

DOCTORAL CONSORTIUM

**A RUBRIC TO GUIDE THE DESIGN,
DEVELOPMENT AND ASSESSMENT OF MOBILE
CLINICAL DECISION SUPPORT SYSTEMS**

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Abstract Clinical decision making is vital for healthcare provision. Sound clinical decision support systems (CDSS) have therefore become crucial for healthcare delivery. This research aims to develop a rubric to guide the design, development and assessment of mobile (i.e., Smartphone or Tab-based) CDSS, combining socio-technological factors and decision-making principles.

Keywords:

clinical
decision
support
systems,
task
technology
fit,
mHealth,
smartphone.



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1 Introduction

1.1 Background

Clinical decision making is a vital component in healthcare. Shortcomings in clinical decision making can lead to medical errors—i.e., human errors in healthcare provision (Makary & Daniel, 2016). Medical errors then lead to adverse health and cost implications (Makary & Daniel, 2016). Therefore, accurate and effective clinical decision making becomes essential.

The complex cognitive process of clinical decision making involves the interplay between knowledge of pre-existing pathological conditions, explicit patient information, nursing care and experiential learning (Banning, 2008). The thought process behind clinical decision making has evolved around a hypothetico-deductive approach, that involves acquiring initial cues, generating hypotheses, and making evidence-based decisions (Banning, 2008), (Jones, 1995), (Barrows & Tamblyn, 1980). Later on, this hypothetico-deductive approach has evolved with the addition of multiple nuances, and has evolved into various clinical decision-making models—some of them involving with Clinical Decision Support Systems (CDSS) as well (Banning, 2008). CDSS have evolved starting from documentation support, to facilities such as electronic medical records, to even more recent developments that provide clinicians the right information at the right time.

Earlier, these CDSS came in the form of paper-based record keeping systems and legacy-based desktop computer platforms (Skyttberg, *et. al.*, 2016). As healthcare evolved further, limitations of such systems as well were identified and requirement and space for further improvement were understood (Skyttberg, *et. al.*, 2016). The call for improvement of CDSS in terms of mobility, interoperability and scalability has become evident (Skyttberg, *et. al.*, 2016), (Ulapane & Wickramasinghe, 2021). At the same time, technology has advanced to facilitate ideal technological capabilities to make these advancements through technology generations like Industry 4.0 (Lasi, *et. al.*, 2014) and Healthcare 4.0 (Wehde, 2019). In such a backdrop, a modern-day interest has become mobile device-based (e.g., Smartphone and Tab-based) CDSS, that have the potential to deliver the technological needs while catering process needs like mobility, interoperability, and scalability. Therefore, an important question faced today, has become how we can design these mobile device-based

systems to best deliver for CDSS requirements. Looking into that question is the focus of this research.

1.2 Motivation

This research is motivated foremost by the shortcomings of clinical decision making that are evident (Makary & Daniel, 2016) and the health and economic implications (Shreve, *et. al.*, 2010) of that. As said before, shortcomings in clinical decision making are a cause of medical errors. Medical errors are: Human errors in healthcare provision (Makary & Daniel, 2016).

The implications of medical errors can be seen well by a 2016 Johns Hopkins study (Makary & Daniel, 2016). According to (Makary & Daniel, 2016), medical errors are the third-leading cause of death in the United States. The projected cost of these errors to the U.S. economy per year has been approximately \$20 billion (Shreve, *et. al.*, 2010). From these costs, 87% have been direct increases in medical costs of providing services to patients affected by medical errors (Shreve, *et. al.*, 2010). Another study (Arlen, 2013) points out that medical errors have increased average hospital costs by as much as \$4,769 per patient. Some of the burdens posed by medical errors, or shortcomings in clinical decisions can thus be summarised.

Secondly, this research is motivated by the potential of mobile technologies to improve clinical outcomes through enabling better clinical decision making. A good example providing evidence for this potential is the Australian study (Chahal, *et. al.*, 2020). This study reports a work carried out between June 2013 and March 2018, where the efficacy, safety and sustainability of a risk-stratified thromboprophylaxis protocol implemented as a Smartphone App was studied in 24,953 surgical admissions at a dedicated cancer centre. By final implementation, a program compliance of 91% has been observed. A reduction of postoperative venous thromboembolism rates from 3.1 per 1000 surgical admissions to 0.6 per 1000 surgical admissions has also been observed. A decline of postoperative bleeding rates from 10.0 per 1000 surgical admissions to 6.3 per 1000 surgical admissions has also been observed. Sustained improvement has been observed for more than 3 years after implementation. Thus (Chahal, *et. al.*, 2020) has been one promising study that has exhibited how mobile device-based technologies can help improving healthcare outcomes.

Furthermore, since healthcare has some quite well-established workflows that go coupled with years of education and training, introducing digital technology to clinical workflows is not particularly easy. This introduction has been found to carry quite a number of issues as well. These issues however, are not often only technology-related; they tend to be more people and process-related (Ulapane & Wickramasinghe, 2021). Therefore, one of the main challenges of today, is to think about how to do better design, to make best use of technology by understanding and addressing the entailing people and process issues as well. This need for thinking of better design is a third motivation behind this research.

1.3 Scope

The research question revolves around the design and development of clinical decision support systems. As such, the focus is on digital technology-enabled decision support systems in clinical practice.

When it comes to CDSS, there are numerous types including paper-based systems, to legacy-based desktop systems, to more recent mobile device-based (e.g., Smartphone or Tab-based) systems. The call for mobility, ease of use, interoperability and light-weight stand out as important requirements for effective use of CDSS in clinical care (Skyttberg, *et. al.*, 2016). Therefore, the interest nowadays is towards introducing mobile device-based CDSS to healthcare (Ulapane & Wickramasinghe, 2021). Facilitating to that space, the digital health technology focus of this research is mobile device-based (i.e., Smartphone and Tab-based) CDSS. Paper-based and legacy desktop-based systems are out of the scope.

Some of the more serious, and even life-threatening medical errors happen in tertiary and quaternary care where patients undergo treatment under hospital admission (Makary & Daniel, 2016). As such, this research targets that clinical care space (i.e., tertiary and possibly quaternary care). Primary and secondary care will be out of scope. Thus, our technology design will focus on the hospital and ward setting, but not the operating theatre. The target group of technology users will be the tertiary care clinicians (specifically, doctors and nurses).

2 Problem statement

2.1 Research question

Motivated by the lack of a systematic approach to develop mobile digital technologies of healthcare, this research explores the possibility for clinicians to use personal and hand-held mobile devices like Smartphones and Tablets in a hospital setting (more specifically, in a tertiary care setting or above) as Clinical Decision Support Systems (CDSS). The related research question can be stated as:

How can mobile device-based CDSS be designed and developed to be more useful and usable for tertiary care clinicians?

2.2 Significance of the research

As said before, shortcomings in clinical decision making can lead to medical errors—i.e., human errors in healthcare provision (Makary & Daniel, 2016). Medical errors can lead to adverse health and cost implications (Makary & Daniel, 2016).

When considering the context of surgery in the above light, postoperative venous thromboembolism (VTE) remains an important cause of morbidity and mortality (Chahal, *et. al.*, 2020). Approximately 2–13 in every 1000 elective surgical admissions in Australia develop a symptomatic postoperative VTE and this is associated with a 10% case fatality rate (Chahal, *et. al.*, 2020). Prevention of VTE remains a worldwide priority safety initiative, with the Agency for Healthcare Research and Quality ranking this the number one patient safety practice for hospitals (Chahal, *et. al.*, 2020). As such, this research is carried out in partnership with a leading cancer hospital in Australia, with the aim of reducing VTE. The specific focus will be to design and develop a Smartphone App (called the CLOTS App) that will help tertiary care clinicians in reducing VTE.

This research will have a contribution to knowledge as well as a contribution to practice. The contribution to knowledge will be a rubric that combines socio-technological factors and fundamentals of decision-making to ensure strong task technology fitness of mobile device-based CDSS. The contribution to practice will be a rubric that can be used by designers, technology developers, change managers,

and other spearheads to guide the design and development, as well as the rating of task technology fitness of mobile device-based CDSS.

3 Literature review

Since this research is about developing mobile device-based CDSS, we are interested in the human activity of clinical decision making and the technology aspect of CDSS. Clinical decision making is a subset of the broader topic of decision making. Furthermore, CDSS are a subset of the broader topic of decision support systems. Therefore, the two key knowledge fields relevant to be reviewed for this research are seen as: (1) Decision making and clinical decision making; and (2) Decision support systems and clinical decision support systems. Then, since we are interested in developing superior mobile device-based CDSS, it is also important to understand the state of the art and the critical issues faced when using mobile CDSS. Therefore, as the third component of this review, a brief analysis of the critical issues faced by mobile CDSS are presented.

3.1 Decision making and clinical decision making

Decision making: Decision making is a cognitive process It results in the selection of a belief or a course of action among several possible alternative options. This process can be rational or irrational. Rational decision making is what is focused on in this research. A common way of classifying decision making involves the following threefold classification: i) Unstructured decision making; ii) Structured decision making, and iii) Semi-structured decision making (Sharma & Thakur, 2015). Next, it is important to know about strategies and procedures followable to perform decision making. These are commonly known as decision-making models. DECIDE (Guo, 2020) and the 7-Step model (Brown, 2012) are two widely accepted generic and rational decision-making models. These models, sometimes with slightly varying terminology, are often taught in leadership and/or management training. Then comes another important decision-making model from Herbert A. Simon's (Simon, 1997). Simon's model can be used to present a perspective that unifies and generalises decision-making models, including the likes of DECIDE and the 7-Step model (Ulapane & Wickramasinghe, 2021). Simon's decision-making model includes the following four main phases: (1) Intelligence phase; (2) Design phase; (3) Choice phase; and (4) Monitor (or Review / Implementation) phase. Simon (Simon, 1997)

also discusses the ideas of Bounded Rationality and Satisficing as undeniable constraints for decision making. The recent work by (Ulapane & Wickramasinghe, 2021) presents a review about decision making models.

Clinical decision making: Clinical decision making is a subset of general decision making. Yet, clinical decision making is a unique process that involves the interplay between knowledge of pre-existing pathological conditions, explicit patient information, nursing care and experiential learning (Banning, 2008). Clinical decisions can mainly be viewed through a two-fold categorisation: (1) Diagnostic decisions (i.e., determining “what is true?”); and (2) Treatment planning decisions (i.e., determining “what to do?”) (Wasylewicz & Scheepers-Hoeks, 2019). Historically, two models of clinical decision making have been recognised: (1) The information processing model; and (2) The intuitive-humanist model (Banning, 2008). More recently, a third model of clinical decision making has been proposed, namely, O’Neill’s clinical decision-making model (Banning, 2008), (O’Neill, *et. al.*, 2004), (O’Neill, *et. al.*, 2005). The information processing model and O’Neill’s clinical decision-making model are both rooted on a hypothetico-deductive approach that assists clinical and metacognitive reasoning (Banning, 2008), (Edwards, *et. al.*, 2004). Thus, the hypothetico-deductive approach can be considered the most enduring clinical reasoning model in medicine (Edwards, *et. al.*, 2004). This hypothetico-deductive approach can summarily be understood via the following four stages: (1) Cue recognition or cue acquisition stage; (2) Hypothesis generation stage; (3) Cue interpretation stage; and (4) Hypothesis evaluation stage (Banning, 2008), (Edwards, *et. al.*, 2004). Not many works have mapped clinical decision making onto the fundamentals of general decision making. Catering to that void, the recent work by (Ulapane & Wickramasinghe, 2021) has presented a perspective for understanding clinical decision making via general decision-making principles.

3.2 Decision support systems and clinical decision support systems

Decision support systems: Decision support systems are information systems-related tools that assist the process of decision making. Decision support systems can be understood as “Inquiring Systems” as proposed by C. West, Churchman (Churchman, 1971). Inquiring Systems can be interpreted as “Systems” that can be put into practice when attempting to solve a problem, or to find a satisfactory answer to a problem. Going with the general interpretation of “Systems”—a System has

Inputs, Outputs, and a Process in between. Similarly, Inquiring Systems too have Inputs, Outputs, and Processes in between. The output of an Inquiring System is "true knowledge", or at least knowledge that can be best agreed upon. A distinctive feature of Inquiring Systems is them containing elaborate mechanisms for "guaranteeing" that only "valid" knowledge is produced. Apply that Inquiring Systems architecture onto an Information System, that would intake several inputs from a user, and outputs knowledge that is guaranteed to be true to some established criteria. Such an Information System essentially functions as a Decision support system. Churchman's work (Churchman, 1971) has discussed several ways of Inquiring by the names of Leibnizian inquiry; Lockean inquiry; Kantian inquiry; Hegelian inquiry, and Singerian inquiry. The recent work by (Ulapane & Wickramasinghe, 2021) argues how clinical decision making quite often aligns with the Lockean inquiry.

Clinical decision support systems: Clinical decision support systems (CDSS) can mainly be classified in the following threefold approach: (1) Diagnostic assistance providing systems; (2) Treatment planning assistance providing systems; and (3) Diagnostic and treatment planning assistance providing systems (Wasylewicz & Scheepers-Hoeks, 2019). There are other lenses as well through which CDSS can be classified according to specific technicalities of the systems (Wasylewicz & Scheepers-Hoeks, 2019). As said in the Introduction, the main focus of this research is mobile device-based (e.g., Smartphone, Tablet) CDSS. Irrespective of how CDSS are classified, and irrespective there being no shortage of technology, some common issues with CDSS are reported in literature. These issues can vary from fitness for purpose of technology, to perception and tendency or lack of it to adoption shown by people. The recent scoping review by (Ulapane & Wickramasinghe, 2021) looked specifically into the critical issues reported in recent extant literature surrounding mobile device-based CDSS. Issues identified can be summarised as: complexity & performance issues; difficulty to validate; cost; data quality; lack of generalisability, expandability, scalability; lack of streamlining with clinical workflow; privacy issues; surveillance capitalism; risks and accountability; policy and legislative challenges; slow or low adoption; personal biases; and competence (or lack of it) in technology (Ulapane & Wickramasinghe, 2021), (Shaw, *et. al.*, 2019). There is also call for better standardisation of mobile health solutions (Lee, *et. al.*, 2018). Despite there being no shortage of technology capability in present times, the emergence and reporting of such a large spectrum of issues related to mobile technology in healthcare evidence

the lack of a systematic approach for mobile technology development for healthcare. Although there are some metrics for this purpose (Mathews, *et. al.*, 2019), they are likely to be developing and not cover a broader and more complete spectrum of socio-technical aspects. Motivated by that gap, this research aims to develop a rubric to guide the design, development and assessment of mobile CDSS in a way superior fitness for purpose is ensured.

Intelligent clinical decision support systems: Clinical decision support systems (CDSS), and more generally most decision support systems that have been developed to assist clinicians often are based on static data which may be out of date. Intelligent decision support systems are an emerging tool that addresses this limitation of static nature that may be there in CDSS. Intelligent CDSS may have artificial intelligent methods which could be applied to actively survey or mine the latest, or updated clinical rules or guidelines. By so doing a decision support system could contain timely updated information for clinicians, which is of significant value in fast changing situations such as minimally understood emerging diseases and epidemics (Ciolko, *et. al.*, 2010).

Table 1: provides a summary of how decision support systems and clinical decision support systems can be scoped

Decision support systems	Clinical decision support systems	Intelligent clinical decision support systems
Can be viewed as an “Inquiring System”	Can be viewed as an “Inquiring System”	Can be viewed as an “Inquiring System”
Provides “verified” outputs for matching inputs	Provides “verified” outputs for matching inputs, in a clinical context	Provides “verified” outputs for matching inputs, in a clinical context
Traditionally, static in nature (i.e., outputs may be out of date at a particular time of use)	Traditionally, static in nature (i.e., outputs may be out of date at a particular time of use)	An emerging field that uses Artificial Intelligence to address the static problem by actively mining most updated information

3.3 Critical issues with mobile device-based CDSS

The niche for mobile device-based CDSS as opposed to traditional paper-based and legacy-based CDSS systems comes from the need identified for CDSS to be mobile, interoperable, and scalable in order to cater the modern needs (Skyttberg, *et. al.*, 2016), (Ulapane & Wickramasinghe, 2021). Furthermore, the advancements in Internet of Things (IoT) have made it possible to design mobile systems to address the modern needs of healthcare, if the designs can be integrated smoothly with clinical workflows and change management can be handled. However, provided that healthcare has some quite well-established workflows that go coupled with years of education and training, making a technological intervention to a clinical workflow is not particularly smooth, and can result in quite a number of issues. These issues can vary from fitness for purpose of technology, to perception and tendency or lack of it to adoption shown by people. A recent 2021 scoping review by (Ulapane & Wickramasinghe, 2021) found a number of issues reported in recent extant literature about mobile CDSS. These issues can be summarised as: complexity & performance issues; difficulty to validate; cost; data quality; lack of generalisability, expandability, scalability; lack of streamlining with clinical workflow; privacy issues; surveillance capitalism; risks and accountability; policy and legislative challenges; slow or low adoption; personal biases; and competence (or lack of it) in technology.

Moreover, slow adoption rate or the low adoption rate when it comes to adoption of some technology developments in healthcare is a serious issue (Kharrazi, *et. al.*, 2018). There is also call for better standardisation of mobile health solutions (Lee, *et. al.*, 2018).

Despite there being no shortage of technology capability in present times, the emergence and reporting of such a large spectrum of issues related to mobile technology in healthcare, evidence the lack of a systematic approach for mobile technology development for healthcare. That gap stands a motivator behind this research.

4 Theory

In this section, the theoretical lens that will be used to guide this research is summarised. The research question and the specific context in focus deals with introducing a digital health solution to support a healthcare task, and enquiring how this solution can be designed to maximise the benefits to the healthcare task. As such, this work focuses on maximising the fit of a technology (a digital health technology in this context) to a manual task (a healthcare task in this context). A well-known theory that covers our question at hand, is the theory of **Task technology fit** (Goodhue & Thompson, 1995). Therefore, **Task technology fit** assessment is taken forward as the primary and an ideal guide for this work.

Then, the target users of this technological tool are tertiary care clinicians as said before. Tertiary care clinicians cannot be taken in isolation and they have to work within and aligned with their work environment—i.e., hospitals and wards. In those environments they do have established workflows. As such, in this context the clinicians must be considered in conjunction with their work environment, or their organisation. Therefore, factors about the organisation needs to be taken into consideration as well, as when the organisational norms are supportive of the introduction of a technology, that will play a key role in successful implementation and eventually help in performance enhancement. Expanding from our baseline theory of Task technology fit, the secondary theory of Fit-viability (Liang, *et. al.*, 2007) helps in forming foundation to assessing how organisational factors play in the success of technology introduction. Therefore, we take the theory of Fit-viability assessment as well to consideration.

The research design (provided in Figure 1 in Appendix 1) has two key phases of research: (1) In-depth analysis of literature, and (2) An exemplary case study. Hermeneutic analytic techniques will be conducted in the in-depth analysis of literature. Then, the case study will follow a positivist approach. Therefore, Robert Yin's case study methodology (Yin, 2017) will be closely followed. Furthermore, since the case study involves designing an artifact, Design science research methodology (Peffers, *et. al.*, 2007) will be followed to guide the design.

5 Methodology

Overview: This study adopts a positivist approach involving methodological triangulation, mixed method analysis, and an exemplary case study.

This research will have two phases. The first phase will focus on an in-depth analysis of literature. Hermeneutic (Kafle, 2011) and Thematic analysis (Boyatzis, 1998) will be used to conduct the qualitative analysis of findings from the literature. The second phase is an exemplary case study surrounding designing a mobile CDSS for tertiary care clinician. This case study will involve: 1) An interview study involving clinicians and requiring written feedback from clinicians after testing beta versions of the App, and 2) A co-design study to improve the CLOTS App. Hermeneutic (Kafle, 2011) and Thematic analysis (Boyatzis, 1998) will be used to conduct the qualitative analysis of the oral and written feedback from clinicians. The co-design study with the CLOTS Smartphone App will involve an Agile App development workflow, based on Design science research methodology (Peffer, *et. al.*, 2007). In addition to acquiring feedback from clinicians, online capturing App usage statistics will also be employed to permit quantitative analysis of App usage trends. The two phases will address the two sub research questions which are:

1. What are the key issues that influence the successful design and development of mobile device-based CDSS as identified in extant literature?
2. What are the key issues that influence the successful design and development of mobile device-based CDSS as identified through end user clinicians' perspectives?

This approach will permit identification of key issues that influence the success of mobile device-based CDSS through two research phases using different research methods. Triangulation of the findings from both phases will result in identification of the key issues to answer our main research question. The two research phases are detailed in the following sections. Figure 1 (in Appendix 1) displays the research design.

Phase 1: In-depth analysis of literature: In this component, extant literature will be systematically reviewed. The purpose will be to identify key factors that influence successful designing and developing of mobile device-based CDSS, and also to articulate an adequate theoretical lens that captures these issues.

Data collection: Data collection will be done by logically creating a search string and performing literature searches in standard medical databases like PubMed, Medline, and Embase. Resulting literature will be screened for relevance first by reading titles and abstracts, and then doing full text analysis of most relevant works.

Data analysis: Data analysis will be done via full text review. This will be carried out through interpretation of texts respecting the hermeneutic circle (Kafle, 2011), and the identified issues will be classified under emerging themes using thematic analysis (Boyatzis, 1998). Since the identified issues are unlikely to be reported as quantitative data, a quantitative bias assessment is likely to be unnecessary, thus, our analysis is expected to be purely qualitative. However, depending on our findings, it might be necessary to do a bias assessment.

Expected outcomes: The expected outcome of this component of the study will be a list of issues and assignable themes. Assessment of the findings is expected to be done through focus groups involving senior clinicians. The findings will form the focus of a peer reviewed paper.

Phase 2: Exemplary case study: This case study will be focused on rebuilding and improving the CLOTS App. The CLOTS App supports prevention of thromboembolism in Oncology surgery patients. The study will follow Yin's case study methodology (Yin, 2017) and design science research methodology (Peppers, *et. al.*, 2007) to facilitate co-design (Steen, 2013). Thus, the question that defines the case study will be: "How can a mobile CDSS be designed and developed to support tertiary care clinicians in preventing thromboembolism in Oncology surgery patients?" Then, the design of the case study will be a single holistic illustrative exemplary case study on improving the CLOTS App.

Data collection: Data collection will be done via two means: (1) Obtaining feedback by clinicians; (2) Online collecting of App usage data. Several app-interfaced online, email, and virtual meeting opportunities will be given to primary users of the CLOTS App to provide feedback and express their expectations regarding improvements to the app. Furthermore, an agile framework will be carried out in redesigning and improving the CLOTS App taking into account good practices reported in literature and the expectations as reported by potential users (i.e., clinicians). Along the agile framework, recording of improvements done, issues encountered, user feedback

received from clinicians, and app usage statistics of primary user clinicians will be carried out.

For the interview and focus group components, ten to twenty clinicians (the sample size is chosen respecting the norms of qualitative interview of experts and the Delphi method (Hallowell & Gambatese, 2010), primarily from the Peter MacCallum Cancer Centre who use the current version of the CLOTS App will be invited to participate in semi-structured interviews regarding their experience with the CLOTS App. The interviews will explore into what clinicians find helpful about CLOTS, what clinicians find as shortcomings, and what are the clinicians' expectations of an ideal mobile CDSS.

Data analysis: Clinicians' feedback will be analysed qualitatively. Emerging themes from the interview responses (and other qualitative oral and written feedback provided by clinicians) will be identified, and Thematic analysis (Boyatzis, 1998) will be conducted. The App usage statistics collected will be analysed quantitatively, to find which models in the App are most commonly used, which models and pathways are rarely used, and also potential decision pathway mistake / confusion patterns, and clinicians' usage practices of the App (i.e., for example, as a casual educational tool, or a situation-specific decision support tool).

Expected outcomes: The expected outcome of this component of the study will be a list of issues as identified by clinicians regarding the good design of a mobile CDSS. Assessment of these findings will be carried out through disclosing the findings in focus groups involving clinicians and also unit testing of the redeveloped versions of the CLOTS App. Reporting of these outcomes will be done in the form of one or two articles published in indexed journals.

Lastly, the findings from the two research phases will be triangulated. This would constitute a methodological triangulation, helping ensure quality of and consistency of the findings. These findings will be used to construct a rubric that provides good practice guidelines to help the design and development of mobile CDSS.

The research design is depicted in Figure 1 (Appendix 1).

6 Expected outcomes

Contribution to knowledge: A rubric that combines socio-technical factors and fundamentals of decision-making that need to be considered to ensure strong task technology fit of mobile device-based CDSS.

Contribution to practice: (1) The improved CLOTS App (artifact). (2) A rubric that can be used to guide the design and rate the task technology fit of mobile device-based CDSS.

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Appendix 1: Research design

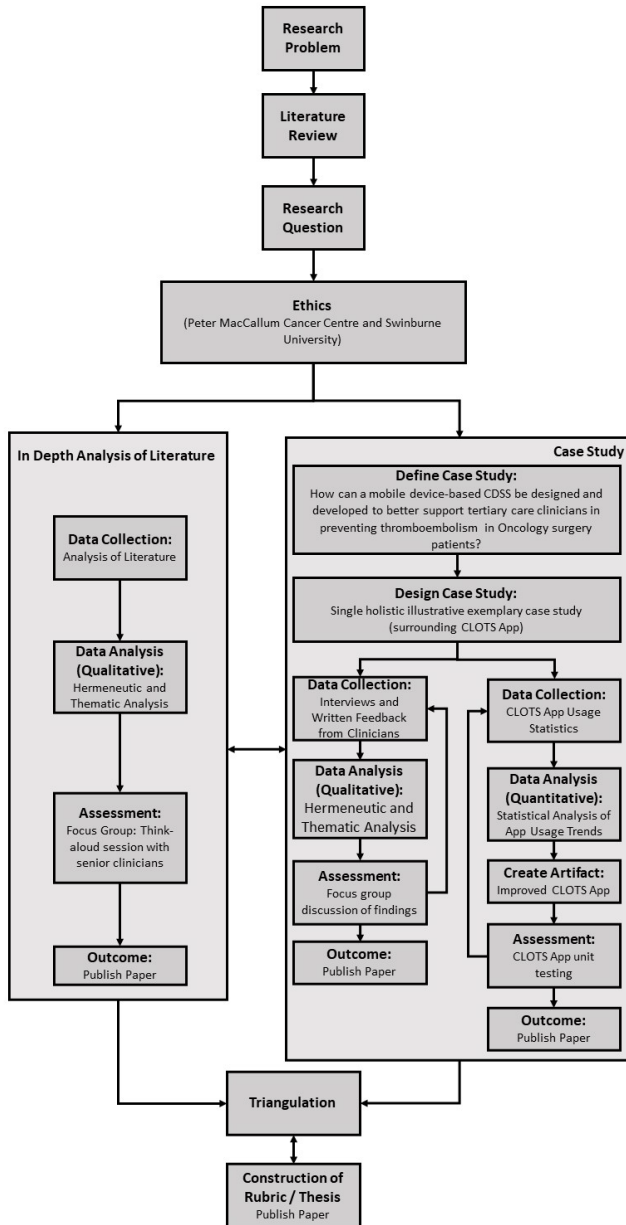


Figure 1: Research design

