would be readily assisted (Group 2a), and those that would not be assisted until it was clear they were blocked (Group 2b) to evaluate the effect of familiarity with touch devices when assessing the usability of the design.

Task execution was categorised in terms of

1. Efficient execution (completed without errors)
2. Effective execution (completed with errors)
3. Whether guidance was necessary
4. Whether it was safe to use (errors were rare, and could easily be rectified)
5. Whether it was learnable (easy to learn and understand to a new user)
6. Whether it was memorable (whether the design's behaviour was consistent. If guidance was given in a previous task, that the design was understood when later faced with a similar task)

Defects that were discovered during the testing were categorised as either

1. Software defects (application bugs)
2. Usability defects, or
3. Content ambiguity

Usability issues that were problematic but that were not application defects, but rather the Android platform hardware or software conventions, were identified for inclusion into training and were categorised as

1. Training issues.

These findings would feed into the next iteration of the system development. In the case that a software change could rectify the issue while following Android platform conventions, this change was made. When the behaviour could not be changed (operating system behaviour rather than application behaviour), or where software would not be changed in favour of following Android platform conventions the issue would be discussed in the planned user training.

3.5.3 SUS Survey Analysis

The SUS usability scale by (Brooke 1996) was used to assess the usability as experienced by the nurses and SpRs after completion of the pilot study. Of the 9 nurses working in the IR and Breast Imaging procedures, 5 completed the SUS Usability survey, of the 5 SpRs performing procedures during the pilot study, 1 completed the SUS Usability survey. The instructions in Brooke's paper were used to calculate the final usability score out of a possible 100 for each participant. The Bangor et al. (2009) method for mapping this usability score to an adjective rating scale was then applied.

3.5.2 Electronic Checklist data Collection and Analysis

In order to facilitate indirect observation and store metrics of the user interaction with the app, logic was built into the final software release which captured quantitative tracking data in the application database, which was used to extract usage statistics, see Figure 3.1. In particular time values and statuses were recorded on checklist creation, update and completion, in the episode_preprocedure_checklist table, as well as on each individual checklist item in the episode_preprocedure_checklist_item table. The checklist status field indicated the progress achieved along the series of 7 application screens (see Figure 3.2 and 3.3) needed to complete a checklist entry record. These screens were termed "milestones," and where the screen supported a save/resume function, the milestone was further divided into logical stages within that milestone. The checklist stage value was recorded in the database episode_preprocedure_checklist state field.

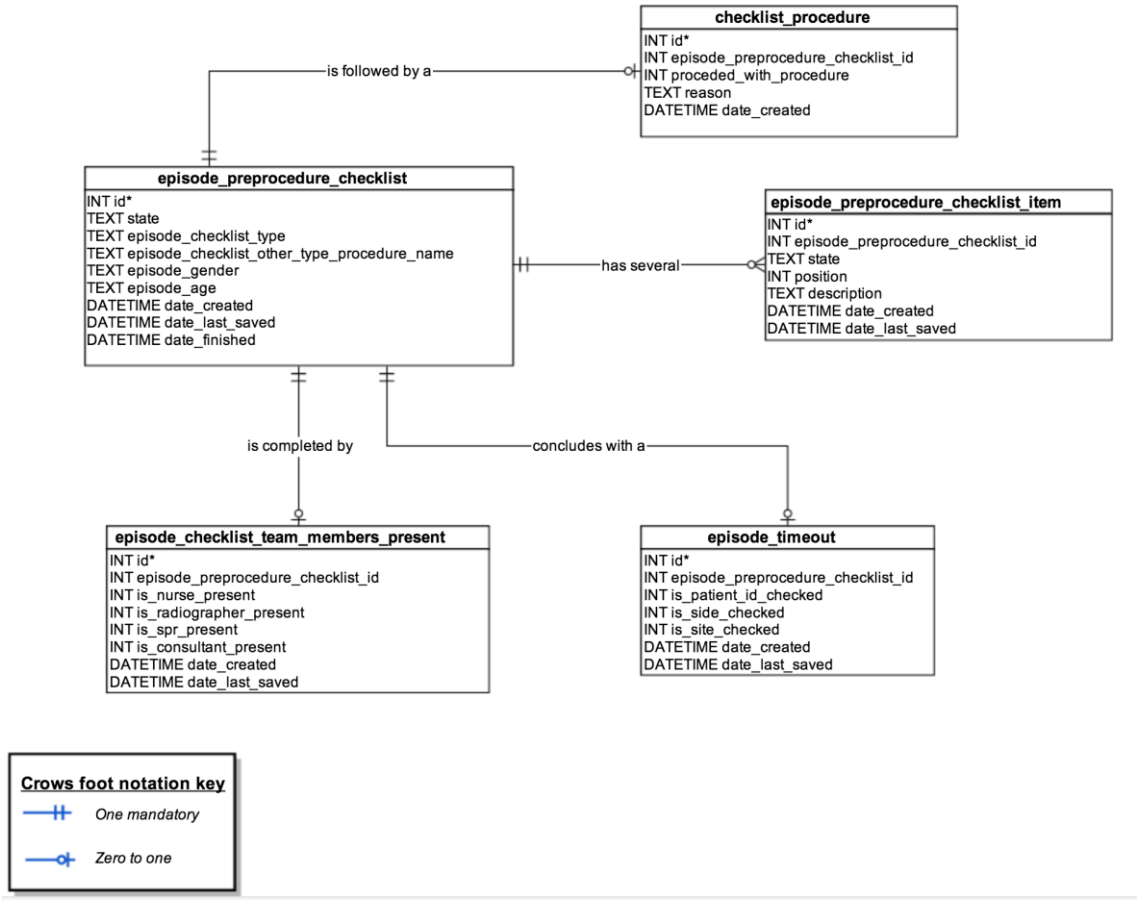


Figure 3.1: Application Database Design: Entity Relationship Diagram

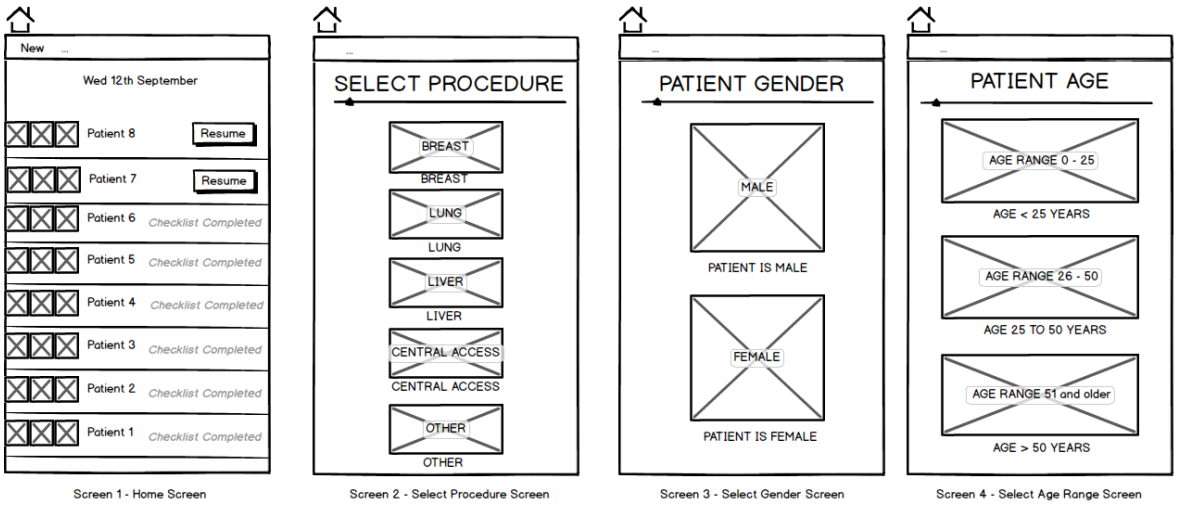


Figure 3.2: Wireframes of app screens 1 to 4

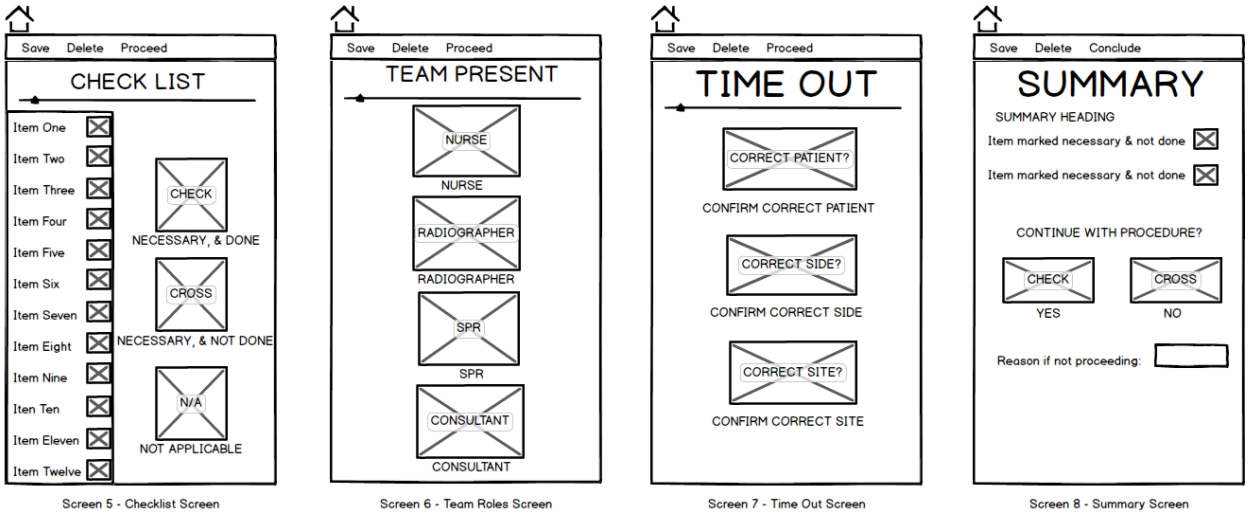


Figure 3.3: Wireframes of app screens 4 to 8

The list of milestones and the mapping to the stages within each milestone is illustrated in Figure 3.4. This mapping will be described in the text following Figure 3.4.

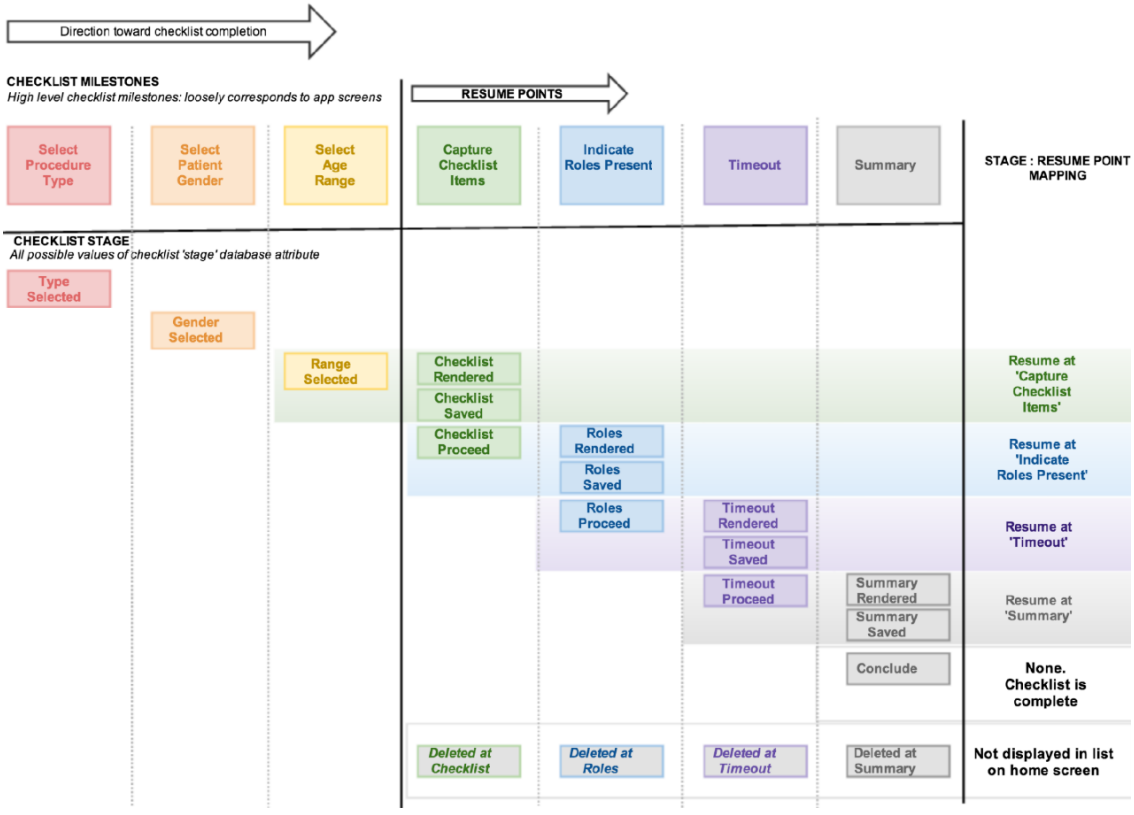


Figure 3.4: Checklist milestones (screens) and stages within milestones

The seven milestones shown in Figure 3.4 show how a checklist progresses from start to completion. They are:

1. Select Procedure Type

2. Select Patient Gender
3. Select Age Range
4. Capture Checklist Items
5. Indicate Roles Present
6. Timeout
7. Summary

Milestones 1 to 3 do not support save functionality. These milestones are marked by stage values as follows:

Milestone 1 – Select Procedure Type

1. Type Selected

Milestone 2 – Select Patient Gender

1. Gender Selected

Milestone 3 – Select Age Range

1. Age Range Selected

Milestones 4 to 7 support save and resume functionality, as well as deletion. Resume is initiated from the home screen. A resume point is the screen upon which the checklist completion will recommence. Milestones 4 to 7 are further broken down into the following stages:

Milestone 4 - Capture Checklist

1. Checklist Rendered
2. Checklist Saved
3. Checklist Proceed
4. Deleted at Checklist

Milestone 5 – Indicate Team Roles Present

1. Roles Rendered

2. Roles Saved
3. Roles Proceed
4. Deleted at Roles

Milestone 6 - Timeout

1. Timeout Rendered
2. Timeout Saved
3. Timeout Proceed
4. Deleted at Timeout

Milestone 7 - Summary

1. Summary Rendered
2. Summary Saved
3. Summary Proceed
4. Deleted at Summary

The state field on the episode_preprocedure_checklist_item table of Figure 3.1 was used to record whether each checklist item on Screen 5 of Figure 3.3 was skipped, checked, marked with a cross, or marked not applicable.

Reports drawn on the data above will be discussed in Chapter 4 and 5. Areas of interest are

1. The number of checklists completed
2. The time taken to complete checklists
3. Whether checklists are abandoned
4. Whether checklist items are skipped
5. Whether certain checklist items are routinely skipped, or marked not applicable
6. Where available, a comparison of the number of procedures completed with the number of checklists captured

3.6 Qualitative data sources

3.6.1 Exit interviews SpRs

Of 5 SpRs performing procedures during the pilot study in the IR room, were interviewed (which accounted for the surgeons in the room completing procedures on 19 of the 21 days of the pilot study.)

3.6.2 Exit interviews Staff Nurses

5 of the 9 nurses circulating in IR and the breast clinic, were interviewed in the exit interviews.

3.7 Qualitative data: Collection and Analysis

Interviews between the researcher and participants were recorded and transcribed and then checked by the individual participant before analysis took place. As shown in Figure 3.5 the transcribed interview data was coded and quotes were grouped, these groups identified conclusions, which were discussed as the themes identified in the qualitative analysis findings in section 4.6.4.

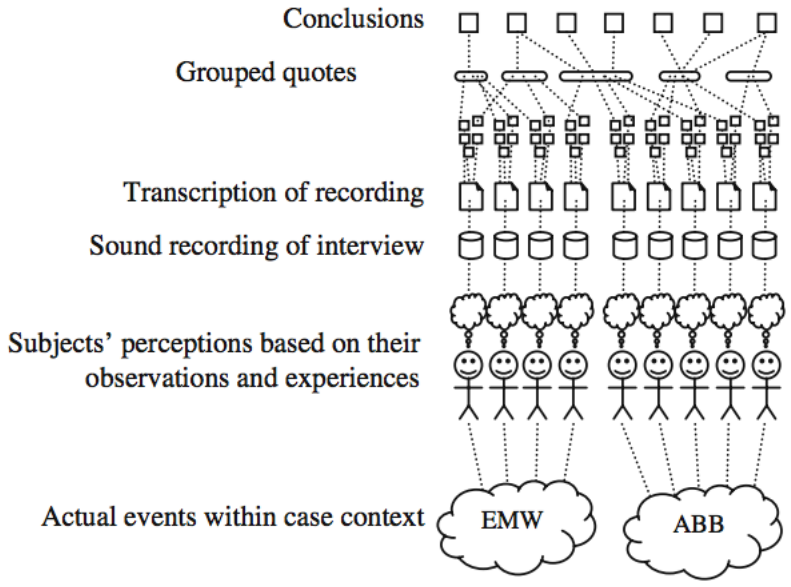


Figure 3.5: Methodology for qualitative analysis of exit interviews

Source: (Runeson and Höst 2009)

3.6 Ethical Considerations

Runeson and Höst (2009) describe that research is essentially an exercise of trust between the researcher and the organisation allowing access for the study. This relationship however needs more formal governance to ensure the rights and responsibilities implicit in the interaction are clearly stated and understood, and that both parties are protected. It needs to be made clear from the onset how confidential information may be handled and what type of information is candidate for publication. Many countries require that research proposals need to pass ethics review boards at universities.

Key ethical factors identified by Runeson and Höst (2009) include

1. Informed consent
2. Review board approval
3. Confidentiality
4. Handling of sensitive results
5. Inducements
6. Feedback

The research proposal for this study was submitted to the Trinity College Dublin ethics board for the school of Computer Science and Statistics and the research was approved. The proposal included examples of the web survey that was to be sent, the general topics to be discussed in the semi structured interviews, and copies of the informed consent forms and information sheets that would be signed and given to each participant.

Consent agreements are usually captured as a contract between the researcher and individual participant. Participants in this study received

- an information sheet briefing them on the background of the study, and
- an informed consent form detailing amongst others,
    - information regarding the protection of their confidentiality,
    - details on the aim of the study,
    - the intended publication,

- the purpose of the research,
- detailed information describing the voluntary nature of their participation, and
- the right any participant had to withdraw at any stage with no penalty.

The information sheet and consent form are attached as Appendix G and H.

3.7 Conclusion

This research design and methodology chapter covered all the elements involved in the planning of the research study and included the approach to the research methodology, population and sampling, data collection and analysis and ethical considerations. The next chapter will detail the results of the software development exercise, the CIRSE IR checklist adaptation, the usability testing and inspections, the findings from both the SUS and Survey Monkey surveys, the results of the pilot study, and the themes drawn from the exit interviews.

Chapter 4 Implementation and Results

4.1. Introduction

The purpose of this study was to design and construct an app to support the capture of pre-procedural safety checklists and to then evaluate the usability and acceptability of the app and the suitability of the tablet device within a clinical workflow. This chapter will describe the factors influencing the selection of the appropriate hardware and software for the study and the iterative process of checklist content adaption for local practice. The results of the web survey of clinicians working in radiology in Ireland will then be examined. This will be followed by the application design and development which involved usability testing, inspection and user training. Thereafter findings will be presented as drawn from observations of the tablet in use, the usability survey, the electronic checklist data, and themes that emerged from qualitative analysis of the exit interviews with SpRs and nurses.

4.2 Selection of hardware and software

In terms of the selected hardware, touch screen devices come in many sizes, such as the smaller screens of smart phones e.g. iPhones or Android phones, or the slightly larger devices such as tablet devices e.g. iPads or Nexus tablets etc.. It was envisaged that the device would be shared by clinicians, so it was decided to use a tablet rather than a device with a smaller screen. As previously stated the cost of tablet devices is steadily falling, and as a result they are becoming more prevalent. This is in part due to the growing availability of inexpensive Android tablet devices (IDC 2013, Xu 2012). The Google Nexus device was selected due to its low cost and the fact it is has a very high system specification and screen resolution.

In terms of the software chosen, there is debate on the trade-offs to be made when creating mobile software, i.e. whether to build a responsive web site which is designed to degrade gracefully to best suit the screen size of the client device and thus has the advantage that it can be used on many types of devices via the web browser, or build a native app. Building a native platform application makes more of the physical device's

capabilities available, but use of the application is restricted to the specific hardware platform (Boudreaux 2013).

The two deciding factors in this study that resulted in the creation of the native app rather than a responsive web implementation was that firstly, patient data cannot leave the hospital premises due the Irish Data Protection act (*Data Protections Acts* 1988 and 2003), so a web implementation would need to be hosted on the hospital intranet which is necessarily very strictly controlled, making updates and changes to a web implementation difficult and time consuming.

Secondly all room walls in the radiology department are lined with lead to protect people passing by from radiation, so devices within these rooms cannot access the internal Wi-Fi network. As such the app needed to be able to store the records without network access, and work in an offline mode. This was best achieved by a native implementation which could store data directly on the device.

The next section will discuss the development of the checklist content before the pilot study.

4.3 Checklist Content Adaptation to Local Practice

The WHO and CIRSE recommend the adaption of checklist content to better suit local practice.(Lee et al. 2012, WHO 2009a). (Verdaasdonk et al. 2009) describe a model for the creation and refinement of checklist content as shown in Figure 4.1. The model describes an iterative process of refinement (see step 13) once initial checklist content has been approved (step 8).

The CIRSE checklist content was used as the basis of the checklist content which in effect completed steps 1, 2, 3 and 4 of the Verdaasdonk model. Due to unfamiliarity with the checklist the incorrect phase was chosen by the researcher, the Clinical Director and a SpR. The 'Preprocedure Planning' phase was selected which is, as described in section 2.3.4, meant to be completed the day before when the procedure is ordered and

scheduled, rather the phase completed immediately before the procedure, 'Sign In'. This omission was not catastrophic because the 'Preprocedure Planning' checklist items prepare the items that are then verified during 'Sign In,' so in effect they correlate. When the content was adapted to suit local practice by the Clinical Director in IR, himself a consultant radiologist, he rephrased the 'Preprocedure planning' items to better reflect what should be checked immediately before a procedure, e.g. changing the original 'Preprocedure planning' item: 'Fasting order given' to 'Fasting?' which better matches the 'Patient Fasting' check of the CIRSE IR checklist 'Sign In' phase. It was probably due to that rephrasing that the mistake was not detected by the researcher, the nurses or the Clinical Director until half way through the pilot study.

A paper version of the 'Pre-procedure Planning' phase of the checklist was designed (step 5) and the 2 week paper trial version was used to complete steps 6 and 7, the review and testing of the checklist.

Feedback about irrelevant content, or recommended additions to the content was encouraged on these forms when testing the checklist. Only lung biopsy and liver biopsy were included in scope for IR as they were the most frequently completed procedures. All and breast clinic procedures were included.

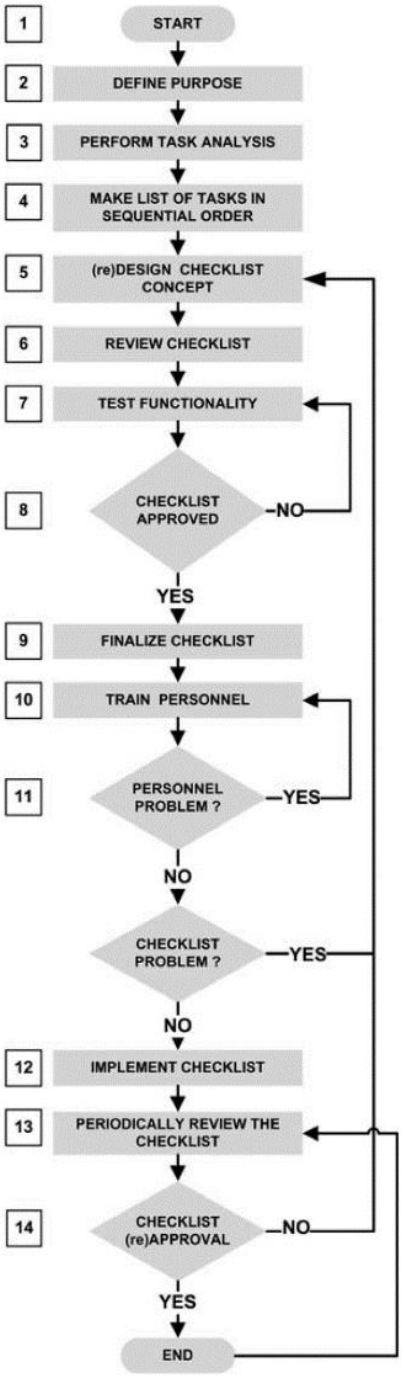


Figure 4.1 The Verdaasdonk et al model for checklist development and implementation

At the end of the trial when the paper copies were collected for feedback it was discovered that no checklists had been completed for lung and liver biopsy, and 10 had been returned for breast procedures.

And while this information was not ideal, it was very helpful and it was decided to include all IR procedures for the electronic version. The feedback collected on the paper forms together with 'Pre-procedure Planning' content adapted to suit local practice by the Clinical Director in IR was used to approve and finalize the checklist content as per steps 8 and 9.Different checklist content was created for breast procedures and IR, due to the feedback received on the paper forms from the breast nurse and the difference in procedure types completed in either department as described in Section 1.2. These content lists were used populate the checklist application. The personnel were trained per step 10. No personnel or checklist problems were reported as per step 11, and the pilot study commenced with the electronic checklist being implemented into clinical use as per step 12, and is discussed further in Section 4.5.6 and Section 4.6.

The first version of the content was used for 12 days, and was then reviewed as in step 13. It was then discovered by a nurse that the 'Sign in' was the correct phase to use. The checklist content was updated for both breast and IR procedures. The second version of the content was used for 8 days. The results of this update can be seen in the number of items marked not applicable after the content update, and will be highlighted and discussed in Section 4.6.2.

Before discussing the checklist application development and user testing in section 4.5, the next section will discuss what findings were taken from the Survey Monkey web survey of the exposure to and use of touch devices by clinical users working in radiology in Ireland, the preferences they report on checklist format, and their experience with and attitudes toward safety checklists.

4.4 Survey Monkey web survey of Radiologists, SpRs in IR, Radiography nurses and Radiographers

Of the 69 clinicians surveyed, 40 consultants out of a population size of approximately 300 responded (23% response rate), 5 SpRs out of a population of approximately 75 responded (0.6% response rate), 15 Radiology nurses and nurse managers out of a population of 40 responded (37.5% response rate), and 9 out of an estimated population of 700 members of the Irish Institute of Radiographers and Radiation Therapy members responded (0.01% response rate).

Clinical demographics

30% of the respondents worked in IR, and 39% of those remaining worked in a mixture of the disciplines including IR, Computerised Tomography (CT), Ultra sound (US), MRI, Fluoroscopy and Breast Imaging. Over 78% of respondents had worked in hospital medicine for more than 8 years.

Touch device use

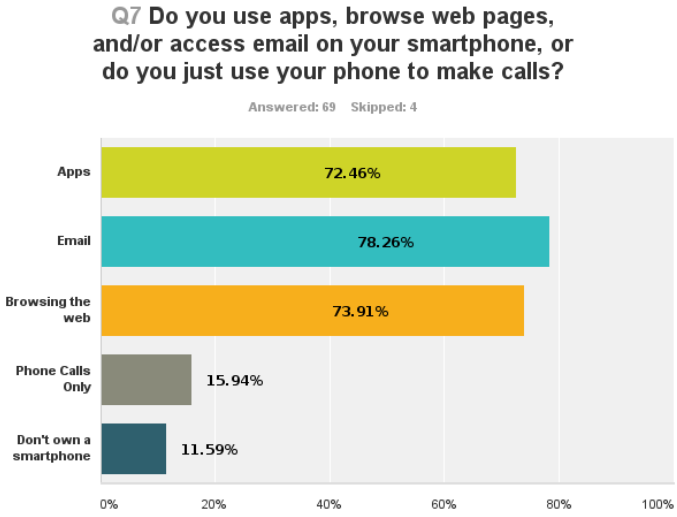


Figure 4.2: Web survey - nature of touch device use

87% (n=60) of all respondents owned a smartphone with a touch screen, which in finer detail is 76% of nurses (n=11), 100% of the SpRs (n=5) and 87.5% (n=35) of the consultant respondents. Of the 87%, 51.5% had owned a smartphone for 2 years or longer. As

shown in Figure 4.2 smartphone users used their phones predominantly to check email (78%) browse the internet (74%) and use native platform apps (72.5%). As such 87% of the clinicians surveyed could be considered habitual touch device users, and over 72% use the device for to access touch screen user interfaces. Over half of the clinicians surveyed (52%) own a tablet device. 55% used tablet devices routinely, with 40% using tablet devices daily.

Safety Checklist training and experience

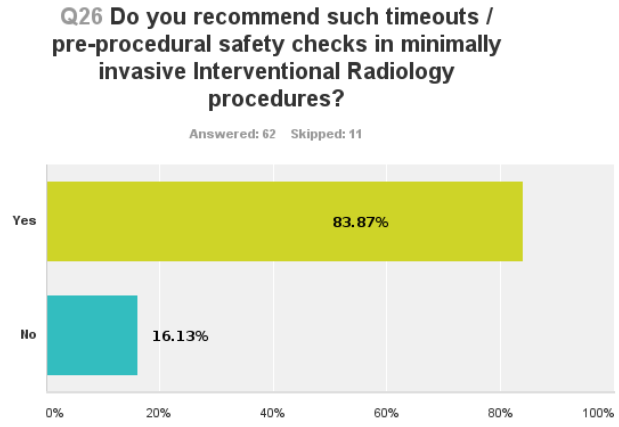


Figure 4.3: Web survey: Checklist use for IR is recommended

While 80% of clinicians had received no training in the use of WHO or Joint Commission Unified Protocol checklists, 30 % asserted that they had detailed knowledge, and 41% had some high level knowledge. For only 20% of the respondents had training been arranged or provided by hospitals. In spite of that over 75% of clinicians had experience in using checklists in hospitals, with almost half (48%) having over 3 years' experience. Significantly 83% of the respondents felt that checklists had effectively improved patient safety, 94% considered safety checklists to be worthwhile and necessary in their workflow at their hospital, and 84% would recommend such checklists and timeouts in minimally invasive IR procedures. Respondents indicated that checklists were mostly initiated by nurses (54%) or consultants (30%), and that the team members actively participating in checklist completion were again, mostly nurses (88%) and consultants (50%) followed by SpRs and registrars (50%)

Barriers to implementation

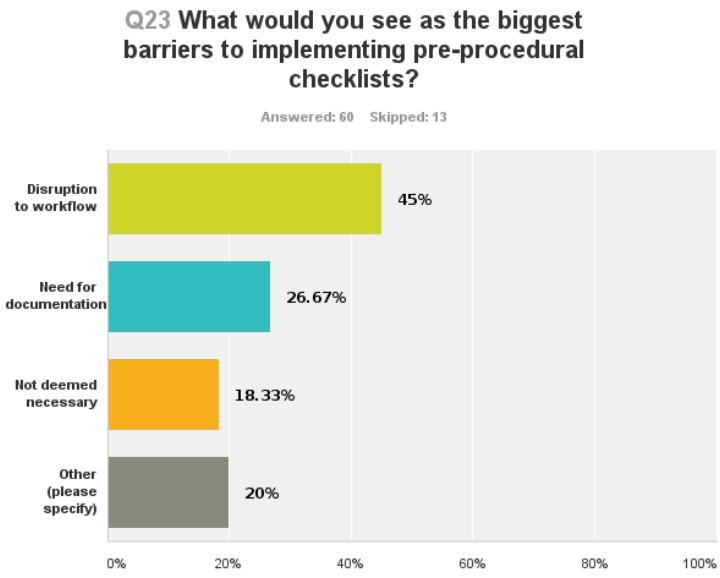


Figure 4.4: Reported barriers to checklist implementation

The need for documentation (27%) was second only to disruption to workflow (45%) as the most significant barrier to checklist implementation as shown in Figure 4.4. Other factors included 'culture change', 'lack of familiarity', 'lack of a responsible individual or leader that would initiate the checklist' and 'high workload'. In response to later survey questions other contributing factors were that it had become too repetitive, and that too many checklist questions were being asked, and that it was not compulsory. Many respondents recommended brevity and the use of common sense, and the inclusion of relevant content only.

Paper or electronic checklist format

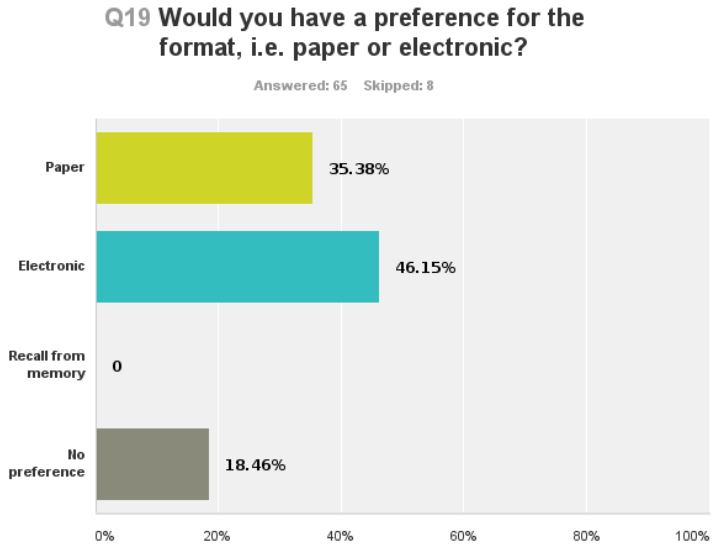


Figure 4.5: Web survey: Checklist format preference

It was interesting to note that while most of the checklists that had been used by respondents were paper (73%) or recalled from memory (11%), and that while 94% of respondents had never used an electronic checklist, that 46% would prefer to use an electronic format, as opposed to 35% that preferred paper (18% had no preference). Reasons for the preference included data availability via the EPR, and that electronic data was not as likely to be lost as a piece of paper.

4.5 Application Design, Development and Usability Testing

As stated in section 2.9.1 the XP software methodology deliberately manages emergent or changing requirements through the software development process (Fruhling and Vreede 2006). Several iterations of development occur each lasting about 2 weeks, at the end of which an interim release is available which contains the features necessary to satisfy the user requirements that were selected for that iteration and which have passed the acceptance tests for those stories. On inspection of the interim release by the customer or representative, functional changes or new features are identified and prioritised for inclusion into the next cycle of development. Once the full application

feature set is complete the final release is issued, the system design and behaviour is documented.

The app went through three iterations with the clinical representatives before the final application was delivered. During this time one usability test, two usability inspections and one technical inspection was completed.

4.5.1 XP Iteration 1

The initial requirements were provided by the Clinical Director of IR at the study site. The application was to allow the user to select a procedure type, and proceed to capture the checklist items. As described in section 3.4.4 the app would also collect data used when answer the research questions.

The requirements for iteration 1 are as shown in the UML Case diagram in Figure 4.6. Each oval, called a case, represents an element of system functionality. The <<include>> arrow indicates that completion of the base case requires the completion of the included case, for instance in the requirements for iteration 1, 'New Checklist' represents the requirement to create a new checklist record, and in order to do so the user needs to select a procedure type and then capture the checklist items, so in the Figure 4.6 'New Checklist' includes 'Select Procedure Type', and 'Capture Checklist Items'.

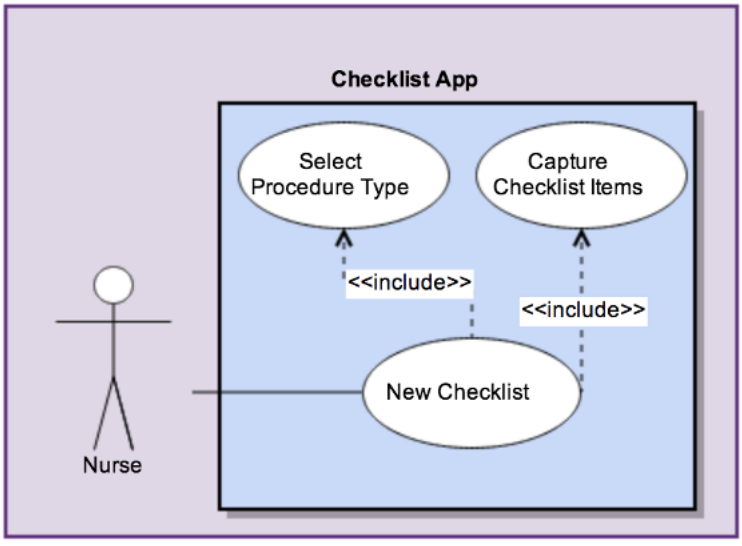


Figure 4.6: User requirements for Iteration 1

Technical inspection

Before the interim release to the clinical representatives the app was examined by a senior software engineer specialising in Android development for a technical inspection. The inspection studied the app in terms of Android application design patterns and conventions (Google 2013). As a result the 'Save' and 'Exit' buttons were placed in the action bar (the action list is collapsed and displayed as three back dots in the top right hand corner in Figure 4.8), and the application was restricted to render only in profile orientation mode.

Usability inspection

An initial usability inspection test was also completed before the interim release. It was recommended to increase the text size, and to ensure that checklist items did not scroll off the screen.

The final wireframes describing the functionality of Iteration 1 were as follows:

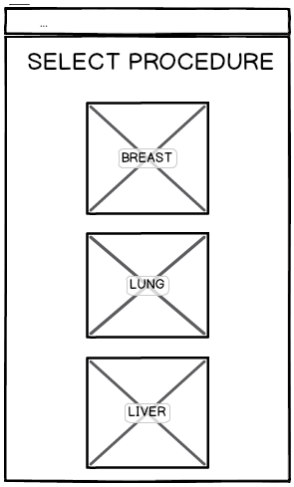


Figure 4.7: Iteration 1, Wireframe 1

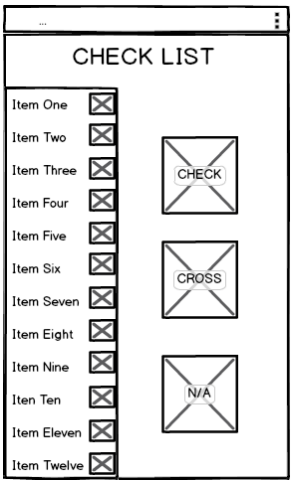


Figure 4.8: Iteration 1, Wireframe 2

In iteration 1 when the application was launched, the user would be presented with screen 1 as shown in Figure 4.9, which offered the selection of procedure type: breast imaging, lung biopsy or liver biopsy. When the image was touched, the app would render screen 2 as shown in Figure 4.10 which lists the checklist content items, with the input buttons to mark the currently highlighted item with a check, a cross or as not applicable.

Figure 4.9: Iteration 1, Screen 1

Figure 4.10: Iteration 1, Screen 2

Save and Exit buttons were stored in the action tool bar (in collapsed form this renders as the three white dots on the top right hand corner of screen 2 in Figure 4.10). The 'Back' button is provided by the Android operating system (in the black bar at the footer of Figure 4.9 and 4.10), and thus was not provided again in the application in accordance with Android design conventions (Google 2013). In terms of usability engineering, Nielsen recommends following platform conventions when developing user interfaces, due to habitual users' familiarity with those conventions and enables more intuitive use of new sites Buttons were big enough to be comfortably pressed by fingers on a touch interface. Attractive images were selected to create the procedure type buttons and the cross check and not applicable buttons to improve on the aesthetic of the app, and make it more pleasant to use. This was done to attend to the usability concerns of user satisfaction, and attractiveness(Madan and Kumar Dubey 2012).

4.5.2 Usability Test

Usability testing was completed on the Iteration 1 interim release as shown in Figure 4.9 and 4.10. As described in Section 3.5.2, 6 volunteer nurses completed the tasks listed below while observed by the researcher. The 6 nurses were divided into 3 groups, novice

users in Group 1(n=2), habitual users who were not assisted in Group 2a (n=2), and habitual users who were assisted in Group 2b (n=2). Participants were given 10 tasks or instructions to complete as follows:

Instructions

Task 1. Please open the application

Task 2. Please start a new lung biopsy checklist

Task 3. Please indicate that Item 1 was checked

Task 4. Please indicate that Item 2 was not checked

Task 5. Please skip Item 3 and indicate that Item 4 was not applicable

Task 6. Please save the checklist

Task 7. Please exit the checklist

Task 8. Please start a new lung biopsy checklist

Task 9. Change your mind and start a breast checklist instead

Task 10. Mark item 1 as checked, change your mind and mark it not checked

Observation Codes

The observations noted down of the task execution attempts were later categorised with the codes as listed in Table 4.1.

Table 4.1 Usability test observation codes

Observation Code		
TASK COMPLETION	DEFECTS	TRAINING
E1 - Efficient	SOFTWARE DEFECT	T1 – switch on
E2 - Effective	B1 - BUG 1 – skip breaks	T2 – unlock screen
G – Guidance necessary	B2 – BUG 2 – highlight broken	T3 – Back button built into device, not in app
S – Safe to use	B3 – BUG 3 - n/a button image needs improvement	
L - Learnable	USABILITY DEFECT	
M - Memorable	U1 – USABILITY DEFECT 1- Save action collapsed	
	U2 – USABILITY DEFECT 2- Exit action collapsed	
	U3 – USABILITY DEFECT 3- Home not enabled	

	U4 – USABILITY DEFECT 4- Press and hold not enabled	
	C – Content ambiguity	

The aim of the usability testing exercise was to make the changes necessary to have all tasks completed by all participants efficiently (E1 code). The usability problems in Table 4.2 are identified by the following codes from Table 4.1, **B**x for bug codes, **U***x* for usability defect codes, **C** for content ambiguity issues, and **G** and **T**x – where guidance or training was necessary. In Table 4.2, the 'Task' columns 1 through 10 represent the tasks, the 'Participants' rows 1 through 6 represent the participant. Each table cell contains codes for the observations recorded per participant, per task. When each column is examined, wherever the code continued per cell is not an E1 for efficient completion, that cell is a target for usability improvement.

Usability test observations

The usability test concluded with the following results as shown in Table 4.2:

- Green row = Group 1 (Novice Users)
- Blue row = Group 2a (Habitual users, without assistance)
- Orange row = Group 2b (Habitual Users with assistance)

Table 4.2 Usability test observations

		Tasks									
		1	2	3	4	5	6	7	8	9	10
Participants	1	**G, T1, T2**	E1	E1, B2*	E2, B2, G	E1, B1*	U1, G	E1	E1	T3, G	E2, B2
	2	**E2**	E1	E1	E2, C	E1, B1*, B2*	U1, G	E1	E1	E1	E2, B2
	3	E1	E1	E2, B2	E2, B2	E2, B3, G	U1, G	E1	E1	U3, E2	E2, B2
	4	G, T1, T2	E1	E1, B2*	E2, B2, G	E1, B2*	U1, G	E1	E1	U3, T3, G	E1, B2*
	5	E2, G	E1	E1	E1	E1	U1, G	E1	E1	U3, G	E1, B2*
	6	E1	E1	E1	E1	E1	U1, G	E1	E1	E1	U4, G

In the 60 tasks completed in total,

- 29 tasks were completed efficiently (E1 code), labelled in white
- 31 tasks revealed usability difficulty
    - 7 tasks were completed efficiently (E1 code), but with hesitation due to the existence of a software defect (B1*, B2*), labelled in lightest pink
    - 24 tasks were not completed efficiently,
        - 8 were completed without guidance and training, but with error (Effectively, e2) , labelled in mid pink
        - 16 could not be completed independently and required training and guidance (n=16), labelled in darkest pink

From Table 4.2 it is seen that both novice and habitual touch device users (participants 1, 2, 4 and 5) required assistance and training when switching on the tablet, and unlocking the screen lock. Thus familiarity with iOS devices like iPads and iPhones did not help. Only the users known to own Android smartphones completed this task efficiently. Thus training was needed on the use and operation of the hardware.

The visual design, and choice of images rather than text was effective on screen 1, as novice and habitual users completed task 2 and 8 efficiently.

Software defect B2 clearly affected all of the users who were not assisted (n=4) when completing tasks 3, 4 and 5, and 10 causing hesitation and error.

Usability defect C, or content ambiguity was only experienced by one user, participant 2, but this was noted.

All users had difficulty finding the ‘Save’ action bar item (usability defect U3) in Task 6 but once shown, had no difficulty finding the ‘Exit’ button (usability issue U2) in Task 7. Thus following the Android Action bar convention, but making sure it was not collapsed, could be usable if the users were taught where to find it.

Task 9, which involved using the Android operating system ‘Back’ button, was also problematic for both novice and habitual touch device users, due to usability defect U3. This task could be improved by implementing the ‘home’ button feature: enabling the

icon rendered in the top left hand corner of Figure 4.6, to should return the user to the first application screen Figure 4.5 when clicked, and by supplying training.

Thus by introducing training to address issues T1, T2 and T3, and fixing software defects B1, B2, B3, and usability defects U1, U2, U3, C, 30 of the 31 usability problems would be addressed. Issue U4 only happened once, and could be addressed by guidance and training rather than implementing a completely new model, for one episode of difficulty.

A quick demonstration during the training would provide guidance for all tasks. The software and usability defects were scheduled for inclusion in Iteration 2. The user training was scheduled to occur before the pilot study.

4.5.3 XP Iteration 2

The iteration 1 interim release was demonstrated to the Clinical Nurse Manager and Clinical Director in IR, who accepted the Interim 1 release, and requested the following features for the next iteration:

1. Indicate Patient Gender
2. Indicate Patient Age Range
3. Indicate Team Roles present during checklist completion
4. Acknowledge time out checks, of correct patient, side and site

During the Usability test described in section 4.2.3 the staff nurses, who were more familiar with the workflow in the IR and breast clinic requested the following user requirement.

1. Save a checklist and resume its completion later, due to multiple patients in various rooms being seen concurrently by a single nurse in the Breast Imaging facility.

The save and resume requirement made it necessary for the app to display the list of checklists, and allow the user to identify and resume a previously saved checklist.

After completion of the usability testing the new user requirements identified for Iteration 2 by the CNM, CD and staff nurses were as follows:

1. List checklists
2. Save, Resume, Delete checklist
3. Indicate Patient Gender
4. Indicate Patient Age Range
5. Indicate Team Roles present during checklist completion
6. Acknowledge time out checks of correct patient side and site
7. Conclude Checklist

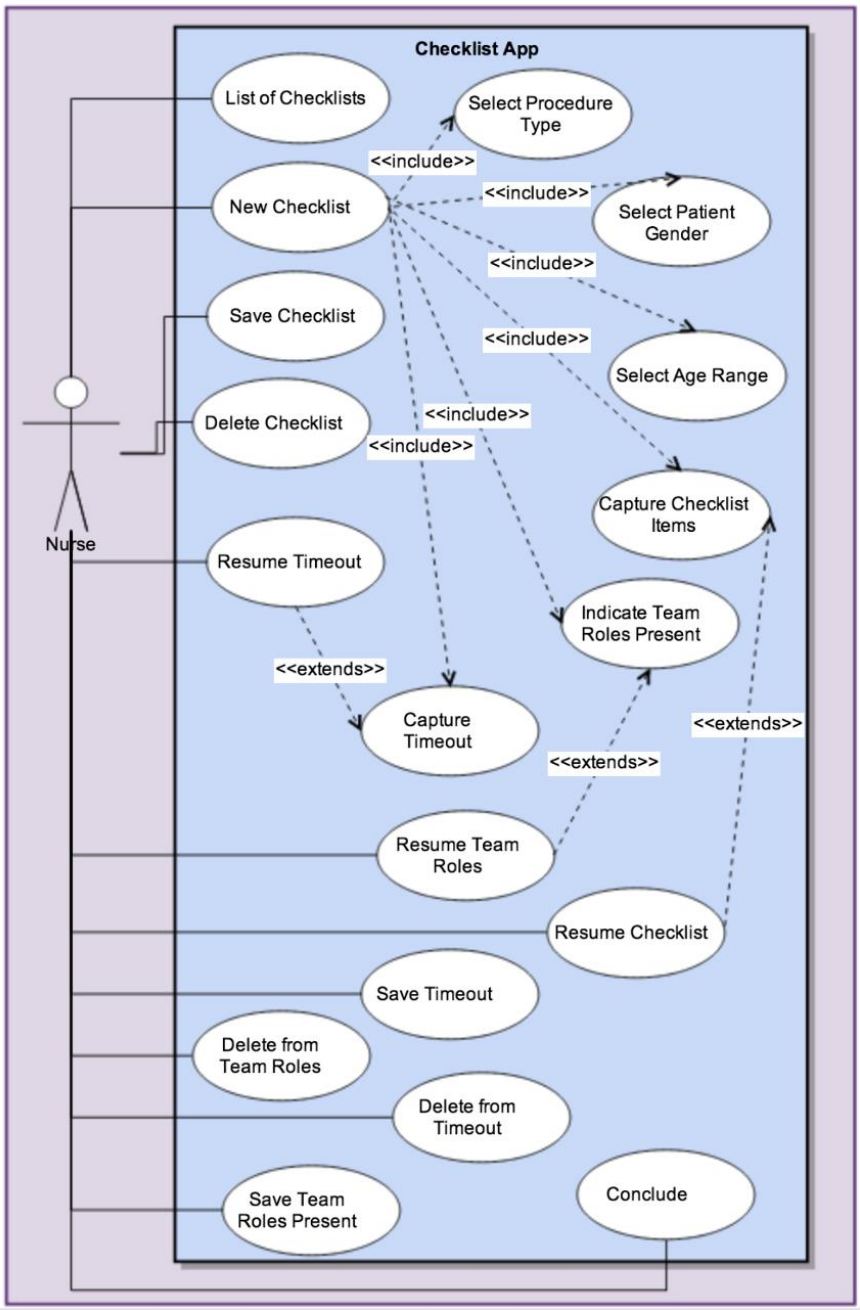


Figure 4.11: Final requirements for iteration 2 from CNM, CD and staff nurses

The UML case diagram in Figure 4.11 extends the app functionality by adding the following use cases: creation of a 'New Checklist' includes 'Selection Procedure Type', 'Select Patient Gender', 'Select Age Range', 'Capture Checklist Items', 'Indicate team roles present' and 'Capture Timeout', 'List existing checklists', save, resume and delete checklists. Checklist records may be saved resumed and deleted at various stages: on the checklist items screen; the indication of roles present screen and the timeout screen. In the case diagram above, the resume checklist, resume team roles and resume timeout use cases were marked as extensions of their respective base use cases above, as they extended the functionality of the base case in certain scenarios by allowing previously saved information to be loaded into the relevant screen to be modified.

The Iteration 2 user requirements were identified by the clinical users to improve the data being captured which could be later reported on, and would better suit the clinical workflow in the study site, and introduce the timeout phase of the checklist as described in the WHO implementation manual. The CNM immediately recognised the term 'Time Out,' these additional features were requested by the clinical users to create a more suitable and acceptable app. (Buzink et al. 2010) stresses the importance of engaging the clinical users deliberately, and creating a sense of ownership and participation with them when designing and introducing an innovation into their workflow. This they assert is crucial to encouraging the adoption and successful implementation of such an innovation,(Buzink et al. 2010). Therefore the requirements and feedback given by the clinical representatives was valued highly, and as far as possible within the time constraints of the study was used to extend the features of the application.

4.5.4 Usability Inspection

(Nielsen 1994) describes a usability inspection as the evaluation of an interface without the presence of end users but is rather based on heuristics, or experiential knowledge. Due to the higher complexity of the app and the new scenarios now possible after the introduction of the new user requirements, the potential for disorientation within the screens was introduced. Wireframes for the iteration 2 features were designed and underwent a usability inspection with a usability expert before the app was updated. The recommendations from this inspection are listed below.

Recommendations

1. Only the checklists for the current day be visible on the list of checklist records to keep it manageable and not infinitely scrolling as time progressed.
2. Display the current date as a heading above the list of checklist records to indicate that it was the daily list of saved records, and that past work hadn't disappeared overnight.
3. The list was to be sorted in reverse order, with the most recently made checklist record on top of the list.
4. Checklist entries on the list were to be identified by the 3 images pressed when selecting procedure type, gender and age, and the checklist record was named 'SAVED CHECKLIST' plus the index within the day's list. This was necessary due to the data protection constraints on the research project, in which patient confidentiality is protected, and identifiable patient information is not captured or stored.
5. From Screen 2 in Figure 3.2 through to all except the last screen of Figure 3.3 a progress bar was introduced below the title on each screen involved in creating the checklist. This was to help the user orientate themselves within the sequence of screens by showing the degree of completion.
6. Colour coding on the progress bar was recommended to visually 'label' each screen. The familiar logical progression through the rainbow spectrum was suggested. The same colour was then used to label the resume button displayed on the list in Figure 4.13 as a visual cue to indicate the degree of completion of a saved, but not yet completed checklist

The final design of the list screen is shown in Figure 4.12, and 4.13. The action bar was used to provide the 'create new checklist' function as shown in the header of Figure 4.12. The information drawn from the usability test of 4.4.3 was taken into account, and the action item was not collapsed but always displayed.

Figure 4.12 Screen 1: List

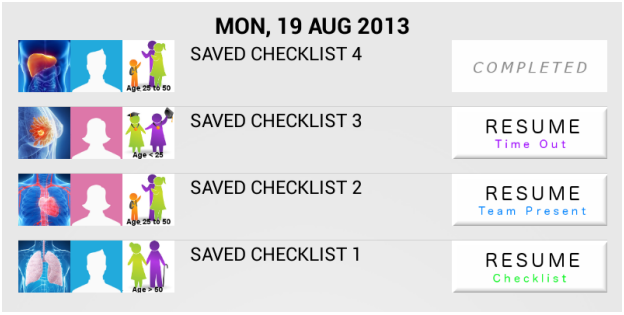


Figure 4.13: List detail

Content ambiguity was further addressed by redundantly labelling all buttons, as shown in Figures 4.14, 4.15 and 4.16, and labelling actions in the header together with action icons as shown in Figure 4.17.

Figure 4.14: Checklist screen

Figure 4.15: Team role screen

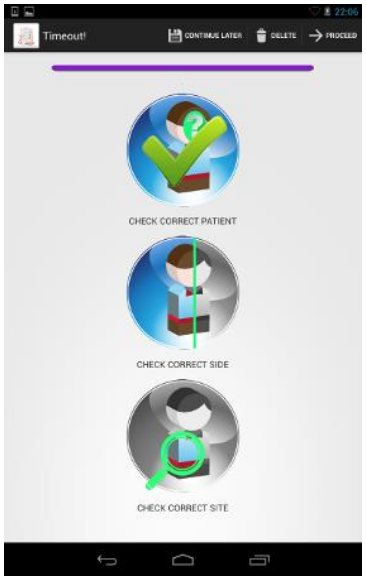


Figure 4.16: Timeout screen

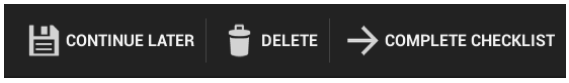


Figure 4.17: Action bar detail

4.5.*5 XP Iteration 3*

The iteration 2 interim build was demonstrated to the Clinical Director of IR and a SpR training in IR at the study site and a staff nurse. The build was accepted and the final requirement was requested.

The Clinical Director, nurses and the researcher observed that semantic ambiguity remained around some of the checklist content. The CIRSE IR checklist provided 'Yes', 'No', and 'Not applicable' options when marking checklist items (Lee et al. 2012) but it was not immediately clear if 'Yes' and 'No' were to be understood as indicating whether the check took place, or that they were recording the outcome of that check. E.g. 'Yes I have checked whether the patient is fasting', and 'No I have not checked whether the patient is fasting' or rather that 'Yes' and 'No' were signalling the outcome of the check i.e. that it literally meant 'Yes the patient is fasting', or 'No the patient is not fasting'.

This was further confused by the 'Not Applicable' option. In the afore-mentioned case, was the 'Fasting?' item to be marked 'No' or 'Not Applicable' if the patient was not fasting, whether fasting was or was not required for the procedure.

An attempt was made to resolve the ambiguity around the three options by using the first interpretation: that users would be indicating whether the checks took place rather than the outcome of the check i.e. 'Yes I have checked whether the patient is fasting' rather than 'Yes the patient is fasting.' This interpretation was chosen by the Clinical Director and the researcher because not all outcomes of checklist items could be answered by a 'Yes' or 'No' response, e.g. "MRSA/VRE status" and because the app was purely a checklist, and was not to be confused with detailed nursing documentation about the procedure.

This interpretation was indicated by labelling the Check button "Necessary and Done" which would be used to indicate that a necessary check was performed, the cross button was labelled "Necessary and Not done" to indicate that a necessary check had not been performed, and the Not Applicable button was labelled "Not Applicable" to indicate that the check item was not necessary for the particular case.

The Clinical Director asked for a last screen, which would list any items marked with a cross, i.e. checks that were deemed necessary but not done to notify the clinician, and ask whether it was intended to proceed with the procedure, as show in the wireframe in Figure 4.18. The save, delete, conclude actions were available in the action bar, and the progress bar was removed, as conceptually the checklist was complete. This warning or information screen was displayed in all cases to capture whether it was planned to perform the procedure, and warnings did not block the clinician from concluding the checklist.

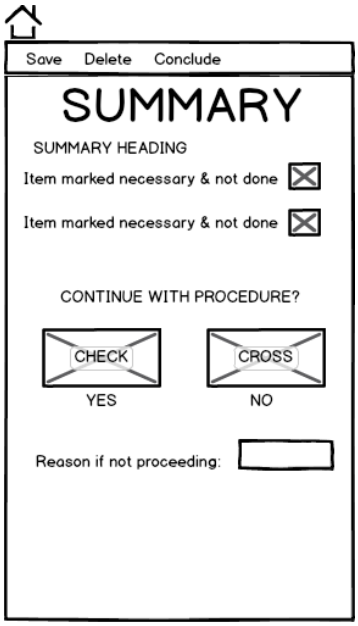


Figure 4.18: Iteration 3 Summary wireframe

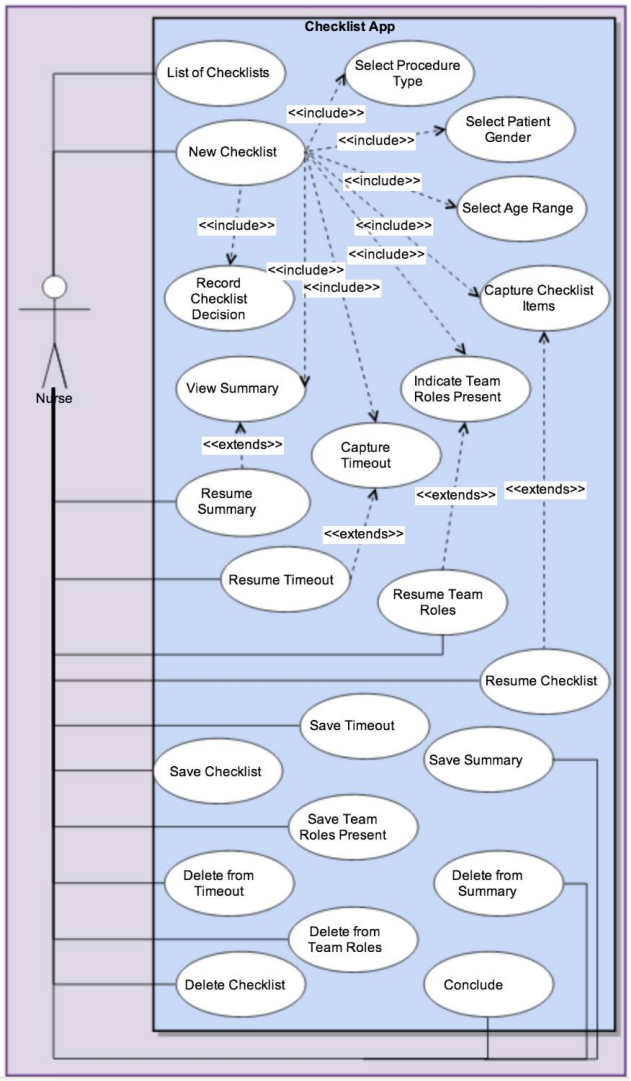


Figure 4.19: UML Final System User Requirements

As a result the final user requirements and behaviour of the app is described by the UML in Figure 4.19. The new use cases 'View Summary' with its associated 'Save', 'Delete' and 'Resume' use cases, and the 'Record Checklist Decision' use case were added. The third interim release of the app was accepted as the final XP project release.

In conclusion the final app functionality is described in the Activity Flow diagram of Figure 4.20 which shows that from the list of checklists, a new checklist could be created, which would follow the sequence of screens 'Select Procedure', 'Select Gender', 'Select Age' through to the 'Capture checklist items' screen. From the 'Capture checklist items screen', the process branched, and the user could either continue through to indicating clinical roles present, or alternatively save the state and return to the list, or delete the checklist and also return to the list. On the clinical roles

present screen the same branching was possible, the user could either proceed directly through to the timeout screen, or save and return to the list, or delete and return to the list. On the summary screen, it was possible to conclude, save or delete the checklist, all of which returned to the list screen. From the list screen it was possible to resume checklists at points determined by where the record was saved: either on the Capture checklist items screen, the Indicate roles present screen, the capture timeout screen or the view summary screen. It was not possible to go back to an earlier screen to update content captured before the resume point screen. The app screens of the final release are listed in Appendix I.

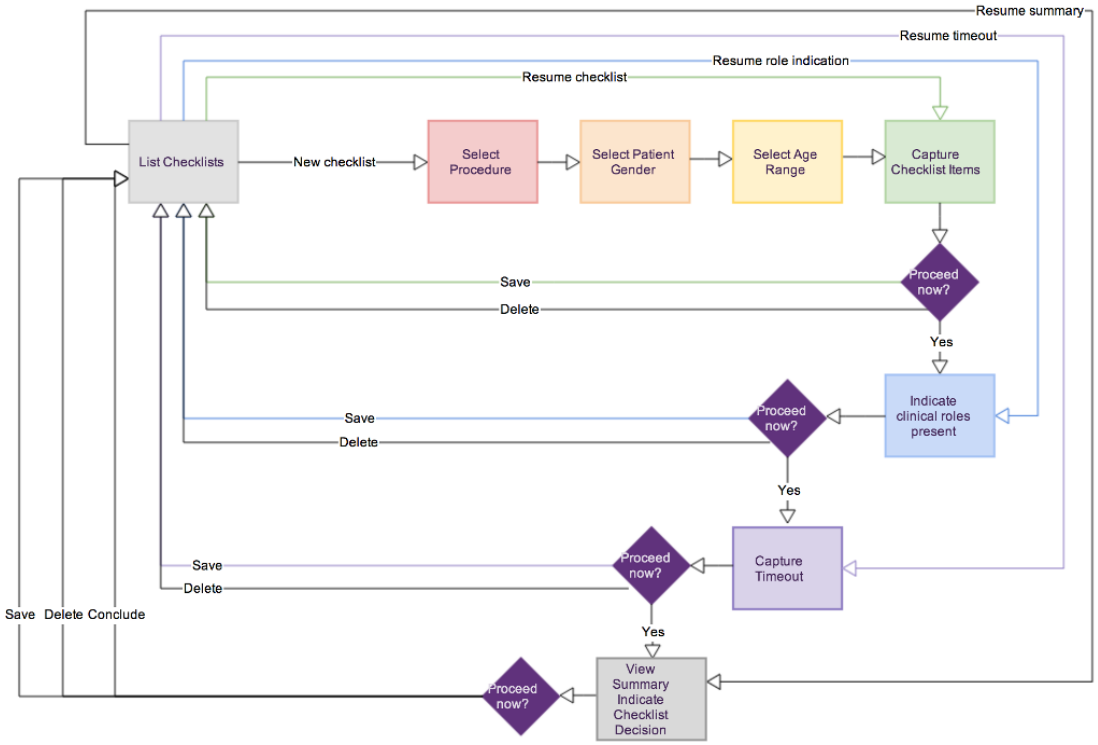


Figure 4.20: Final app activity flow diagram

4.5.6 User Training and deployment of tablets

Once the app functionality was completed, the 8 staff nurses and the Clinical Nurse Manager (9 nurses in total) were briefly shown how to use the application and what features were available. This took about 10 minutes before their daily rounds. Two tablet devices preloaded with the app were distributed. One was shared by the nurses in the IR room, and one was to be used in the breast clinic. The goal set by the researcher

and the Clinical Director was to gather 50 recorded checklists during the month long pilot study.

4.6 Evaluation of the tablet and app in use in clinical workflows

The app was used on two tablet devices for the month of July in the breast clinic, and IR room at the study site. The usability and acceptance of the app and the suitability of the tablet device will be evaluated based on data derived from observation, the electronic data captured on the two tablets, a usability survey completed after the pilot concluded, semi structured interviews held with the staff nurses and SpRs involved during the pilot study, and the physical condition of the tablet computers after the pilot study concluded.

4.6.1 Observation

Two of the issues that were raised when introducing a touch device into a sterile theatre were the concerns around infection control and the sterile field within which procedures are conducted, as well as the feasibility of using tablet touch screens, when clinicians are typically gloved.

Procedures were observed for two weeks before the pilot study, and then again for two weeks during the use of the tablets. The IR nursing records book which contains a daily record of every procedure performed in the room, showed that 159 procedures were completed during 21 days of the pilot study at an average of 7.6 per day. Of these 82 were categorised as smaller procedures averaging 4 per day.

As is shown in Figures 4.21, 4.22 and 4.23 only certain team members involved during procedures are remain sterile during the procedure, i.e. the SpRs or consultants operating in the sterile field.

Figure 4.21 Tablet in theatre on top of the paper chart in the foreground

In Figure 4.21 the tablet is seen in the foreground lying on top of the paper chart outside of the sterile field. Circulating nurses are not in the sterile field and pass objects to the members operating within the sterile field in a very controlled manner, never directly touching the implements, drapes or surgeons. As such these circulating nurses routinely hold pens and touch paper charts during the duration of the operation and are not always wearing gloves.

Figure 4.22 Nurse operating tablet without gloves

Figure 4.23 Nurse and SpR completing the checklist

In Figure 4.22 and 4.23 a nurse is seen operating the tablet without wearing gloves, and in Figure 4.23 the SpR, already scrubbed and in the sterile phase is accompanying the nurse while completing the checklist, but does not touch anything.

It was observed by the researcher that during the pilot, nurses completed the checklist on the app in one of two ways. Checklists were either completed together with the SpRs before commencement of the procedure or alone after the procedure had started, having done the checks with the existing paper form as shown in Figure 1.1. The tablet was stored in the locked controlled drugs cabinet overnight in the IR room, and in the breast clinic nurse's office.

4.6.2 Electronic checklist data

Data was collected on two tablets, which were in use in two different clinical workflows. As mentioned in section 4.3, the checklist content was updated after 12 days of use when it was discovered that the incorrect phase of the CIRSE checklist had been used to create the original content.

As shown in Figure 4.24, 134 checklists were entered into the application during the pilot study (averaging 6.4 per day), of which 110 were concluded and 13 were deleted. The time taken to complete checklists is shown in Figure 4.25, and was under 1 minute in 68.2% (n=75), and under 4.5 minutes in 83.7% (n=102) of cases. Only 12 checklist items skipped out of a total of 1404 checklist items offered.

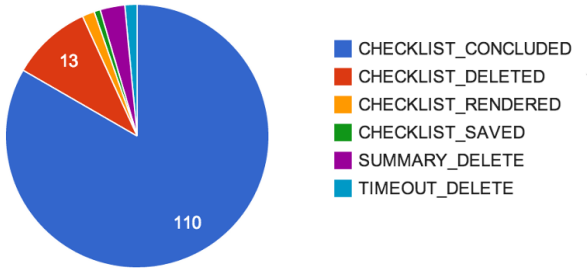


Figure 4.24 Total checklist completion/deletion during pilot study

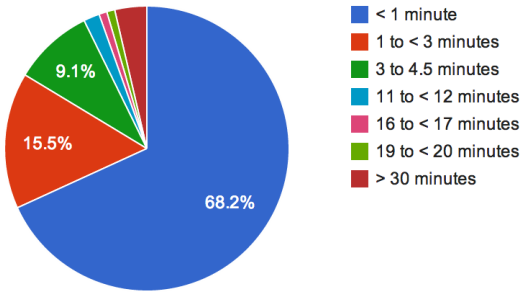


Figure 4.25 Time taken to complete checklists

The electronic data will now be discussed in terms of the two departments IR and the breast clinic.

IR

As described in section 1.2, the IR room handles patients that have been scheduled for various diagnostic or therapeutic procedures. Patients are operated on one at a time, and procedures in the IR room can range from bigger procedures like Embolization and

TIPS procedures, to smaller more routine procedures like the insertion of Picc lines and Lumbar Punctures. Two or more radiology nurses and a radiologist assist the SpRs and consultants performing procedures.

During the month of use in July, 61 checklists were recorded on the IR tablet. 7 of these records were entered by the researcher during testing and were disregarded. Of the remaining 54, 8 were marked as having been deleted by the clinical users, leaving 46 checklists records that were concluded, as shown in Figure 4.26

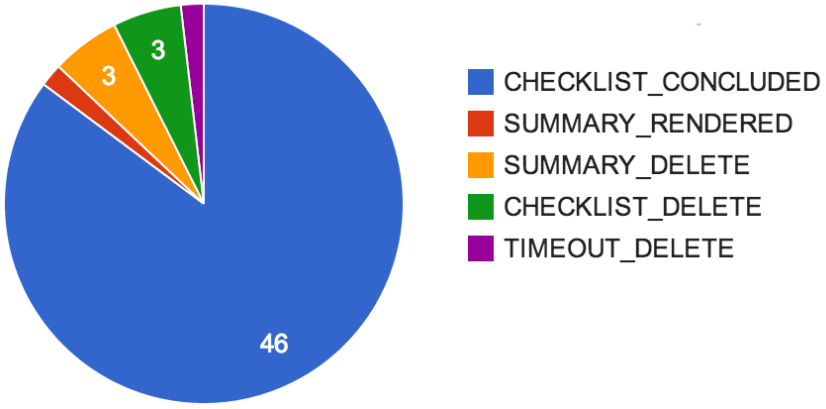


Figure 4.26 Interventional Radiology checklist completion/deletion during pilot study

Figure 4.27 shows that of these 46, 37 % (n=17) were completed in less than one minute, 26.1% (n=12) were completed between 1 and less than 3 minutes, and 19.6 % (n=9) were completed in between 3 and 4.5 minutes. Thus 82.7 % of the checklists captured in IR were captured in under 4.5 minutes.

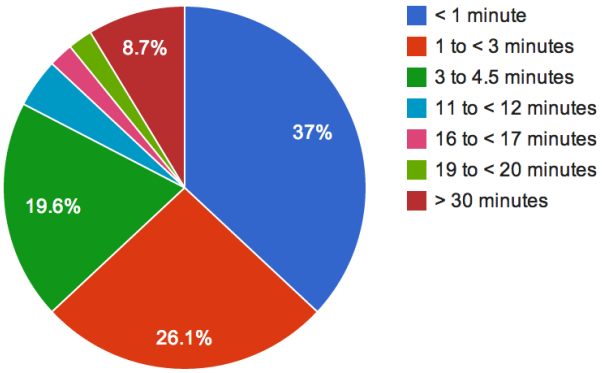


Figure 4.27 IR time taken to complete checklists

During the 12 days that the first version of the IR checklist content was used, 26 checklists were captured averaging 2 per day. The items most skipped were 'Discussed with referring Physician / MDT' (n=5) and 'Prior imaging reviewed' (n=3) out of a total of 11 skipped items. The items most marked 'Not Applicable' were 'Anaesthesiologist needed' (n = 18), 'Anticoagulant stopped' (n=9) and 'Contrast allergy prophylaxis needed' (n=6) out of a total of 50 items marked not applicable, which revealed an average of 2 items marked 'Not Applicable' per checklist record. The items most frequently marked 'Not Applicable' were all removed in the second version of the content.

During the 8 days that the second version of the IR checklist content was used, 21 checklists were captured, averaging 2.6 per day. No items were skipped. The items marked 'Not Applicable' most often were 'Consent and complications discussed' (n=8), 'All records with patient' (n=6) and 'Allergies and/or prophylaxis checked' (n=2) out of a total of 16 items, which revealed an average of 1.3 items marked 'Not Applicable' per checklist record.

The change from version 1 to version 2 removed unnecessary content and lowered the average number of items skipped from 2 to 1.3 per checklist record as seen in Figure 4.28 where the orange areas indicate not applicable items. After the change in content which takes effect at checklist 27, fewer items are labelled 'Not Applicable'. Thus it was possible to identify irrelevant checklist content for removal.

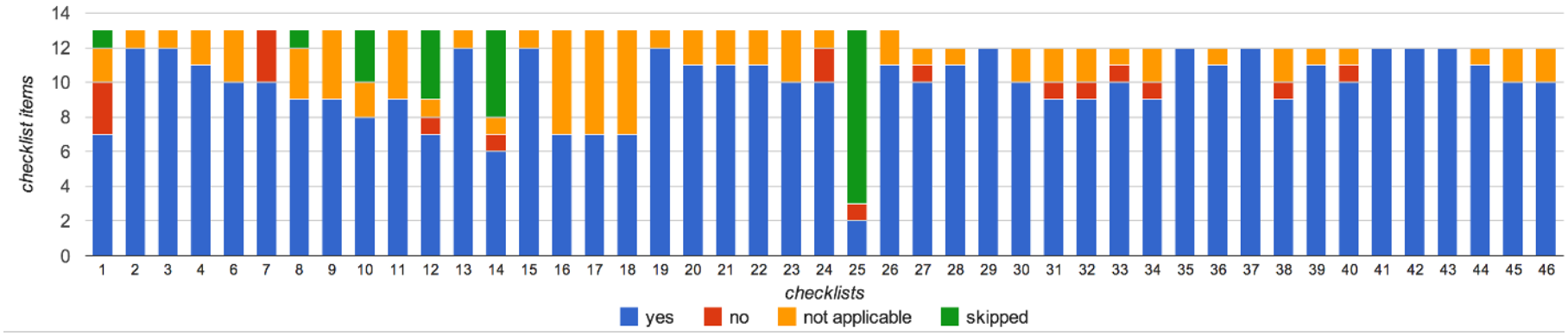


Figure 4.28 IR ratio of checklist items, marked yes, no, not applicable or skipped

Correspondingly, slightly more checklists were completed daily on average after the content update (from 2 to 2.6). . It should be noted that the content, rather than the application was changed.

Of the 46 completed checklists, nurses were present at the timeout in 44 of the cases (95%), SpRs were present in 43 of the cases (93%), consultant doctors were marked present during 12 of the cases (26%), and radiographers were present in 32 of the cases (70%). Consultant doctors were rarely involved in checklist completion and timeout, with nurses and SpRs being most frequently marked present, followed by radiographers.

Four cases indicated that the procedure was not completed after the checklist, no reason was given why.

Breast Clinic

As described in section 1.2 the breast clinic serves outpatients and procedures are rarely more invasive than tissue biopsies. One nurse assists one or more consultants and SpRs and several patients may be undergoing imaging or biopsy procedures at once. Several rooms are used for patients in the breast clinic.

During the month of July, 88 checklists were recorded on the breast clinic tablet. 9 of these records were entered by the researcher during testing and were disregarded. Of the remaining 79, 12 were marked as having been deleted by the clinical users either on the checklist, timeout or summary screen, leaving 67 checklists. 3 of these were abandoned after the checklist was rendered or saved and were never resumed, leaving 64 records that were concluded, as shown in Figure 4.29

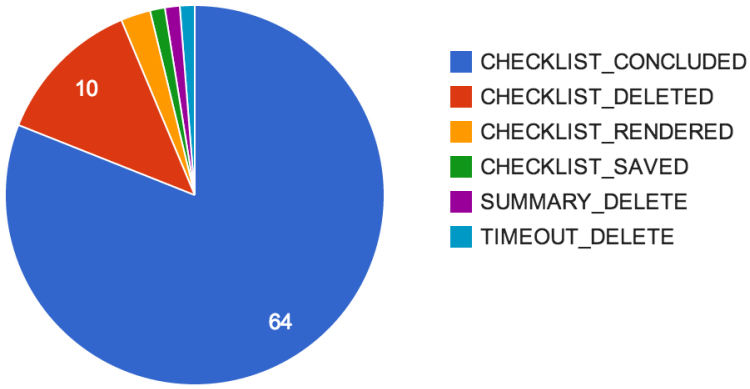


Figure 4.29 Breast Clinic checklists captured

Of these 64 concluded checklists, 90.6 % (n=58) were completed in less than one minute, 7.8% (n=5) were completed in between 1 and less than 3 minutes, and 1.6% (n=1) were completed in greater than 3 and less than 5 minutes. Thus 98.4 % of the checklists captured in the breast clinic were captured in under 3 minutes as shown in Figure 4.30.

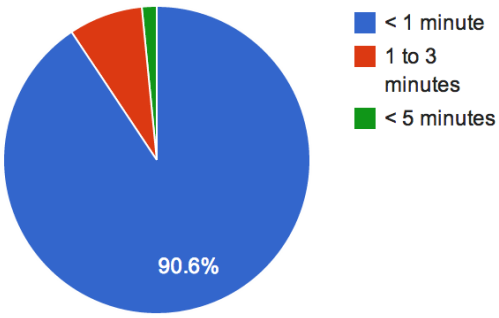


Figure 4.30 Breast Clinic time taken to complete

During the 12 days that the first version of the Breast Clinic checklist content was used, 49 checklists were captured, averaging 4 per day. Only one item was skipped 'Discussed with referring Physician / MDT' (n=1). The items most marked 'Not Applicable' were 'Written Consent' (n=43) 'Currently taking anticoagulant medication' (n=43), and 'Post procedure Bed required' (n=42) out of a total of 187 items marked not applicable, which revealed an average of 3.8 items marked not applicable per checklist record. The checklist content was obviously a lot less relevant for the breast clinic procedures. Items most frequently marked 'Not Applicable' were all removed in the second version.

During the 7 days that the second version of the breast clinic checklist content was used, 15 checklists were captured, averaging 2.1 per day. No items were skipped. The items marked not applicable most often were 'IV access' (n=15), 'Patient Fasting' (n=15), 'Monitoring equipment attached' (n=15), 'Allergies and/or prophylaxis checked' (n=15), 'Consent or complications discussed' (n=15) and 'Anticoagulant stopped' (n=15) out of a total of 108 'Not Applicable' items, which revealed an average of 7.2 items marked 'Not Applicable' per checklist record.

The change over from version 1 to version 2 removed unnecessary content, but dramatically increased the average number of items marked 'Not Applicable' from 3.8 to 7.2 per checklist record. This can be seen in Figure 4.31 where the orange areas indicate 'Not Applicable' items, and after the change in content which takes effect from checklist 50, the items labelled 'Not Applicable' almost double. Thus it was possible to identify that more irrelevant content had inadvertently been added.

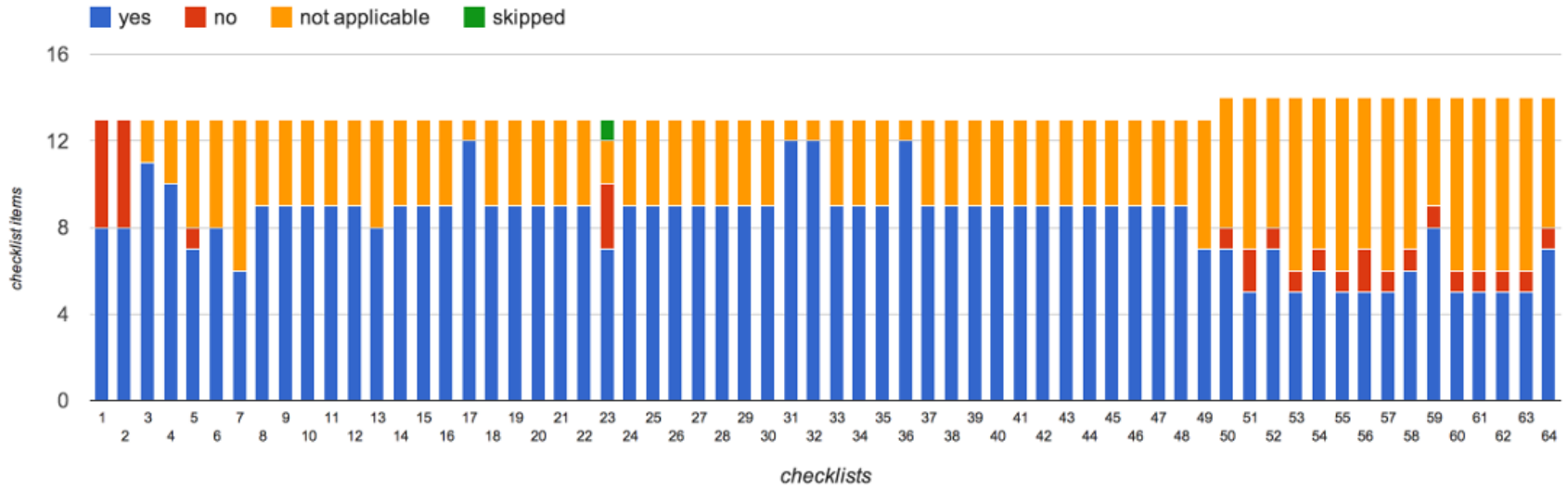


Figure 4.31 Breast Clinic ratio of items marked yes, no, not applicable or skipped

It is interesting to note that correspondingly, fewer checklists were completed daily on average after the content update, dropping from an average of 4 per day to 2.1. It should be noted that the content, rather than the application was changed.

Of the 64 completed checklists, nurses were present at the timeout in 64 of the cases (100%), SpRs were present in none of the cases, a consultant doctor was marked present during 1 case (0.1%) and a radiographer was marked present during 1 case (0.1%). Consultant doctors and radiographers were almost never involved in the checklist completion in the breast clinic and timeout as indicated on the tablet. Nurses were always marked present, and SpRs were never present during pre-procedure checklist completion.

It was never indicated that the procedure was not completed after the checklist.

4.6.3 Simple Usability Survey

The SUS Simple Usability Survey (Brooke 1996) was completed by 5 nurses and 1 SpR. The totals returned were 90, 75, 70, 100, 95 and 87.5 out of a possible 100. Thus the average survey result was 86.25 out of 100, which equates to an 'Excellent' rating in the (Bangor et al. 2009) adjective rating scale as shown in Figure 4.32.

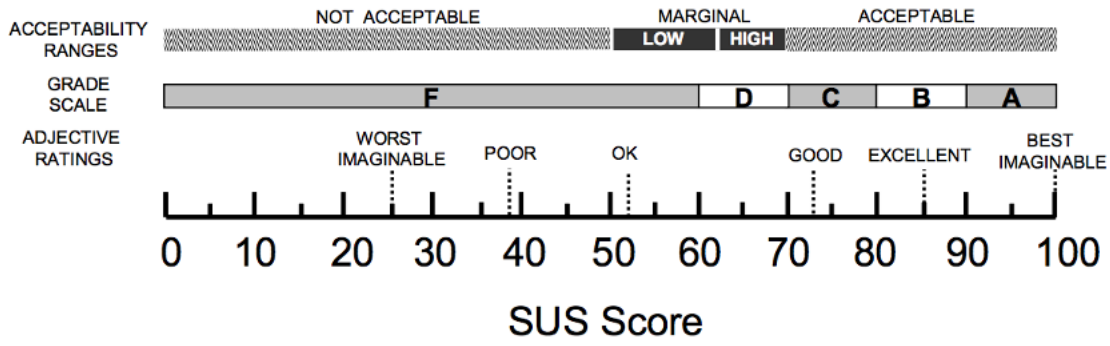


Figure 4.32 The Bangor et al adjective rating scale

Source (Bangor et al. 2009)

4.6.4 Themes that emerged from the exit interviews

<u>SpR Exit Interviews</u>

3 of the 5 SpRs performing procedures in IR during the pilot study were approached for interview. All 3 agreed to participate (100 %). The SpR participants performed procedures in the IR Room on 20 of the 21 days of the study.

Interviews were recorded, transcribed, and sent back to the participants to verify the accuracy of the transcribed version and all replied that the transcriptions were accurate. The text was then coded. Participant interviews were assigned numbers to protect anonymity and analysed using an editing approach (Robson, 2002). Inductive reasoning was used along with the a priori codes 'Usability', 'Acceptance', and 'Suitability' to derive the predominant themes.

Nine themes arose from analysis of the interviews: ‘Efficiency’, ‘Checklist content and procedure coverage’, ‘Sterile environment and tablet operators’, ‘Workflow’, ‘Usability’, ‘Suitability’, ‘Acceptance’, ‘Interactivity and Design’ and ‘Electronic Data’.

Efficiency

All SpRs agreed that checklist completion was very quick, and reported that it took 1.5 to 2 minutes at most, and that it was felt to be faster than paper.

Checklist content and procedure coverage

Opinion was divided on whether the app, or rather more specifically the checklist content in the app should be used for every procedure in IR. SpRs described what they termed 'bigger' or 'smaller' cases i.e. the bigger , more complex procedures as opposed to the more routine simpler procedure types which account for over half of the procedures performed monthly. One SpR felt that the full checklistcontent was not entirely relevant for the smaller routine procedures and that using it in its complete form for every procedure could result in a sense of redundancy, irrelevancy or check-list fatigue. The other two SpRs felt that safety checklists should be completed as a matter of routine before every procedure due to the unpredictability of the patient's day to day condition; the busyness of the procedure room; and the fact that things get missed, which could cause poor outcomes if not detected. All three SpRs mentioned the value in having procedure specific checklists, which may be less extensive for the smaller cases, but which would ensure that basic fundamental checks be completed as a matter of routine in every case.

Sterile environment and tablet operators

None of the SpRs interviewed had any concerns about the presence of the touch device in the sterile OR. Two SpRs had not touched the tablet at all during the pilot, and said that it had been operated by the nurse outside the sterile field. One SpR had operated the tablet when preparing for procedures before he scrubbed in. When discussing infection control, none had concerns about the tablet contaminating the environment and mentioned that the tablet itself could be protected from receiving contamination

from ill patients either by wiping it down with alcohol which is routine in the cleaning of the equipment within the theatre, or that if necessary, that it could be encased in a disposable sterile covering.

Workflow

All SpRs agreed that the introduction of the tablet and safety checking app created a minimally disruptive, and positive change to their workflow. They noted that while safety checking is already being done, that the execution can be somewhat haphazard and unstructured. The app and tablet was felt to organise the effort and the team members performing the checks and they were seen as a good and efficient addition to safety checking. One SpR stated that the more checks there were the better. All agreed that it resulted in a necessary change and created a more focussed safety checking atmosphere. It took less than 2 minutes to complete, and it was possible to do so in communication with the nurse while scrubbing in or putting on the surgical garb.

Usability

All SpRs stressed that the checklist was completed very quickly. The app was felt to be very straightforward, and that it was efficient. All SpRs felt that the app layout was visually easier to use in terms of completing checklist documentation than scanning through the black and white printed out A4 pages of the standard procedure documentation shown in Figure 1.1.

Suitability

When asked about the suitability of the tablet, one SpR mentioned that he felt the tablet was a very good way of doing it, that team members were not bound to workstations and could move around freely. All commented on the mobility and flexibility afforded by the tablet that the team could meet anywhere convenient and that the SpRs could multitask and complete the checklist while scrubbing in or could be in proximity to the patient. An SpR mentioned that if the monitoring equipment had already been attached to the patient that he could listen to the monitors and communicate with the patient while completing the checklist. One SpR noted that using the tablet meant that there

was no writing down. Two SpRs noted that capturing the data electronically meant that it could be available on the EPR which was seen as a great advantage. One SpR noted that a little coordination was needed, to gather the nurse, the tablet and the SpR to the patient's bed side.

Acceptance

One of the SpRs remarked that he wished that the tablet would be available in his eventual place of work. All three noted that it was beneficial, using words like nice, good, necessary, simple, straightforward and convenient. One SpR noted that the simplicity and efficiency created a sense of reassurance that safety matters had been attended to, and that it improved safety awareness. The improved structure and organisation of safety checking was noted by all and welcomed. It was noted by the researcher that the SpRs offered to teach one another how best to operate and integrate it into the workflow, and in effect were advocating use of the app and tablet to one another, and teaching one another how best to use it. Some SpRs interviewed had not been briefed on the pilot before their involvement and were curious and took the initiative by approaching nurses to find out more about the project and gave positive feedback after the pilot.

Interactivity and Design

All SpRs felt that the app design and interactivity helped to easily complete the checklists. One SpR noted that the visual aids and feedback made it easier and very efficient, in contrast to having to scan through multiple pages of black and white printed out documents. He noted that the coloured icons - the green check mark icon and the red cross icon - gave helpful visual feedback and aided with completion. Another SpR referred to the visual aspect as the handiest part, noting that it focussed attention through the flow of screens, controlled the methodical completion thereof and guided the user through to checklist completion. Breaking the functionality up into several uncluttered screens created a clear concise progression, and when it concluded the SpR felt reassured that all concerns had been addressed. SpRs highlighted that not every part of the existing nursing documentation is relevant for every procedure and time is wasted checking and double checking that the relevant sections have been completed. The

design was felt to be user friendly and attractive, and the SpRs noted its simplicity and clarity which was felt to streamline the documentation process. The design was felt to make it faster and the use of images resulted in less reading.

Electronic Data

Two SpRs noted the advantage to capturing the data electronically. This was felt to improve the availability and access to the checklist data through the EPR, and could be used for reporting, or auditing as well as checklist content refinement over time. By examining the data the hospital could refine the checklist content by discovering what should be added to the lists, and what had been frequently marked not applicable, and thus could safely be removed.

Nurse exit interviews

6 of the 9 nurses assisting in procedures in the IR room and the breast clinic during the period of the study were approached for interview. 5 agreed to participate (83 %).

All interviews were recorded, transcribed, and sent back to the participants to verify the accuracy of the transcribed version. One change was requested and was made and the text was then coded. Participant interviews were assigned numbers to protect anonymity and analysed using an editing approach (Robson, 2002). Inductive reasoning was used along with the a priori codes 'Usability', 'Acceptance', and 'Suitability' to derive the predominant themes.

Ten themes arose from analysis of the interviews: 'Tablet as a change agent', 'Efficiency', 'Focus', 'Acceptance', 'Usability', 'Suitability and the sterile environment', 'Theft and security', 'Checklist content and procedure coverage', 'Data availability', and 'Design'.

Tablet as a change agent

The nurses interviewed did not feel that the introduction of the tablet and the app caused disruption to their workflow, but rather that it organised the already existing process of checking, and created a 1 to 2 minute window of time where methodical

focussed checking could take place in collaboration with the doctors. An interesting observation was that while checklists are very familiar to nurses who complete them routinely before procedures, the pilot study and introduction of a tablet device signalled a change in culture, even if it was understood to be temporary. The curiosity of colleagues and the attention drawn by the device was felt to create an opportunity to introduce check listing to the doctors. One nurse noted that SpRs themselves indicated they had previously just presumed that the checks were taking place and that the tablet was drew their attention to the process. Nurses were then able to then involve the doctors more easily. Nurses noted that the physical device afforded them the opportunity to draw attention to the process of checking and involve the doctors more so than before.

Efficiency

4 out of 5 of the nurses remarked at the speed at which checklists could be completed, noting that writing in patient MRNs, and names and further information such as lab results would not be necessary in an app integrated with the EPR, which would speed things along. One nurse mentioned that she had expected the checklist to take longer than it did. Responses varied, some nurses saying that it felt like a matter of seconds, others that it took between one to 2 minutes. It was noted by several nurses that checklist completion was quicker on the tablet application than would be possible on paper.

Focus

The tablet was felt by the nurses to create a greater sense of focus on safety both among the nurses and the doctors. One of the nurses mentioned that because it was a bit different, both due to the presentation as a list as opposed to the format on the nursing documentation, and due to the fact that the physical device was being carried around, that she felt more focussed on checking the items. Other nurses agreed that the app required that one pause and attend to the list of checks and reminded them to involve the Registrar or another nurse so that two people were checking together. Usually the workflow is busy and rushed, and as one nurse said ‘you can lose the run of yourself.’ Prior to the pilot study various checks were being completed independently by members

of the group rather than systematically being checked off. Using the app for a minute or two ensured that all checks were completed. Many nurses mentioned that it increased the focus on the safety aspect within the IR room.

Acceptance

It was noted by nurses that due to the fact that it was a trial, and that the existing safety checking was still being completed on the usual nursing documentation that there was occasional reluctance among fellow nurses and doctors to use the app. The duplication of safety checking effort was noted and because it wasn't officially necessary there was occasionally a bit of resistance. One nurse describes it as 'getting vibes' as the completion of the checklist effectively would stop people in their tracks, particularly when the room was busy with many procedures or there were many people in the room for a procedure. Some nurses also suggested that some of the older staff were not interested in the newer technology and would not participate. Some of the novice touch device users from the usability testing however found it very interesting and enjoyed the tablet and the application and required no assistance. Several of the nurses thought that the resistance was more due to the duplication of work than the app and that if the app were implemented as the single form of official documentation necessary before procedures that it would be used. All of the nurses interviewed liked the tablet and app and felt that if it were integrated with the EPR that it would be better than the paper documentation.

It was interesting to note that the breast clinic nurse stated that due to the busyness of the breast clinic that safety checks are completed verbally with no paper chart on hand to store a paper record of the checks. She felt that an electronic checklist integrated with the EPR would however usable if records of safety checks needed to be kept and it was felt that this would improve the patient's safety and overall journey.

A further interesting finding was that one nurse thought the safety check listing to be more important in the IR procedures than in the more invasive surgical procedures due to the higher number of smaller procedures being completed daily in IR. The high throughput of cases was felt to require an extra layer of routine safety checking.

Finally all nurses interviewed liked the app and tablet, and felt that these were generally liked among the clinicians.

Usability

Four of the five nurses interviewed required no help to use the application, one nurse had missed the user training and requested a little help at first. Three nurses did report that content ambiguity remained and that this caused discussion and need for assistance. The nurses did however distinguish between the usability of the application itself and the ambiguity raised by some of the checklist content as described in section 4.4.5. The application was found very simple to navigate through and use, but it was not always clear how to respond to some of the checklist items i.e. whether one was marking that the act of checking was completed, or capturing the outcome of the check as discussed in section 4.4.5.

Suitability and the sterile environment

None of the nurses interviewed had any concerns about the sterility of the device or infection control noting that many similar tools are already being used and that routines and protocols are already in place, such as wiping down the computer monitor screens with alcohol before each procedure. Other nurses indicated that they would complete the checklist before preparing the patient or the sterile trolley of procedure equipment for the doctors. There are already protocols in place for taking off gloves and washing hands before handling pens and charts. One nurse noted that due to the instilled training that instinctively one would never pick up the tablet while wearing gloves.

Suitability

The workflow differed between the IR room and the breast clinic. In the IR room the tablet device remained in the room and shared among all the nurses assisting with procedures. In the breast clinic the tablet was kept by the single nurse assisting several consultants and SpRs in several rooms. As such the question of suitability uncovered a range of issues some peculiar to the breast clinic environment, and others that were

common to both. Size was a factor in the breast clinic, as the nurse would typically be carrying the tablet on her person from room to room. The nurse went to extra effort to either hide the tablet device under trolleys in the rooms of the breast clinic or lock it away in her office as it was too big to comfortably fit in her scrubs pocket along with her beeper. As she was assisting in several rooms this became problematic, and as a result checks were done verbally as before, but then captured on the application retrospectively for fear of losing the device or it being stolen. Damage to the device was not of concern as it had a special carrier sleeve that cushioned it. She suggested that if the tablet had been slightly smaller and could fit in her pocket that it might have been more suitable to her workflow.

Theft and security

In the IR room, the concern over theft was also mentioned and the device was routinely locked in the controlled drugs cabinet overnight. The risk remained that it could be stolen during the day as many different people enter and exit the IR Room when bringing and fetching patients. This was noted by several nurses who acknowledged that is was not possible to be mindful of the device all the time. The size of the device was less of an issue than the fact that it was portable and could easily be stolen.

Checklist content and procedure coverage

Opinions were mixed among the nurses as to whether the app should be used for every procedure and suggestions for procedure specific content were raised. It was noted by nurses that the standard paper nursing documentation is completed for every procedure and that the problem of irrelevant content is also noted in the paper format. This standard paper documentation as shown in Figure 1.1 is used across all procedures, and as a result of the problem of irrelevant content, it is currently under review. This review process was noted to take a lot of time. The issue of content ambiguity and that certain desired features were not implemented yet, and that the app was felt to capture insufficient information in certain cases was however seen to be a minor issue that could easily be ironed out.

Data availability

Several nurses remarked on the potential advantages to having the checklist data available electronically. If the application was integrated with the EPR it was noted that the checklist could not get lost as is the case when paper forms fall out of the patient charts. It was also noted that the checklist data could be entered and viewed from any computer workstation with access to the EPR, so that if a nurse entered the IR room and the tablet was being used by someone and not available (as is sometimes the case with the paper documentation), that she could quickly access the checklist record on the computer workstation to see what had been checked, and what remained to be checked.

Design

Finally all nurses felt that the graphical interface design was appropriate, usable and helpful. One nurse did mention that the icon used to represent the nurse was female, and the icons used to represent the SpRs and consultants were male and that this had caught the attention of a female consultant and was humorously remarked upon. While the exchange was light hearted it was noted that more sensitivity could be used when selecting the representative icons.

4.6.5 Physical condition of the tablet devices after the pilot study

Neither tablets were lost or stolen, and both were returned to the researcher on conclusion of the pilot study. Neither tablet had been damaged, the screens and backs of the devices were examined and no scratches or scuff marks were visible. The tablets were fully functional.

4.6 Conclusion

In summary, the findings of this study show the basic functionality requested by clinicians in order to capture pre-procedural safety checklists in IR and an outpatient clinic via an appl. The app was built iteratively using the XP software development methodology which converted a prototype into the final application over three iterations. User requirements were added after each iteration by clinicians after

examining the interim release. It is further shown that such an application can be engineered to be usable, using usability tests among end users and usability and technical inspections by experts. Both habitual and novice users used the device for a month within their clinical workflow and rated the usability as 'Excellent' in a SUS Usability survey. The app was accepted by all clinicians interviewed, who also mentioned that it was generally liked by most of their colleagues. Tablet devices were found to be suitable to the clinical environment, but the type of clinical workflow affected the preferred size of the device. Risk of theft was a factor in both clinical environments.

134 checklists were entered into both devices during the month long pilot study, (averaging 6.4 per day) and 110 of these were completed. The time taken to complete checklists in the app was under 1 minute in 68.2% (n=75), and under 5 minutes in 83.7% (n=102) of cases and it was felt to be faster and easier to complete that would be possible on paper. The web survey of clinicians involved in radiology in Ireland revealed that 87% of respondents own smartphone devices, and use the touch devices to access email, apps and browse the web routinely. 50% of respondents own tablet devices of which 40% use them daily. As such it would appear that the respondents already use touch devices habitually and are familiar with the technology. 43% of respondents indicated a preference for electronic rather than paper checklists, as opposed to the 37% preferring paper.

Most nurses and all SpRs interviewed liked the application, and recognised its potential and felt it would be better and faster than paper when capturing checklists, but noted that without integration with the existing EPR the app would not be used. The relevance of the content and the degree of content ambiguity were found to have a marked effect on acceptance and usability. Content ambiguity, and desired features were mentioned in several interviews among the participant nurses. Irrelevant content may explain the drop off of average daily checklist completion in the breast clinic after the content was ineffectively updated as described in Section 4.6.2. Nurses did experience some reluctance among a few colleagues to use the application and while this was in part attributed to the duplication of work when completing checklists during the pilot study, it was noted that some older colleagues rejected the newer technology.

The tablet devices were found to be largely accepted and suitable to the clinical and sterile environment, and neither nurses nor SpRs had any concerns about sterility or infection control. The difference in workflow between IR and the breast clinic revealed that if the device was to be carried around, that the size of the hardware would factor into its suitability.

The electronic nature of the checklist data captured during this study made it possible to evaluate and refine checklist content and easily update it, and also to measure the effect after the update. Even though the original CIRSE 'Pre-procedure planning' phase chosen as version 1 of the checklist content was the incorrect phase, the effect was mitigated by the adaptation of the content by the Clinical Director and the nurses to better suit local practice before being used as described in Section 4.3. The content was also changed overnight in the checklist application at zero cost, which would not be possible had paper copies of the checklist been purchased in bulk. The presence of the checklist application was welcomed by the SpRs in IR who felt reassured of the patient's safety when involved in the checklist completion. The introduction of the tablet was felt by some nurses to facilitate change and provide an opportunity to introduce the doctors to pre-procedure safety checking, and to involve them. The use of the checklist and the app was felt by the nurses and the SpRs to organise the completion of pre-procedure safety checking. While the risk remains that portable devices could be stolen, it was possible to secure the tablets, and neither tablet was damaged, lost or stolen.

The potential of having the checklist data available electronically was remarked on both by the nurses and the SpRs. Nurses noted that the checklist could be referenced and completed via workstations and the tablet simultaneously and that the data would less likely be lost. SpRs noted that the electronic data could be used to refine and improve checklist content. Nurses and SpRs proposed the creation of procedure specific checklists.

In conclusion, the design of the app was found to be very usable and was largely accepted, and the tablet device was found to be generally suitable to clinical workflows, but attention to the size of the device was important when it was to be easily carried around throughout the work day.

Chapter 5 Evaluation / Analysis

5.1. Introduction

The aim of this study was to design and build a user-friendly mobile application to support clinicians when completing pre-procedure safety checklists in the IR room and the breast clinic at the study site. Further to this the usability of the application and whether it was accepted by clinicians was also evaluated. Finally the suitability of the tablet device to the clinical environment in IR and the breast clinic was evaluated. The development and evaluation of the application and table device was achieved by:

1. Reviewing the literature to understand the state of the art in electronic checklists and to identify an area of possible further study, after which the exploration and evaluation of inexpensive mobile technology as an implementation platform was identified as the area of interest.
2. Surveying clinicians in radiology in Ireland to understand their familiarity and use of touch devices, as well as their knowledge of, experience with and attitude toward pre-procedure safety checklists.
3. Selecting the most appropriate hardware and software.
4. Adapting and refining the CIRSE checklist content to best suit local practice in collaboration with the clinicians.
5. Building the desired functionality into a tablet application and testing the application for usability.
6. Training the users.
7. Piloting the application for a month in the IR room and breast clinic.
8. Observing the use of the tablet in the IR room.
9. Completing usability surveys and exit interviews among participant clinicians to assess the acceptance, usability and suitability of the implementation, and
10. Examining the electronic checklist data.

As described in section 1.2 safety checks are routinely completed in the IR room and the breast clinic before procedures. In IR these checks are recorded on the standard nursing procedure documentation as shown in Figure 1.1, and in the breast clinic which serves outpatients, the checklist is completed verbally from memory. Neither department use

a formal separate checklist like the IR checklist developed by (Lee et al. 2012) and recommended by the CIRSE as shown in Figure 2.3. The CIRSE IR checklist was selected to be implemented in IR but the Clinical Director was hesitant to introduce another piece of paper documentation to the patient paper chart which the study site is trying to replace with an EPR system as paper documents can easily get lost, are expensive to store and the data they capture is difficult to search or report on. The Clinical Director saw an opportunity to explore the use of tablet devices as a means to capture electronic records of the checklist which could in future be integrated with the EPR.

5.2 Design and Development

5.2.1 Introduction

The first research question in section 1.3 asks how pre-procedural safety checklist activity might be supported by a mobile application. An aim of this study was to develop a suitable and user friendly app to support clinicians when capturing pre-procedure safety checklists. An integral part of the app was the creation of relevant content. An agile software development methodology was selected to iteratively build the application in collaboration with clinicians as explained in section 2.9 in order to elicit the necessary requirements and create a suitable app. Simultaneously the iterative checklist content implementation model as described by (Verdaasdonk et al. 2009) was used to refine, test, approve and finalise the CIRSE IR checklist content to best suit local practice before using it in the app as described in section 4.3.

5.2.2 Content

The (Verdaasdonk et al. 2009) implementation model was found to be very effective and necessary when adapting the content, even when starting from the previously developed CIRSE IR checklist content. The model is iterative, and involves periodic review and the training of personnel. During this study it was experienced how easily a quick assumption can result in inaccurate content or the incorrect implementation of a checklist, as described in section 4.3. It was the experience of the researcher that clinicians, both doctors and nurses, are exceptionally busy and are pressed for time, and the researcher herself was too busy completing the app and inexperienced in the

domain to recognise the content error. The Verdaasdonk model mitigates the risk of decisions made in haste by introducing the review and testing of checklist content before implementation and the periodic review of that content after implementation. The electronic nature of the data captured in the app database made such review easier and faster to do and the update to the content could also happen at no cost overnight.

The initial introduction of the checklist in a paper format during the testing of the content was found to be an effective strategy to change the workflow as a separate act to introducing the tablet and app. This was done to prevent rejection of the app by making it clear that the change to the workflow dynamic and possible increase in effort was not caused by the introduction of the app but rather that it was due to the introduction of a formalised pre-procedural safety checklist exercise.

The app supported multiple checklists so that different content could be provided to IR and the breast clinic. It is also conceivable that if the app was integrated with the EPR, that procedure-specific checklist content could be provided, based on the procedure ordered for the patient. The involvement of the nurses and Clinical Director in adapting the checklist content created a sense of partnership, and may have influenced the acceptance and usability of the content. Checklist content was best kept concise and clear. The average number of 'Not Applicable' items per checklist dropped after the update to version 2 of the content in IR from 2 to 1.3, but increased in the breast clinic from 3.8 to 7.2. The content of version 2 was based on the 'Sign In' phase of the CIRSE IR checklist for both departments and had 12 items in common. This data was clearly shown to be more appropriate to IR than the breast clinic, which revealed how context sensitive valid checklist content is.

As introduced in section 4.5.5, and detected as early as the usability test in section 4.5.2, conceptual ambiguity may be experienced by the users of checklist applications as to whether the checklist is understood to be recording the act of checking or the outcome of the check. The original CIRSE IR checklist was understood to capture whether checks have been performed but not the outcome of the check, and this interpretation was utilised in the app, but nurses requested additional functionality during the pilot study that would allow them to capture the outcome of checks as is typically captured on the

standard nursing documentation. The confusion about what was being captured and the purpose of the app affected the perceived usability of some of the content of the app.

5.*2.3 Application*

As stated in section 2.9, agile software development methodologies prioritise individuals and interaction, working software, customer collaboration and responding to change. The choice of XP, an agile methodology, was found to effectively manage the emergent requirements, facilitate quick acceptance testing, help identify further user requirements and ensured the steady incremental release and availability of working software artefacts (Fruhling and Vreede 2006).

In the XP lifecycle as described by Figure 2.17 user requirements are selected per iteration, with the most important essential functionality being completed first. As previously said, it was the experience of the researcher during this study that clinicians have very little time to spare, especially as this study was a research project rather than a commercial product and their participation was voluntary. The time available was found to be more productively spent when a working prototype was available for examination by the clinicians rather than attempting to make sense of abstract and elaborate system specification documents. The most valuable feedback and necessary changes to requirements came from clinicians after they had been given an opportunity to interact with the latest interim release.

XP also postpones the documentation of system behaviour until the final release artefact has been created as shown in Figure 2.17, which echoed the priorities of this study. Agile prioritises working software over documentation and responding to change over following a plan, both of which were critical to the successful and quick implementation of an app. The XP approach ensured the early interim release of a working software artefact. This artefact served as a prototype and was used to verify the work done to date, and elicit further requirements. Usability testing was also completed on the prototype which tested the usability of essential features of the app and tablet device with the end users. Due to the quick iteration in XP and the steady increment of implemented functionality, usability inspection and updates to the app in

response to the usability test findings were possible. Finally a working software final release was available with enough time for it to be piloted within the clinical working environment for a month.

However, the researcher did experience that a risk with XP is that the user requirements can grow rapidly. The initial requirements for the system were very simple as is shown in the use case in Figure 4.2 which had 3 cases or discrete units of functionality. Within the 3 iterations, the functionality had grown to that shown in Figure 4.16 which contains 23 discrete units of functionality. The limit on the software development activity of this study was time rather than financial cost and so could not be negotiated, but it might be difficult to implement XP in a commercial project due to the ballooning of user requirements. As per Table 2.2 of section 2.9 XP also suited the software development activity of this project because the checklist app was a relatively simple software project – it involved no integration with existing hospital systems and had no external networking dependencies. (Fruhling and Vreede 2006) note that XP best suits smaller development projects and teams due to the lack of detailed upfront architecture and planning, and the informal nature of the user requirements elicitation.

The most valuable aspect to the XP methodology was the constant user feedback received on the interim releases. It was possible to correct and adjust the design to produce an app that best suited the clinicians. It was possible to respond to their suggestions and involve them in the development of the app in order to best suit their workflow. Usability issues could be identified and addressed early.

As described in section 4.5.4 wireframes were used before developing of the second interim release in order to have the interface design inspected by a usability expert before implementation. This prevented rework of the application and saved time. While the application was rated as having 'Excellent' usability after the pilot, it was evident among the exit interviews among the nurses, and from the period of observation that ambiguity and subtle usability issues remained. The design decision to follow the interpretation that checklists record actions and not the outcomes of actions as described in section 4.5.5 proved confusing to several nurses. Perhaps the objective or

purpose of a checklist app was not clarified conceptually. The exit interviews reveal that conceptually nurses understood the app to be an early electronic form of the standard nursing documentation rather than simply a checklist of items to mark off, which underscores the necessity to take the time during user training to explain and define the purpose of a system. We did not have the luxury of time but the researcher feels that it could have been resolved with a few more iterations of content and app refinement.

The effect of the usability engineering was significant. Training on the final application took less than 10 minutes even for novice touch device users, which the Clinical Director found remarkable. Users found the app itself straight forward to use, and only mention the need for help when using the app due to missing the user training, or due to content-related ambiguity issues rather than app interface design and navigation. The usability, use of images and the attention paid to the aesthetics was noted among the SpRs and nurses in the exit interviews.

Finally it was deliberately decided to implement no validation rules in the app. The app was seen as an opportunity to evaluate and refine the checklist content, and gain data on checklist item usage and whether items were skipped, or checklists were abandoned. These data points required that no attempt to block or prevent the user from continuing be put in place. (Burghouts 2010) also recommended that validation or 'stopping rules' be initially implemented flexibly in order to let clinicians become accustomed to the system and let it be workable. As a result valuable data was gathered and it was possible to report on checklist data. It is also worth noting that even though the app gave clinicians the freedom to skip items and abandon checklists that they very rarely did so.

While functionally adequate, it was understood that for the app to be used within a working clinical environment that it would need to be integrated with the patient's EPR and send the data captured into the patient's electronic record.

5.2.4 Conclusion

The Verdaasdonk et al. (2009) model for checklist implementation was found to effectively mitigate the risk of incorrect checklist implementation by supporting the

tests and periodically review of checklist content. The content was reviewed three times during this study which improved the content in all but one scenario. The XP software development methodology and the usability engineering practices of usability testing and inspection were found to effectively enable the quick development of an application that had been reviewed and tested several times by clinical users in order to develop suitable functionality.

5.3 Usability

5.3.1 Introduction

As in section 1.3, the second research question of this study asks how acceptable and usable the pre-procedure checklist app would be to clinicians using it within a clinical workflow. The first aim of this study was to develop a user friendly app, and the second was to evaluate the usability among clinicians.

5.3.2 Content

Care was taken as explained in section 4.3 to refine and develop relevant checklist content for the app by applying the Verdaasdonk et al. (2009) checklist implementation model to the CIRSE IR checklist content. The model describes an iterative approach of checklist refinement, and the checklist content was refined htree times from the initial CIRSE checklist content. At first the 'Preprocedure planning' phase was distributed in paper copies to the two departments to receive feedback, thereafter the Clinical Director rephrased the content and adapted it to better suit local practice, and finally the content was updated half way through the pilot study. Content or conceptual ambiguity was noted early during initial user testing as described in section 4.5.2 and attempts were made to address this by explicitly labelling checklist controls as described in section 4.5.5. However despite these efforts, three of five nurses interviewed reported conceptual ambiguity in some of the checklist content. Among the themes that emerged from the nurse exit interviews in section 4.6.4 conceptual ambiguity was mentioned as having affected the usability. Nurses however distinguished between the usability of the content and the usability of the application interface and felt that the content usability could be easily resolved by updates to the content. Time limitations

prevented further iterative refinement as recommended by the Verdaasdonk et al. (2009) model, which would improve the quality of the content. As argued in section 5.2.2 clarifying the purpose of the application may have also addressed the conceptual confusion by explaining the difference between a checklist which records actions rather than the outcomes of actions and nursing documentation with captures more detail.

5.3.3 Application

As described in section 4.5.2 and 4.5.4 usability testing and usability inspection were used during app development to detect and address usability defects in the interface design. Usability testing evaluates the interface among at least 5 end users in an attempt to detect usability issues (Nielsen 1994). The issues noted were fixed in the next software release. Users were briefly trained before the start of the pilot study. By deliberate usability engineering, and by following usability heuristics an application can be designed to be as user friendly and usable as possible. After the completion of the pilot study the application was rated by both habitual and novice users as having 'Excellent' usability as shown in section 4.6.3. It was interesting to note that after the pilot study the Clinical Director remarked on how little training had been required, and that after less than 10 minutes of demonstration and training that all participant nurses and SpRs were able to effectively use the system. The electronic data examined in section 4.6.3 shows that of 134 checklists, only 3 were abandoned, and of 1404 checklist items, only 12 were skipped. Checklists were completed in less than 4.5 minutes in 87% of the cases and in 68.2% in less than a minute. SpRs and nurses remarked on the efficiency of the app, and felt that checklists were completed faster on the app than would be possible on paper, and that they were easier to complete on the app than on paper. SpRs and nurses reported that the app helped them focus on the act of checking and organised the team and the process. The visual design and interactivity was reported to guide and focus the checklist exercise. Users referred to the app as being 'straightforward to use', 'a good way of doing it', and 'very simple'.

5.3.4 Conclusion

The refinement of content and deliberate the attention to the usability of the app, refined through usability testing exercises, usability inspection and training was largely

successful when aiming to create a user-friendly and usable app. The usability of the content would require further refinement and testing, but the app itself received a rating of 'Excellent' usability by both novice and habitual touch device users after the conclusion of the pilot study.

5.4 Acceptance

5.4.1 Introduction

In section 1.3 the second research question of this study asks how acceptable and usable the pre-procedure checklist app would be to clinicians using it within a clinical workflow. The first aim of this study was to develop a user friendly app, and the second was to evaluate the acceptance among clinicians.

5.4.2 Content

As shown in Figure 2.3 the CIRSE IR checklist provided 'Yes', 'No', 'Not Applicable' options when completing checklist items. As described in section 4.5.5 these actions were labelled 'Necessary and Done', 'Necessary and Not Done' and 'Not Applicable' in an attempt to make it clear that the act of checking rather than the outcome of the check was being captured on the app. One nurse mentioned during observations that she would never mark an item 'Necessary and Not Done', because for reasons of patient safety, an item was either 'Necessary and Done' or 'Not Applicable.'

The importance of relevant content was highlighted in this pilot study. While the app itself was found to be very usable and the tablet was found to be suitable, the content was not as relevant to the breast clinic as it was for the IR room, and the impact of this was clearly visible in the electronic data and was raised during the exit interviews. The breast nurse was an enthusiastic champion for the project and saw great potential for the tablet app. Use of the app was voluntary during the pilot and it was left up to the nurses' discretion as to which procedures checklists would be entered for. The breast nurse was the sole user of the tablet in the breast clinic and as seen in section 4.6.2 she entered twice as many checklists per day as all the participants in the IR room during the same period before the update of the content (4 per day in the breast clinic in comparison with 2 per day in IR). Section 4.6.1 notes that an average of 7.6 procedures

were being completed per day in IR so while the opportunity was there, less checklists were entered on the app.

After the update to the version 2 content, which was less relevant to the breast clinic procedures, the average number of checklists per day dropped by half, with two days in which none were entered. When interviewed during the exit interviews the breast clinic nurse felt that the application had great potential, but that the content should be relevant, and ideally that it be derived from the type of order entered into the EPR for the patient. This could allow the provision of checklist content relevant to the procedure.

Irrelevant content wastes time, can cause confusion and frustration and creates a lack of credibility of the checklist's effectiveness, and user acceptance may decline.

The electronic app can capture data which can be used to create graphs as shown in section 4.6.2 which could help identify checklist content which is routinely marked as being 'Not Applicable.' This information can be used during the periodic review of checklist content in order to remove it to pre-empt any loss of credibility among clinicians and to correct the check list content. In a paper checklist this exercise would be much more difficult, and as is the case in the breast clinic where checklists are performed verbally from memory, this exercise would not be possible.

5.4.3 Application

As described in section 3.3.1 checklist use was optional during the pilot study and nurses were not observed during the first two weeks in IR or at all in the breast clinic. It was remarkable that almost triple the original goal amount of 50 checklists as mentioned in section 4.5.6 were entered voluntarily by participant nurses (n=134). This is despite the acknowledged duplication of work, and reluctance to use the app noted among some colleagues. As advocated by Buzink *et al.* (2010) and Burghouts (2010) clinicians were actively included during this study when developing the desired checklist content, the usability testing and the requirements gathering. As mentioned in section 4.5.3 as far as time permitted, their requirements were implemented, which may have created a sense of participation and ownership of the system.

The exit interviews and electronic data would suggest that application was accepted and clinicians frequently offered suggestions for further features, and felt that the tablet would be a better and faster way to capture documentation than paper. SpRs called the app 'a great way of doing it', and noted that it raised awareness within the IR room on patient safety. Nurses reported that it enabled them to involve the SPRs in safety checking, and organised the checking exercise and nurses voluntarily entered checklists during the period of unobserved use. Some clinicians however did refuse to use the app and mentioned to the researcher during the period of observation mentioned in section 4.6.1 that they did not like new technology and would not enjoy the introduction of the tablet device into their workflow.

High value was placed on of the electronic nature of the data captured by the application, nurses stated that it could not be as easily lost and would be available for audit, reporting and review. This was seen as one of the chief benefits of using the electronic application rather than paper.

5.4.4 Conclusion

The application was accepted by all clinicians interviewed, and it was reported that it was generally liked among their colleagues and its potential was appreciated and noted. Some usability issues due to the checklist content itself were noted, but it was felt that these could be resolved by further content refinement. The duplication of effort was seen to explain most of the reluctance to use the app among some colleagues, but some individuals rejected the newer technology.

5.5 Suitability

5.5.1 Introduction

In section 1.3 the third research question of this study asks how suitable a tablet device would be within a clinical workflow, and the third aim of the study was to evaluate the suitability of the device.

5.5.2 Suitability of the tablet device

As described in section 4.6.1 the issues raised concerning the suitability of using tablet devices in clinical environments included the possible negative effect on OR sterility and infection control, usability of a touch device among clinicians that are typically gloved, the risk of loss, theft or damage to the device, the varying degrees of experience with touch devices among clinicians and the willingness among clinicians to use it. As mentioned in section 2.5.2 and 2.8, cost would also be a factor, as tablets would need to be provided to all clinicians.

As was found during the exit interviews among the nurse and SpR participants in section 4.6.4 none of the clinicians interviewed had any concerns about sterility or infection control due to the introduction of the touch device. Similar equipment is already in use in the theatres and protocols dictate the wiping down of surfaces, including computer monitors with alcohol before every procedure. Nurses are also trained to remove their gloves and wash their hands before handling pens and paper charts. SpRs and nurses would adjust their workflow slightly in order to handle the device without contaminating sterile fields.

Theft or loss of the device was a concern to clinicians interviewed, but it was noted that the risk of theft was not a new issue in the hospital and that security procedures were in place including the nightly locking of controlled drugs cabinets and offices. It had been possible to secure both devices during the pilot and neither device had been damaged, lost or stolen as mentioned in section 4.6.5. Nurses highlighted that some of them do carry beepers at all times, and that if the tablet device was introduced and was a suitable size and could be carried in pockets like the beeper that colleagues would grow accustomed to using it.

As to the willingness of the clinical users to use touch devices, or their experience in using touch devices, the web survey of clinicians involved in radiology in Ireland described in section 4.4 found that 87% of respondents owned smartphones with touch screens. 51% had been using smartphones for over 2 years, and the devices were used to access email, browse the web and use native applications by over 70% of smartphone users. As such many of the respondents would be habitual touch device users.

The theme of suitability arose in the exit interviews and identified the mobility and flexibility afforded by the tablet allowing the team to meet anywhere convenient and that the SpRs could multitask and complete the checklist with the nurses while scrubbing in. The team could also gather around the patient to complete the checklist. SpRs also noted that there was also no need to write anything down, which saved time and that the electronic data would be very useful.

As to cost, the cost of tablet devices is steadily falling (Xu 2012). The Clinical Director felt that android tablet devices were affordable, and could conceivably replace the outdated beeper system at the study site in future and be used to achieve both functional objectives: i.e. electronic documentation input and the beeper system. The Clinical Director also mentioned that theft is an ongoing risk in the hospital, that workstation monitors, COWS, and personal mobile phones have been stolen off the premises in the past so the risk to the tablets is not a newly introduced problem, but one that needs to be similarly addressed as is the case when securing all equipment and personal belongings in the hospital.

5.5.3 Conclusion

The tablet device was found to be suitable to the clinical environment. Clinicians were not concerned about issues surrounding sterility and infection control, as the current protocols in place for handling and cleaning equipment would sufficiently address the presence of the touch device. The tablet was never used by clinicians within the sterile field, furthermore the tablet enabled flexibility and multitasking. The risk of damage was mitigated by the tablet cover, and the risk of theft was not unique to the tablet and could be addresses by the practices routinely in place to secure personal belongings and hospital equipment within in the hospital

5.6 Conclusion

The aim of this study was to build and evaluate a user-friendly app to support clinicians in the completion of pre-procedural safety checklists. The evaluation concentrated on the usability and acceptance of the app among clinicians, and the suitability of the tablet device to the clinical workflow and environment. As described above the app was built iteratively using the XP software methodology as well as using usability engineering

practices. User requirements emerged after inspection of each interim build. The app was found to be suitable and easy to use, and nurses and SpRs noted the actual and potential benefits to using the app as opposed to paper checklists. The content of the app was also adapted to local practice over 3 iterations by the clinical users. The app received a rating of 'Excellent' usability after the 21 day pilot study and users experienced many positive effects on their workflow and safety culture as a result. Three of the 5 nurses interviewed suggested further refinement to improve the usability of the content. The quality of the checklist content had a clear impact on the usability and acceptance of the application. The application was welcomed by the SpRs, and nurses reported that it was generally liked although the duplication of safety checking did cause some reluctance among colleagues to use the app. The tablet device was found to be suitable to the clinical environment, but it was noted that risk remained to the loss or theft of the device. The size of the device was also important in workflows where it would be carried on the nurses' person during work.

Chapter 6 Conclusion and Future Work

6.1 Introduction

This chapter outlines the strengths and limitations of the study and explains how the findings will be disseminated to both the research participants and the study site. The details of the findings will describe the potential for the use of tablets and applications within the clinical environment and finally, this chapter will provide recommendations for future research.

6.2 Strengths and Limitations of the Study

This study provided the researcher and the study site with the opportunity to explore the feasibility of using tablet devices and apps as a means to implement inexpensive electronic checklists within a clinical environment. The findings of the study have revealed the potential opportunity to introduce tablet devices within the hospital to further lower the generation of paper documentation and move more of the patient record into the EPR. The study findings are anticipated to encourage further exploration and possibly lead to the trial implementation of tablet devices at the study site among clinicians to access the EPR. The support and enthusiasm of the Clinical Director, nurses, SpRs, IT department representatives and consultant doctors participating in the pilot study was invaluable. The nurses had the increased burden of duplicated effort when completing safety checklist documentation, participating in usability testing and exit interviews during the 21 day pilot study. SpRs also made time available to be interviewed and accommodated the change to their workflow. The Clinical Director and consultants at the study site permitted the researcher to access to the IR room to observe procedures, provided an office and computer for the researcher to use and bought a tablet device for use during the pilot study. Limitations, whether they be time, money, access or knowledge will always exist within research endeavours, and it is not possible to answer all the questions posed.

There were a number of limitations encountered during the study. Firstly, the time available to refine and understand the content. Conceptual and content ambiguity around the checklist content continued well into the pilot study, and while efforts were

taken to address the confusion and its impact on usability it was a subtle issue that would have required more time to understand and discuss among the clinicians and resolved. Ideally this should have been recognised and resolved earlier and have been addressed in user training before the pilot study started. Time also limited the amount of requested features that could be built into the application.

The breast clinic nurse went out of her way to help the researcher with the study and gave a detailed and extensive exit interview but the busyness of the clinic meant that there was no opportunity to observe the workflow in the breast clinic with the tablet, which would have informed on the research findings.

Finally it would have been very revealing and valuable to interview the nurses who had declined to participate. It would have provided rich information on the research questions about acceptance and suitability. One of the participant nurses was also away during the exit interviews and her insight as Clinical Nurse Manager in the department would have been valued.

6.3 Dissemination of Findings

The results of the findings will be disseminated to the Clinical Director in IR and the Innovation board at the study site. The research participants will receive a summary of the findings from the study; particularly detail on which checklist content items were 'Not Applicable' and should be removed in future use of checklists in both departments. The researcher will present the findings of the study to all interested parties at the study site; and the application may be presented at the international CIRSE congress in Barcelona in 2013. The study was strongly supported by the study site which has encouraged further development of the application and offered time, access to the site and support by personnel.

6.4 Potential for the use of tablets and applications within the clinical environment

The aim of the study was to discover how pre-procedural safety check listing might be supported by a mobile app, and then to evaluate how usable and accepted such an application would be to clinicians, and finally to evaluate how suitable a tablet device would be for use within a clinical environment. The findings of the study will have

implications for everyone considering the use of inexpensive electronic pre-procedure safety checklists, or tablet devices within a clinical environment. The next section will discuss the implications of the findings for the study site and future development on the application.

The study found that tablet devices can be used within clinical environments in IR and the breast clinic to capture patient documentation in an electronic format at source and that the risk of theft can to some degree be addressed. It was also of significance that by starting conservatively and building apps to complete smaller documentation tasks that apps and culture change can be gradually introduced. When specific attention is paid to usability in the construction of the app the amount of training needed was noticeably smaller and apps are more likely to be accepted. The app had a very small set of features, yet had a positive impact to patient safety and the clinical workflow.

It also noteworthy that an iterative process ensures that relevant functionality and content are developed. Both the Verdaasdonk model (used when creating the content) and the XP software methodology (used when developing the application) encourage the quick release of testable versions of the content or application, which is to be tested by the target users or clients to elicit feedback and corrections rather than extensive periods of design and development in isolation from the end users.

6.5 Recommendations for Future Research

The application was developed as a delivery vehicle for electronic pre-procedure safety checklists. It provided 2 checklists: one for the IR room and the other for the breast clinic. The potential of the app to provide procedure specific checklists might be explored, as well as the feasibility of using of the electronic checklist data to refine future checklist content. The duplication of effort due to the pilot study being run while normal nursing documentation was being completed was thought to cause some reluctance to use it among a few clinicians. It would be interesting to examine whether resistance declines when the app is the only mandatory means of documentation for checklists. The pilot study also only lasted for a month, further research will be required to ascertain if the acceptability of the application would improve or decline with prolonged use, and

whether the further refinement of the content would improve the usability and acceptance of the content.

6.6 Reflections on the Study

The researcher would have preferred more time to better understand the content of the application and how best to use it. It would have been valuable to study the checklist in a hospital where it is already in use to understand how it is completed and whether ambiguity was encountered among clinicians using the checklist and whether training or explanation was required. This would have allowed for better training of the end users at the study site and the development of a better application and content.

The researcher does not feel that the issue of content ambiguity was resolved during the study, and while it might be argued that the study was focussed on the design of the app and the usability and acceptance of the app as opposed to the content, delivering the content remained the purpose of the app and when the content is not clearly understood the value of the app is somewhat affected.

The application of the various content and software development methodologies was felt to be a success. The usability engineering and usability testing involved the clinicians early and the application and content was improved as a result. The researcher was free to choose to engage with the end users in order to provide functionality to best support them without the constraints of contract negotiation. This freedom was enjoyed and created a sense of satisfaction –the researcher was able to apply her time and skill to support and help the healthcare service which is under pressure and is so vital.

6.7 Conclusion

In summary, it was discovered that pre-procedure safety checking can be supported by an app, and that such apps can be engineered to be usable and as a result are more likely to be perceived as being usable and be accepted among clinicians. The tablet device was found to be suitable for use in a clinical environment. The introduction of the app and tablet into the workflow in the IR room was reported by clinicians to improve focus on safety checking, better organise the process of checking and allow checklists to be completed very quickly and easily by using the app. The tablet allowed mobility of

the clinicians and flexibility which made it possible to multitask, and also complete the checklist within the proximity of the patient. The app was generally liked by clinicians and received a rating of 'Excellent' usability after a month of use in clinical practice. 134 checklists were captured on the two devices, of which 68% were completed in under 1 minute. Furthermore clinicians could see the potential of the app, and felt that once it had been integrated with the EPR, that it would be better than a paper version of the checklist. The reasons given were that the data would not get lost as easily as paper copies would, and that the electronic data would be more easily accessible for use in reporting, and checklist content refinement.

Studies report that some of the advantages to using electronic checklists as opposed to paper versions are that they facilitate more the more effective use (Norton 2012), are easily updateable (Verdaasdonk et al. 2009), encourage the improved adherence to checklist use and ensure that all items are checked (Mainthia et al. 2012). Electronic checklists are reported to result in better efficacy at detecting risk sensitive events and faults (Buzink et al. 2010), and can collect data that can be reported on. In terms of usability and acceptability, when careful attention was paid to user involvement and the creation of usable systems it has been established that such a system can become part of routine clinical use (Buzink et al. 2010, Mainthia et al. 2012, Robbins 2011).

Pre-procedural safety checklists have been shown to improve patient safety, but checklist implementation has remained a problematic and contentious issue (O'Connor et al. 2013). Affordable ICT solutions may prove to better facilitate the act of checking and make the iterative refinement of checklist content possible. This may result in the more effective use of safety checklists which in turn may improve procedure outcomes and patient safety.

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Appendices

Appendix A: Audit tool Safe Surgery Checklist (*National Policy and Procedure for Safe Surgery* 2013, HSE 2013)

Audit tool Safe Surgery Checklist

Respondent number:_____

Consent

1	Is the consent form available in the Healthcare Record (HCR)	**Yes**		**No**	
2	Is the consent form legible	**Yes**		**No**	
3	Is the consent form signed by a doctor who was present during the surgery?	**Yes**		**No**	
4	No abbreviations used on the consent form?	**Yes**		**No**	
Surgical safety Checklist					
5	Is there an addressograph on the checklist	**Yes**		**No**	
6	Is the date of the operation recorded on the checklist?	**Yes**		**No**	
7	Was the checklist filed with the theatre documentation in the HCR?	**Yes**		**No**	
Sign In *Were each of the following checks completed?*					
8	Patient confirmed identity, site, procedure, and consent	**Yes**		**No**	
9	Surgical site marked / not applicable	**Yes**		**No**	
10	Anaesthetic checklist completed	**Yes**		**No**	
11	Known allergies checked	**Yes**		**No**	
12	Blood loss risk documented	**Yes**		**No**	
13	VTE Prophylaxis check	**Yes**		**No**	
14	ASA grade checked	**Yes**		**No**	
15	Sign in section signed	**Yes**		**No**	
16	Sign in section timed	**Yes**		**No**	
Time out *Were each of the following checks completed*					
17	All team members introduced themselves	**Yes**		**No**	
18	Verbal confirmation of patients name, procedure and incision site	**Yes**		**No**	
19	Verification that patient positioned correctly	**Yes**		**No**	
20	Essential imaging displayed / not applicable	**Yes**		**No**	
21	Antibiotic prophylaxis / not applicable	**Yes**		**No**	
22	Patient specific concerns: Surgeon	**Yes**		**No**	
23	Patient specific concerns: Anaesthetist	**Yes**		**No**	
24	Patient specific concerns: Nursing/Midwifery team	**Yes**		**No**	
25	Equipment issues: Surgeon	**Yes**		**No**	
26	Equipment issues: Nursing/Midwifery team	**Yes**		**No**	
27	Time out section signed	**Yes**		**No**	
28	Time out section timed	**Yes**		**No**	
Sign out					

Were each of the following checks completed					
29	Name of procedure confirmed	**Yes**		**No**	
30	Completion of instrument, sponge and needle count	**Yes**		**No**	
31	Specimen labelling	**Yes**		**No**	
32	Patient specific post-op concerns: Surgeon	**Yes**		**No**	
33	Patient specific post-op concerns: Anaesthetist	**Yes**		**No**	
34	Patient specific post-op concerns: Nurse Midwife	**Yes**		**No**	
35	Sign out section signed	**Yes**		**No**	
36	Sign out section timed	**Yes**		**No**	

Appendix B: Specialist Registrar semi-structured exit interview questions

1. Were you familiar with checklists before the start of this study?
2. Were you briefed / introduced to the study by anyone before you first used the checklist during pre-procedure checking?
3. Roughly how many times were you involved in a timeout? Be it paper / electronic version?
4. Did you find it disruptive?
5. How long did it take?
6. Did it materially change your workflow?
7. As the person performing the procedure, how would you feel about completing the checklist before every procedure?
8. Was the check done quickly?
9. Who touched / operated the tablet app?
10. Did you have any concerns about sterility or infection control by introduction of the tablet to run the checklist?
11. Do you see any advantage to providing the checklist in a tablet application?
12. Did you feel that the user interface visual design including images, layout, and screens helped or hindered checklist completion?

Appendix C: Staff Nurse semi-structured exit interview questions

1. Did you use the checklist app for procedures?
2. Did you find it useful?
3. Did you ever have to ask for help to use the app or tablet?

4. Would you recommend using a checklist (whether paper or app) for every procedure, or is it more realistic to use it in certain cases?
5. Did you have any concerns about sterility or infection control due to the fact that it's a touch device?
6. Did the app have all the features you would need to run pre-procedure checklists in your clinical workflow?
7. Would you have any suggestions / feature recommendations?
8. Can you describe how you used it?
9. Did you ever experience push back / reluctance among your colleagues to use the checklist app?
10. What was the response among staff or colleagues not involved in the usability testing or briefed by the researcher?
11. How did you secure the tablet?
12. Was there risk to the tablet being lost, damaged or stolen?
13. How did you address that risk?
14. Did you like using it? Was it user friendly?
15. Having used it at work, what would you consider the advantages to using the tablet application?
16. What would you consider the disadvantages?
17. Would you like to continue using the checklist?
18. Would you prefer paper or an app integrated with the EPR?
19. Was there any significant change to your experience after new items were introduced and Y/N/NA changed?
20. This study was to test if tablets can be effectively used in check listing in a clinical domain. In your opinion do you think it was successful? Can they be used?
21. If the tablet application was extended to pull in the latest lab results and the ward nurse notes so that you don't need to phone the ward nurses, or log into the PC to get the lab results, and then once complete send the record to the patient EPR, do you think the tablet could streamline your workflow?

Appendix D: System Usability Scale (Brooke 1996)

	Strongly disagree				Strongly agree
I think that I would like to use this system frequently	1	2	3	4	5
I found the system unnecessarily complex	1	2	3	4	5
I thought the system was easy to use	1	2	3	4	5
I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5
I found the various functions in this system were well integrated	1	2	3	4	5
I thought there was too much inconsistency in this system	1	2	3	4	5
I would imagine that most people would learn to use this system very quickly	1	2	3	4	5
I found the system very cumbersome to use	1	2	3	4	5
I felt very confident using the system	1	2	3	4	5
I needed to learn a lot of things before I could get going with this system	1	2	3	4	5

Appendix E: Web survey sent to the Faculty of radiology, Radiographers and Radiology nurses

Safety Checklist Use

PREAMBLE AND BACKGROUND OF RESEARCH:

Following a case of wrong site surgery in 2008, the Health Service Executive issued a directive that acute hospitals institute a correct site surgery policy. This has been met with partial success, with an audit by the HSE reporting that documentation was found to be burdensome, time consuming and that to some surgeons, the checklist covered too broad a range of checks. The purpose of this study is to gain an understanding of these difficulties and attempt to better support clinicians through means of electronic versions and training.

PROCEDURES OF THIS STUDY:

This survey will involve gathering of data on the teamwork and safety climate.

Individual results will be aggregated anonymously and research reported on aggregate results. A comprehensive information form will be made available to all potential participants.

PUBLICATION:

The results of the study will be used for a dissertation in the TCD Masters programme in Health Informatics. The research may be used by others for academic research, and may be presented at selected conferences in Ireland. The results will be made available to all research participants on completion of the research study.

RESEARCHER'S DECLARATION

I confirm that I will:

- Familiarize myself with the Data Protection Act and the College Good Research Practice guidelines
- Provide participants with an information sheet that describes the main procedures
- Obtain informed consent for participation
- Tell participants that their participation is voluntary
- Tell participants that they may withdraw at any time and for any reason without penalty
- Give participants the option of omitting questions they do not wish to answer
- Tell participants that their data will be treated with full confidentiality and that, if published, it will not be identified as theirs
- On request, debrief participants at the end of their participation
- Verify that participants are 18 years or older and competent to supply consent.
- Declare any potential conflict of interest to participants.
- Inform participants that in the extremely unlikely event that illicit activity is reported to me during the study I will be obliged to report it to appropriate authorities.
- Act in accordance with the information provided

PARTICIPANT'S 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.
- I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.
- I understand that my participation is fully anonymous and that no personal details about me will be recorded.
- I understand that if I or anyone in my family has a history of epilepsy then I am proceeding at my own risk.
- I have received a copy of this agreement.

1. **I hereby agree to these terms and would like to participate**

   Yes

   No
2. **Clinical position held.**

   Consultant

   SpR

Radiology Nurse

Radiographer

Other (please specify)

3. **In what clinical area do you mainly perform or assist in radiology procedures?**

   Interventional Radiology

   Ultrasound

   CT

   MRI

   Fluoroscopy

   Breast Imaging

   Mixture

4. **How long have you worked in hospital medicine:**

   < 6 months

   6 to < 12 months

   1 to < 3 years

   3 to < 8 years

   8 to < 13 years

   13 to < 21 years

   21 years or more

5. **Do you own a smart phone, with a touch screen (e.g. IPhone, Android, Windows Mobile etc)**

   Yes

   No

6. **How long have you been using a smartphone?**

   < 1 year

   1 to < 2 years

   2 to < 3 years

   3 years or more

   Never used a smartphone

7. **Do you use apps, browse web pages, and/or access email on your smartphone, or do you just use your phone to make calls?**

   Apps

Email

Browsing the web

Phone Calls Only

Don't own a smartphone

8. **Do you own a tablet computer with a touch screen (e.g. IPad, Android Tablet like a Nexus 7 etc?)**

   Yes

   No

9. **On average how often do you use a tablet computer?**

   daily

   few times a week

   few times a month

   never

10. **Are you familiar with the World Health Organisation's (WHO) Surgical Safety Challenge, and Surgical Safety Checklists (with concepts such as 'Sign In', 'Time Out', 'Sign Out', phases etc.)**

    Some high level knowledge

    Detailed knowledge

    Not familiar at all

11. **Have you ever received training on either the Joint Commission's Universal Protocol, or on the implementation of Surgical safety checklists as recommended by the WHO?**

    Training in neither

    Training in both

    Joint Commission Universal Protocol Training

    WHO Surgical Safety Checklist Training

12. **Who arranged for the training?**

    I looked for a course

    A course was recommended by the hospital

N/A

Other (please specify)

13. Who paid for the training?

I paid for the training

The hospital paid for the training

Shared expense

N/A

Other (please specify)

14. What experience do you have in using preprocedural patient safety checklists:

None

< 6 months

6 months to < 12 months

1 year to < 3 years

3 years to < 8 years

8 years to < 13 years

15. Was that experience gained in Irish hospitals or abroad?

Mostly in Ireland

Mostly abroad

50% / 50% between Ireland and abroad

N/A

16. In your experience have checklists effectively improved patient safety?

Yes

No

N/A (No personal experience)

If 'No', please elaborate

17. If you have used pre-procedural safety checklists, have they been a paper document, in electronic format, or were the steps recalled from memory?

Paper Document

Electronic format (Computer Based etc)

Recalled from memory

N/A (have not used preprocedural checklists)

Other (please specify)

18. **Have you ever used an electronic version of a checklist? (Tablet Application, Desktop Computer, Laptop, Audio playback etc.)**

    Yes

    No

    If yes, please describe

19. **Would you have a preference for the format, i.e. paper or electronic?**

    Paper

    Electronic

    Recall from memory

    No preference

    Reason for preference (optional)

20. **Do you perform a 'TimeOut' before each procedure?**

    Yes

    No

21. **In your experience, who has initiated the pre-procedural checklist?**

    Nurse

    Consultant

    SpR

    Radiographer

    Any team member

    N/A

    Other (please specify)

22. **In your experience, who in the team participates in the completion of the pre-procedural checklist?**

    Nurses

    Consultants

    SpR

    Registrars

    Radiographers

23. **What would you see as the biggest barriers to implementing preprocedural checklists?**

Disruption to workflow

Need for documentation

Not deemed necessary

Other (please specify)

24. **In your experience, what has worked well when implementing pre-procedural checklists? What recommendations would you have?**

25. **Would you consider pre-procedural safety checklists to be worthwhile and necessary in your workflow in your hospital?**

    Yes

    No

    Not Applicable

    Comment

26. **Do you recommend such timeouts / pre-procedural safety checks in minimally invasive Interventional Radiology procedures?**

    Yes

    No

    Comment

27. **Pre-procedural briefings are common in your clinical area.**

    Agree Strongly

    Agree Slightly

    Neutral

    Disagree Slightly

    Disagree Strongly

28. **Radiologists, radiographers and nurses here work together as a well-coordinated team.**

    Agree Strongly

    Agree Slightly

    Neutral

    Disagree Slightly

    Disagree Strongly

29. It is easy for personnel here to ask questions when they don't understand.

Agree Strongly

Agree Slightly

Neutral

Disagree Slightly

Disagree Strongly

30. Team input is well received in my clinical area

Agree Strongly

Agree Slightly

Neutral

Disagree Slightly

Disagree Strongly

Input from Registrar is well received

Agree Strongly

Agree Slightly

Neutral

Disagree Slightly

Disagree Strongly

Input from Nurse is well received

Agree Strongly

Agree Slightly

Neutral

Disagree Slightly

Disagree Strongly

Input from Radiographer is well received

Agree Strongly

Agree Slightly

Neutral

Disagree Slightly

Disagree Strongly

31. **I know the first and last names of the personnel I worked with on the last session.**

    Agree Strongly

    Agree Slightly

    Neutral

    Disagree Slightly

    Disagree Strongly

32. **Briefing the team before the start of every procedure is important for patient safety.**

    Agree Strongly

    Agree Slightly

    Neutral

    Disagree Slightly

    Disagree Strongly

33. **The levels of staff in my clinical area are sufficient to handle the number of patients.**

    Agree Strongly

    Agree Slightly

    Neutral

    Disagree Slightly

    Disagree Strongly

34. **I would feel safe being treated in my hospital as a patient.**

    Agree Strongly

    Agree Slightly

    Neutral

    Disagree Slightly

    Disagree Strongly

35. **I am comfortable reporting any patient safety concerns I may have.**

    Agree Strongly

    Agree Slightly

    Neutral

Disagree Slightly

Disagree Strongly

Appendix F: Usability test instructions

Task 11. Please open the application

Task 12. Please start a new lung biopsy checklist

Task 13. Please indicate that Item 1 was checked

Task 14. Please indicate that Item 2 was not checked

Task 15. Please skip Item 3 and indicate that Item 4 was not applicable

Task 16. Please Save the checklist

Task 17. Please Exit the checklist

Task 18. Please start a new Lung Biopsy checklist

Task 19. Change your mind and start a Breast checklist instead

Task 20. Mark item 1 as checked, then change your mind and mark it as not checked instead

Appendix G: Information sheet for research participants

TRINITY COLLEGE DUBLIN

INFORMATION SHEET FOR PARTICIPANTS

Dear Sir or Madam,

I would like to invite you to take part in a research study entitled "Towards the more meaningful and prevalent use of WHO Surgical Safety Pre-procedural checklists". This research study is being undertaken towards the completion of an MSc dissertation in Health Informatics in Trinity College Dublin (TCD). Please read the following information carefully and ask if you do not understand any part of it or would like more information.

Background of research, and relevance:

Following a case of wrong site surgery in 2008, the Health Service Executive issued a directive that acute hospitals institute a correct site surgery policy. This has been met with partial success, with an audit by the HSE reporting that related documentation was found to be burdensome, and that surgeons considered the checklist to cover too broad a range of checks, and that completing the WHO checklist was too time consuming.

It is hoped to get a better understanding of the perceptions, level of use, and difficulties with implementing the safe surgery checklists, and to determine if IT can play a support role in making the use less burdensome.

What is the purpose of the research study?

This study proposes to investigate the current methodology used when documenting checklist completion by means of paper forms, the user-experience and degree of team collaboration. It is intended to develop an electronic version of an existing checklist together with training materials and run a pilot study to evaluate their impact of on workflow and user experience, if any.

Who is organising the research study?

The lead researcher of this research study is Ms. Debbie Wood, as part of an MSc in Healthcare Informatics in Trinity College, Dublin.

Why have I been chosen?

As a clinician involved in the application of surgical safety checklists your opinion and perspective is valuable in the understanding of the domain and possible areas of difficulty and areas that can be improved.

What will happen to me if I take part?

You will be asked to either:

1) Complete an online safety attitudes questionnaire, or
2) Participate in a semi-structured interview.

C**onflicts of interest**

Please be advised that this research is being conducted by an employee of a company that creates software to provide electronic medical records that run on tablet computers.

Voluntary Participation

Your participation in this study is voluntary and you are free to withdraw at any time without providing a reason. If you are happy to participate please complete the attached consent form and return to Ms. Debbie Wood before completing the semi-structured interview, or safety attitudes questionnaire. Thank you for taking the time to read this correspondence and for considering taking part in the research study.

Expected duration:

The semi-structured interviews will take a maximum of 30 minutes, and the safety attitudes questionnaires should take a maximum of 15 minutes to complete.

Anticipated risks/benefits to yourself as the participant

All data will be anonymised and aggregated. Any direct quotations will first be verified and checked for contextual appropriateness from yourself, and permission will first be requested of you for their use. It is hoped to gain a better understanding of the problems surrounding efficient checklist use, and evaluate the provision of effective information capture support through electronic means, if this proves beneficial.

Procedure to be used if assistance or advice is needed after participation.

In the event that you require further information about this study please contact Debbie Wood who will be happy to answer your questions. Debbie can be contacted by email: or by phone:

Confidentiality - who will know I am taking part in the research study?

All information, which is collected during the course of the research, will be kept strictly confidential. The on line questionnaire will not be able to identify respondents by their email address or IP address therefore all responses will be anonymous. In the extremely unlikely that illicit activity is reported I will be obliged to report it to the appropriate authorities.

I confirm that I will:

- Familiarize myself with the Data Protection Act and the College Good Research Practice guidelines http://www.tcd.ie/info_compliance/dp/legislation.php;
- Tell participants that any recordings, e.g. audio/video/photographs, will not be identifiable unless prior written permission has been given. I will obtain permission for specific reuse (in papers, talks, etc.)
- Provide participants with an information sheet (or web-page for web-based experiments) that describes the main procedures (a copy of the information sheet must be included with this application)
- Obtain informed consent for participation
- Should the research be observational, ask participants for their consent to be observed
- Tell participants that their participation is voluntary
- Tell participants that they may withdraw at any time and for any reason without penalty

- Give participants the option of omitting questions they do not wish to answer if a questionnaire is used
- Tell participants that their data will be treated with full confidentiality and that, if published, it will not be identified as theirs
- On request, debrief participants at the end of their participation (i.e. give them a brief explanation of the study)
- Verify that participants are 18 years or older and competent to supply consent.
- If the study involves participants viewing video displays then I will verify that they understand that if they or anyone in their family has a history of epilepsy then the participant is proceeding at their own risk
- Declare any potential conflict of interest to participants.
- Inform participants that in the extremely unlikely event that illicit activity is reported to me during the study I will be obliged to report it to appropriate authorities.
- Act in accordance with the information provided (i.e. if I tell participants I will not do something, then I will not do it).

Yours sincerely

Debbie Wood

Appendix H: Informed Consent Form for participants

TRINITY COLLEGE DUBLIN
INFORMED CONSENT FORM

LEAD RESEARCHERS: Debbie Wood

BACKGROUND OF RESEARCH: *(explains the background, context and relevance of the research)*
Following a case of wrong site surgery in 2008, the Health Service Executive issued a directive that acute hospitals institute a correct site surgery policy. This has been met with partial success, with an audit by the HSE reporting that documentation was found to be burdensome, and that surgeons view the checklist as covering too broad a range of checks, and that it is too time consuming to complete.

The purpose of this study is to gain an understanding of the mechanism of use of surgical safety checklists in theatres and their perceived usability and value among clinicians by means of semi structured interviews, questionnaires and observation. A Pilot study will be run to evaluate the effect of an electronic version of a surgical safety checklist on the reported documentation burden, and the mechanism of use within the surgical workflow. A small training exercise will also be carried out, and its effect on the perceived value, attitude toward safety and mechanism of use will be measured.

PROCEDURES OF THIS STUDY: (*explains what will happen in this particular study, including duration and risks to the participant)*
The researcher has carried out a literature review of similar projects in the area. The research methodology will involve gathering of data on both the usability, and mechanism of use of checklists, for qualitative and quantitative analysis by observing procedures, recruiting users to complete questionnaires or surveys and in some instances participating in semi structured interviews.

Individual results will be aggregated anonymously and research reported on aggregate results. The data will then be analysed for themes. A pilot study of an electronic version of an existing checklist will then be run, together with brief training to evaluate the resulting perceived usefulness, and ease of use of

the checklist. The number of checklists completed and the perceived effect on the paperwork burden will also be investigated.

A comprehensive information form has been made available to all potential participants.

PUBLICATION: (*explains the intended publication and presentation venues for the research)*
The results of the study will be used for a dissertation in the TCD Masters programme in Health Informatics. The research may be used by others for academic research. In addition the research outcomes are likely to be presented at selected conferences, seminars or workshops in Ireland.
The results will be made available to all research participants on completion of the research study.

RESEARCHER'S DECLARATION
I confirm that I will (where relevant):

- Familiarize myself with the Data Protection Act and the College Good Research Practice guidelines http://www.tcd.ie/info_compliance/dp/legislation.php;
- Tell participants that any recordings, e.g. audio/video/photographs, will not be identifiable unless prior written permission has been given. I will obtain permission for specific reuse (in papers, talks, etc.)
- Provide participants with an information sheet (or web-page for web-based experiments) that describes the main procedures (a copy of the information sheet must be included with this application)
- Obtain informed consent for participation (a copy of the informed consent form must be included with this application)
- Should the research be observational, ask participants for their consent to be observed
- Tell participants that their participation is voluntary
- Tell participants that they may withdraw at any time and for any reason without penalty
- Give participants the option of omitting questions they do not wish to answer if a questionnaire is used
- Tell participants that their data will be treated with full confidentiality and that, if published, it will not be identified as theirs
- On request, debrief participants at the end of their participation (i.e. give them a brief explanation of the study)
- Verify that participants are 18 years or older and competent to supply consent.
- If the study involves participants viewing video displays then I will verify that they understand that if they or anyone in their family has a history of epilepsy then the participant is proceeding at their own risk
- Declare any potential conflict of interest to participants.
- Inform participants that in the extremely unlikely event that illicit activity is reported to me during the study I will be obliged to report it to appropriate authorities.
- Act in accordance with the information provided (i.e. if I tell participants I will not do something, then I will not do it).

PARTICIPANT'S 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.
- I understand that I may refuse to answer any question and that I may withdraw at any time without penalty.
- I understand that my participation is fully anonymous and that no personal details about me will be recorded.
- I understand that if I or anyone in my family has a history of epilepsy then I am proceeding at my own risk.
- I have received a copy of this agreement.

PARTICIPANT'S NAME:

PARTICIPANT'S SIGNATURE:

Date:

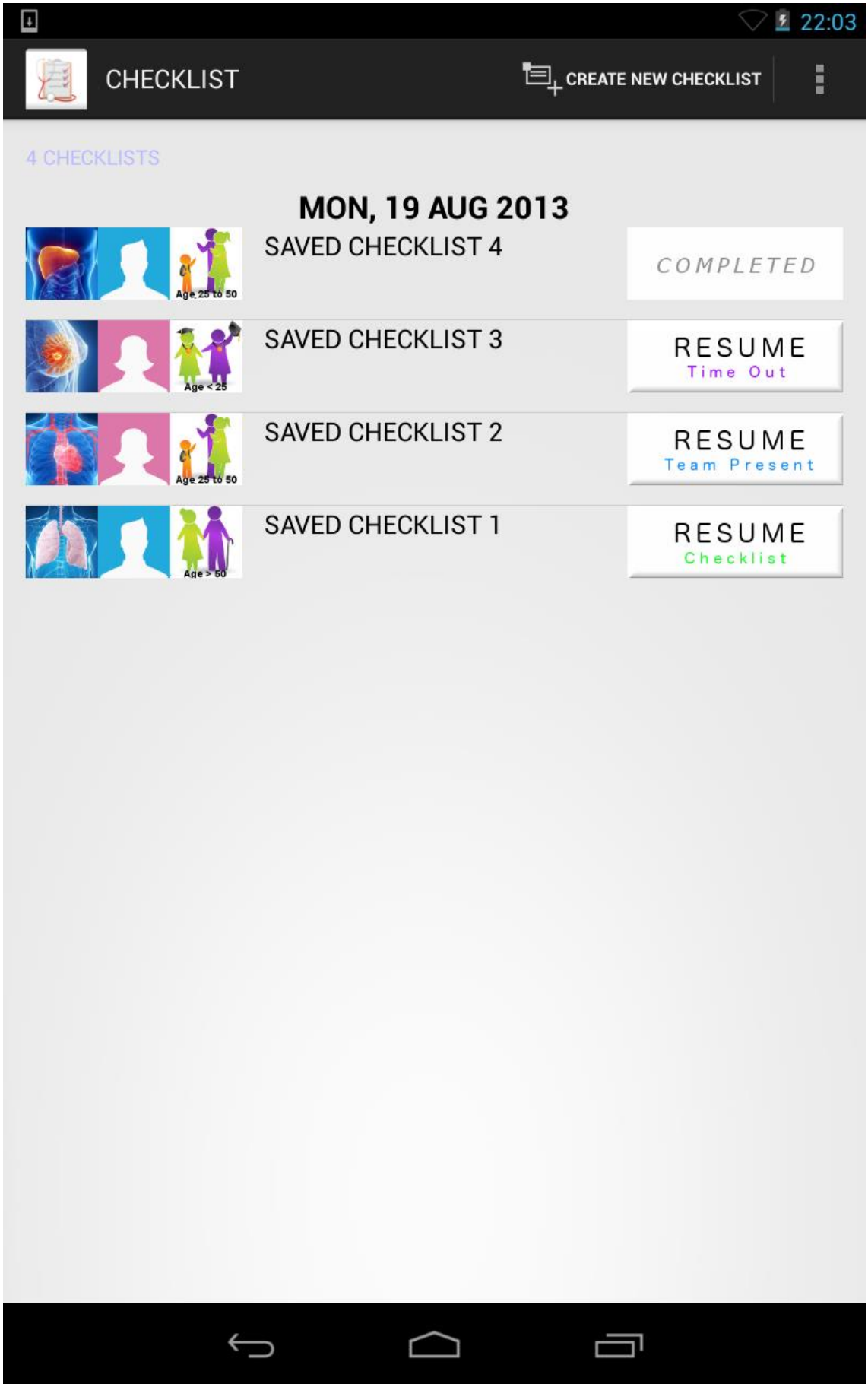
Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation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

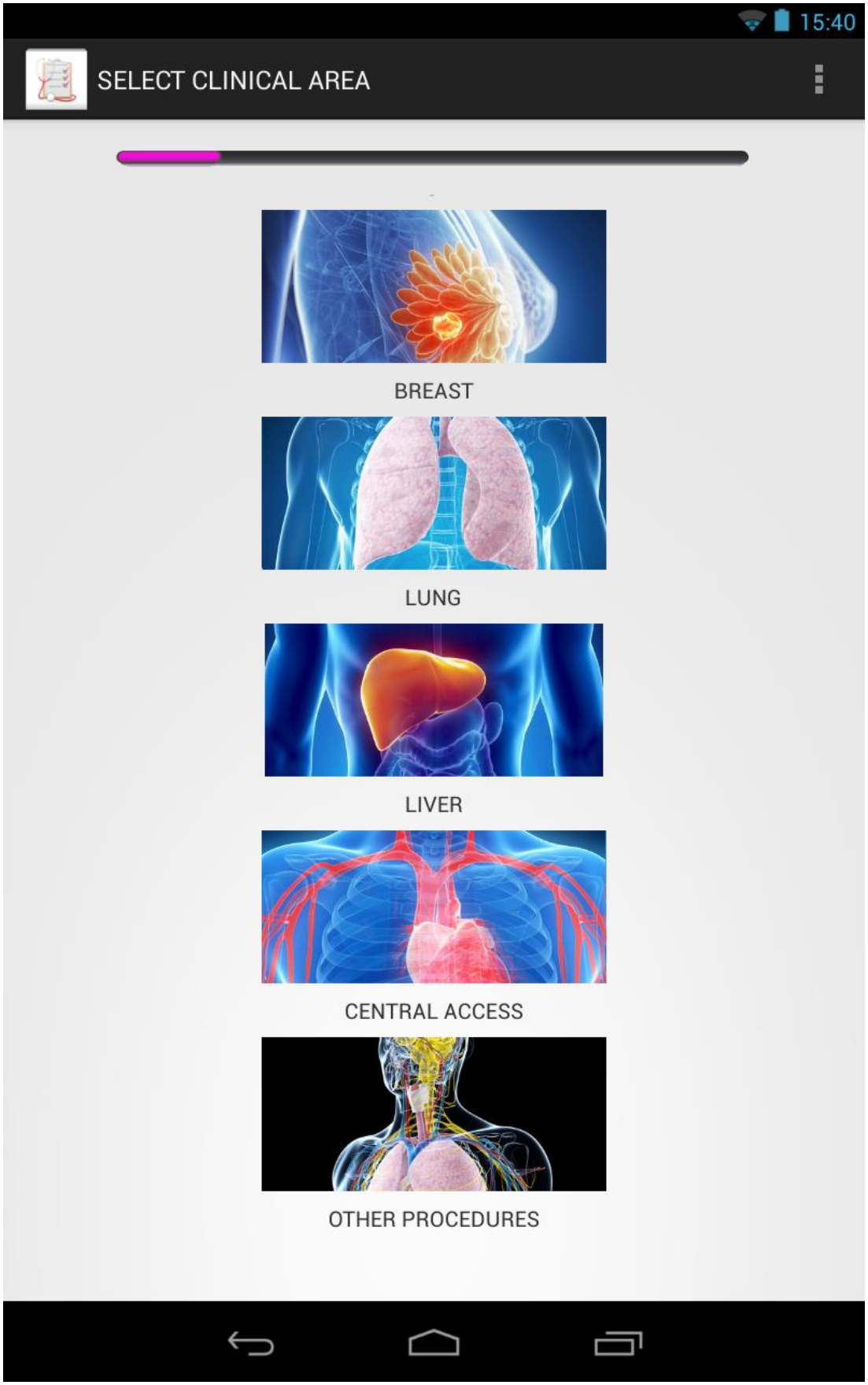
RESEARCHERS CONTACT DETAILS:
Debbie Wood
Mobile:
Email:

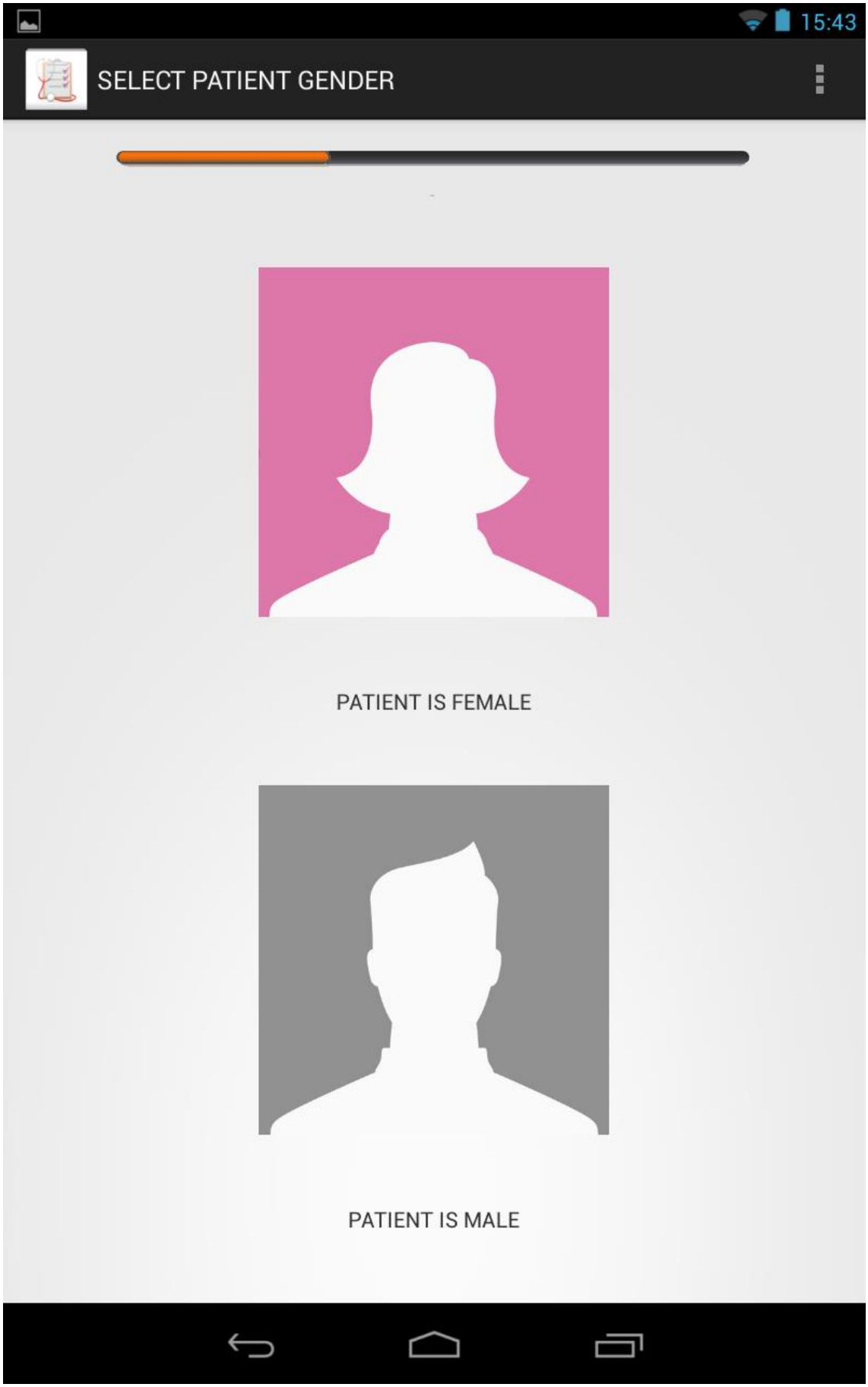
INVESTIGATOR'S SIGNATURE:

Date:

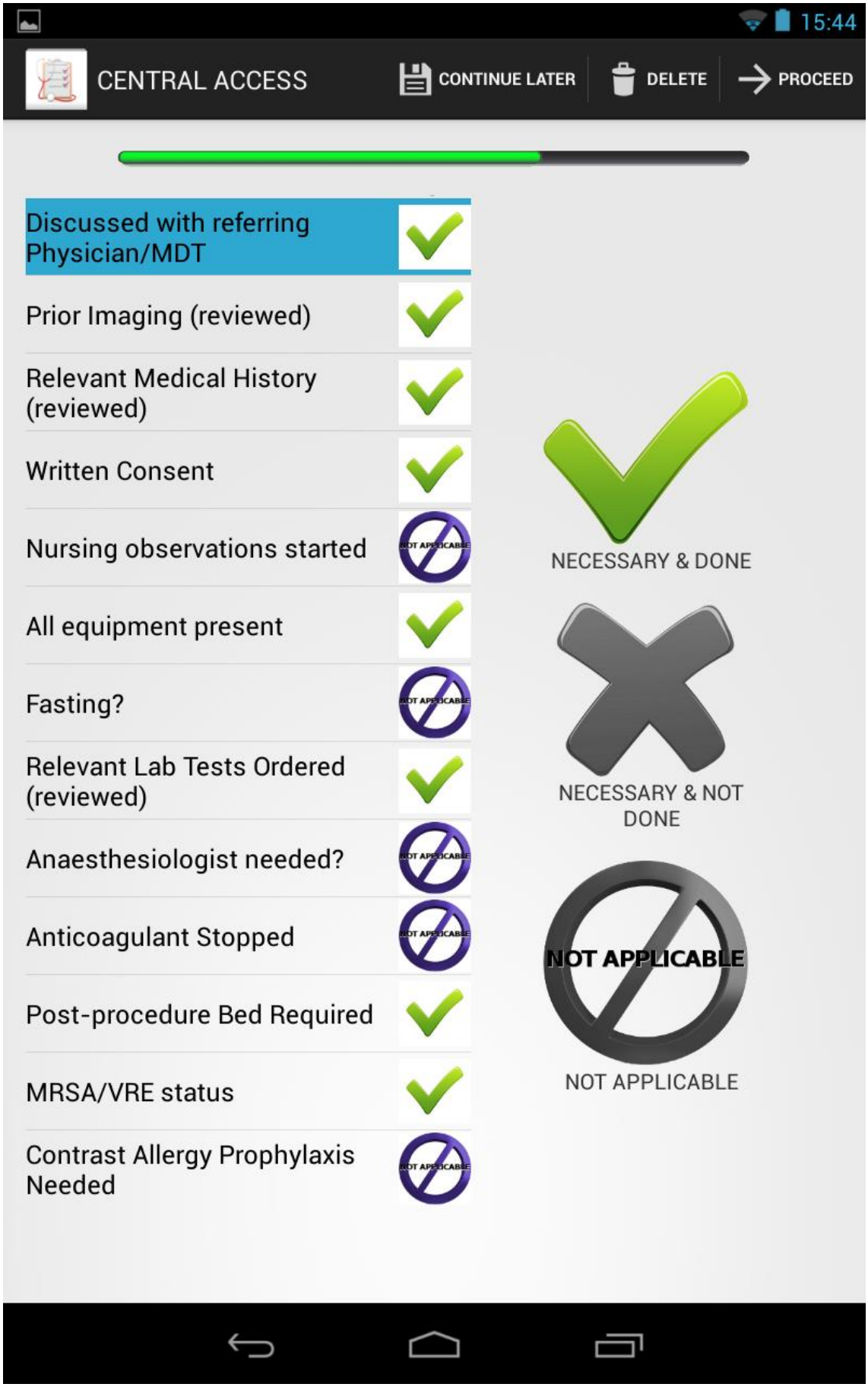
Appendix I: Final app screenshots

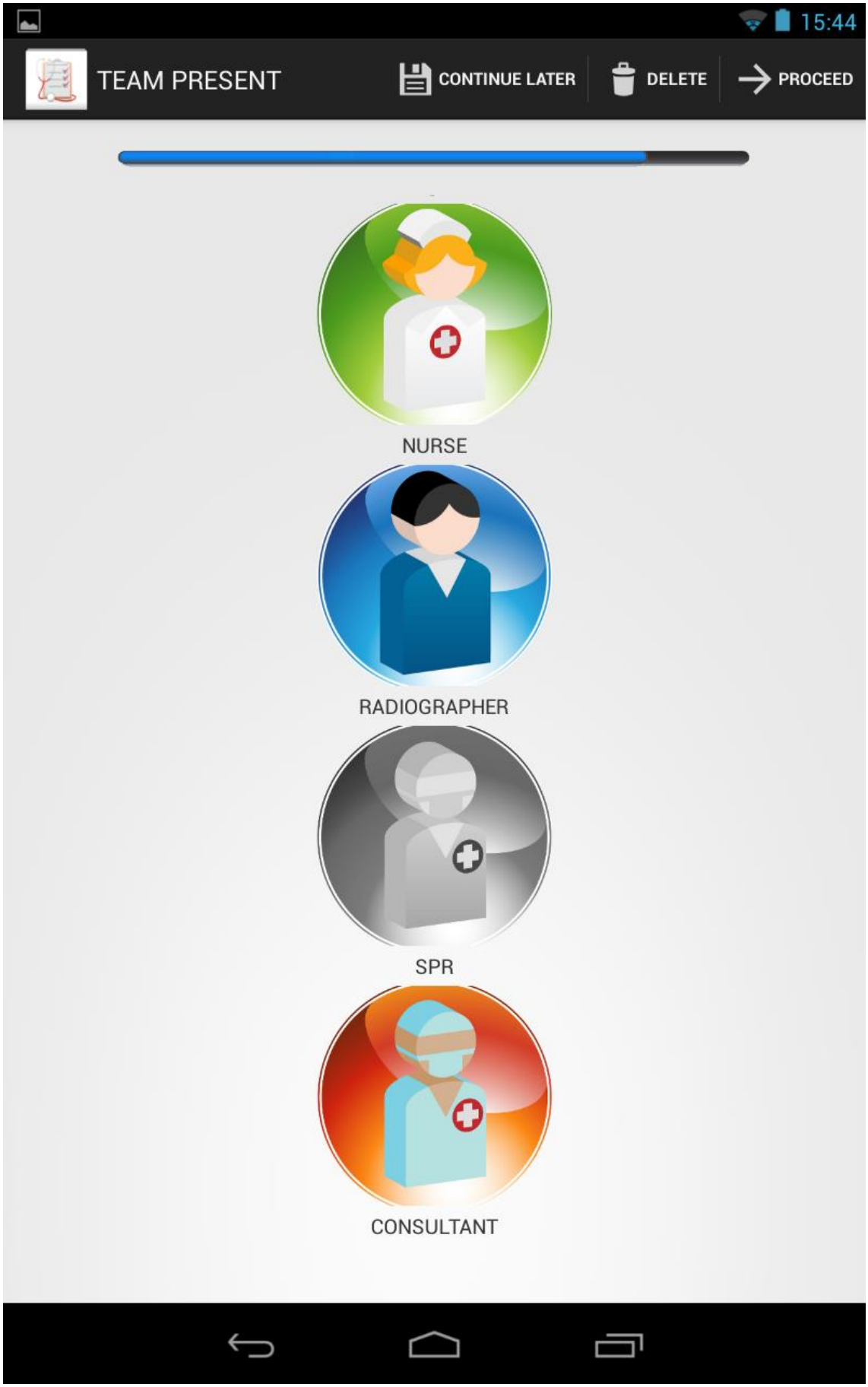

22:03
CHECKLIST
CREATE NEW CHECKLIST
4 CHECKLISTS
MON, 19 AUG 2013
Age 25 to 50
SAVED CHECKLIST 4
COMPLETED
Age < 25
SAVED CHECKLIST 3
RESUME
Time Out
Age 25 to 50
SAVED CHECKLIST 2
RESUME
Team Present
Age > 50
SAVED CHECKLIST 1
RESUME
Checklist

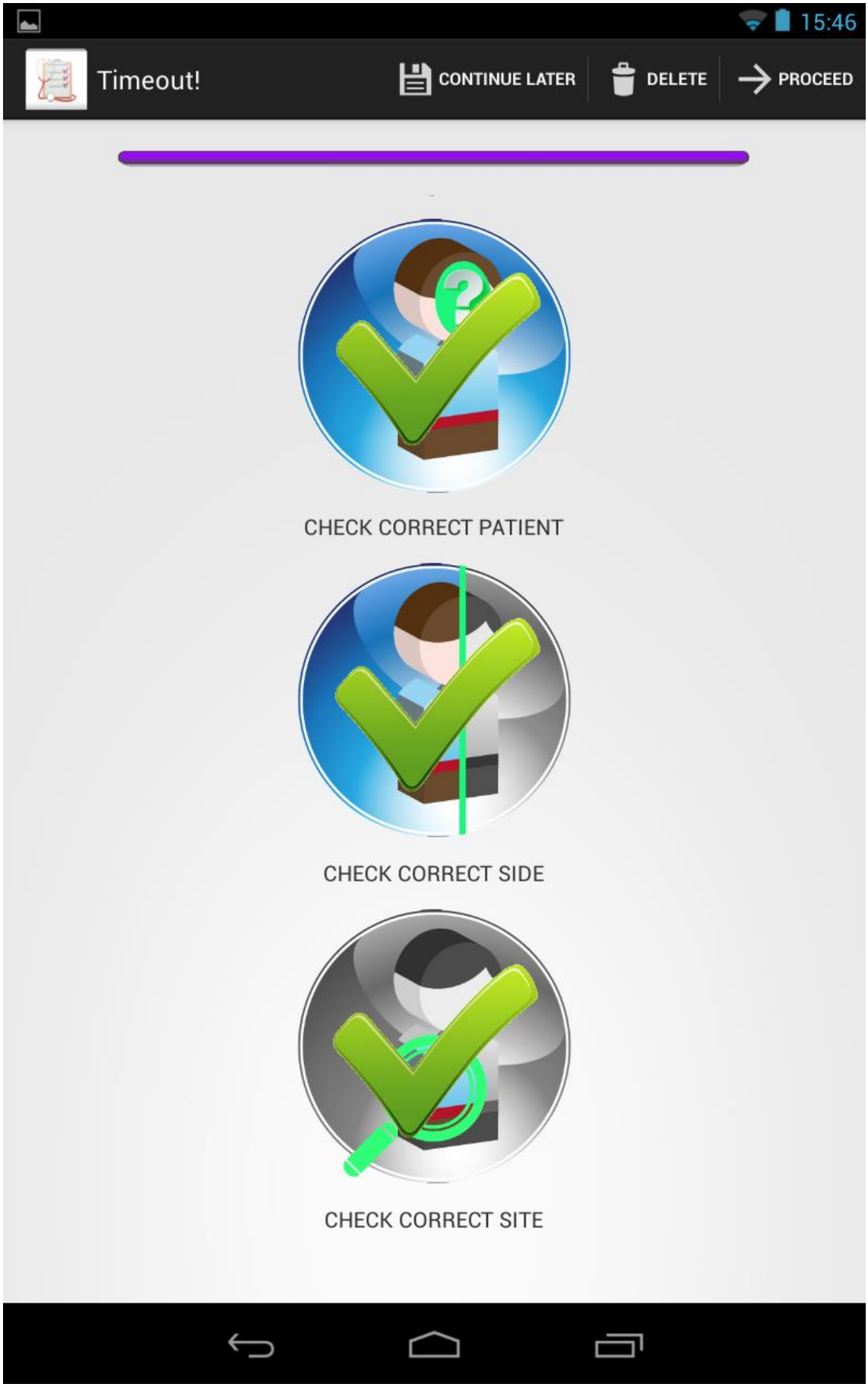

15:40
SELECT CLINICAL AREA
BREAST
LUNG
LIVER
CENTRAL ACCESS
OTHER PROCEDURES

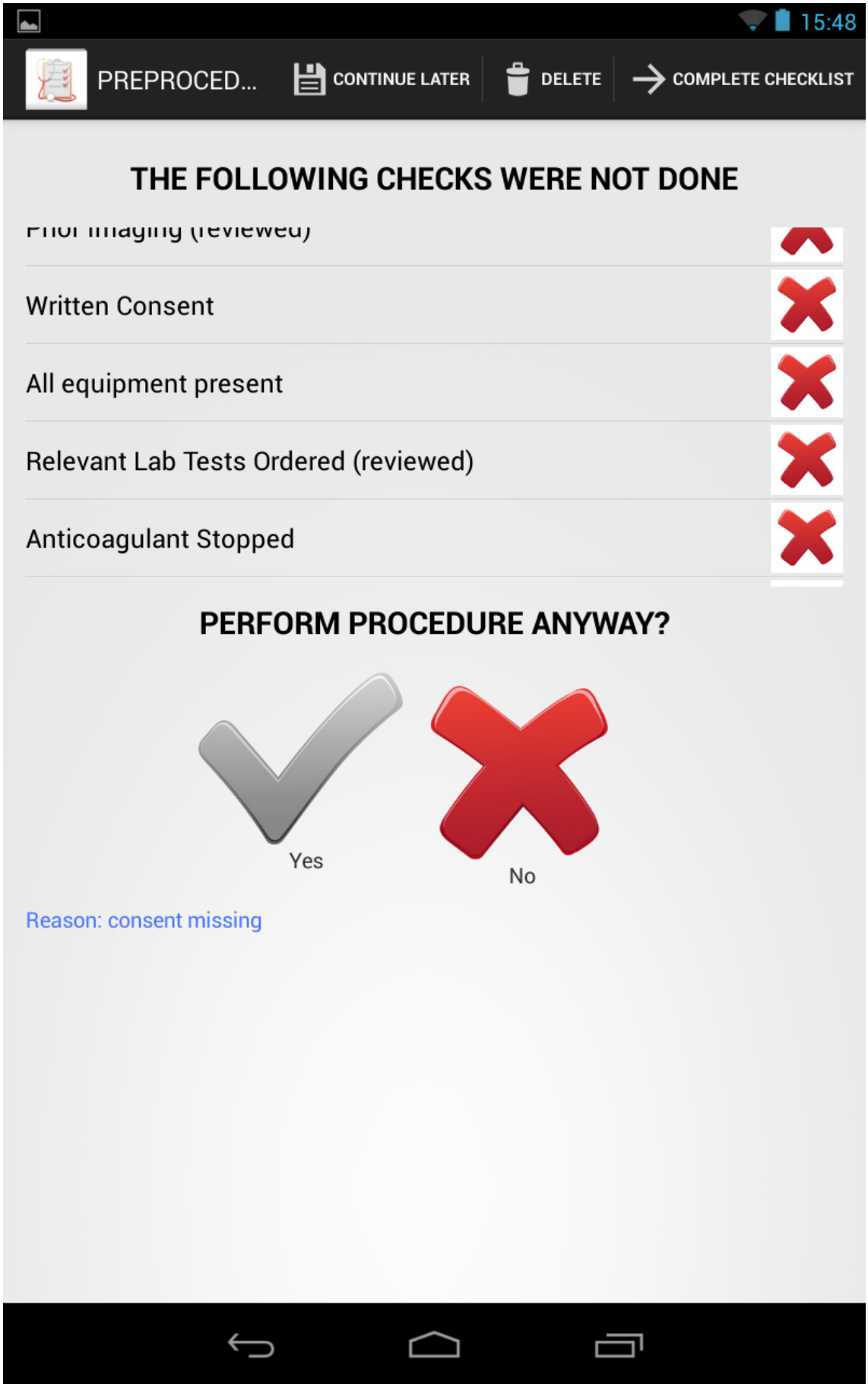

15:43
SELECT PATIENT GENDER
PATIENT IS FEMALE
PATIENT IS MALE


15:43
SELECT PATIENT AGE GROUP
Age < 25 Years
Age 25 to 50 Years
Age > 50 years


15:44
CENTRAL ACCESS
CONTINUE LATER
DELETE
PROCEED
Discussed with referring Physician/MDT
Prior Imaging (reviewed)
Relevant Medical History (reviewed)
Written Consent
Nursing observations started
All equipment present
Fasting?
Relevant Lab Tests Ordered (reviewed)
Anaesthesiologist needed?
Anticoagulant Stopped
Post-procedure Bed Required
MRSA/VRE status
Contrast Allergy Prophylaxis Needed
NOT APPLICABLE
NECESSARY & DONE
NECESSARY & NOT DONE
NOT APPLICABLE
NOT APPLICABLE


15:44
TEAM PRESENT
CONTINUE LATER
DELETE
PROCEED
NURSE
RADIOGRAPHER
SPR
CONSULTANT


15:46
Timeout!
CONTINUE LATER
DELETE
PROCEED
CHECK CORRECT PATIENT
CHECK CORRECT SIDE
CHECK CORRECT SITE


15:48
PREPROCED...
CONTINUE LATER
DELETE
COMPLETE CHECKLIST
THE FOLLOWING CHECKS WERE NOT DONE
Written Consent
All equipment present
Relevant Lab Tests Ordered (reviewed)
Anticoagulant Stopped
PERFORM PROCEDURE ANYWAY?
Yes
No
Reason: consent missing