Mobile Clinical Decision Support Systems: A Pathway from Design to Commercialization

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A smartphone-based clinical decision support system (CDSS) has been designed for perioperative patient management in cancer care. A systematic design approach to ensure fit-for-purpose of such mobile CDSSs is lacking. This study attempts to fill that void by reporting on the pathway we took from design to commercialization. Our pathway is governed by the design science research methodology and the theory of task technology fit. Our experiences are generalizable and can provide guidance to many mobile clinical decision support solutions in healthcare.

Keywords:
clinical decision support systems, commercialization, design science research methodology, perioperative, surgery, task technology fit, smartphone

University of Maribor Press

DOI https://doi.org/10.18690/um.fov.6.2023.27
ISBN 978-961-286-804-8

1 Introduction

Clinical decision making is a complex and cognitively demanding process. It involves the interplay between tacit and explicit knowledge and includes observation, information, knowledge, experience, caring, and incidental learning (Banning, 2008). Medical errors could result from shortcomings in clinical decision making (Makary & Daniel, 2016) and manifest as adverse health and cost implications. As such, effective and accurate clinical decision making becomes essential for quality healthcare delivery.

Technology has been introduced to healthcare over the years to support clinical decision making. Clinical decision support systems (CDSSs) has been one such use of technology. CDSSs have advanced over the years. Starting from paper-based systems they have evolved to legacy-based computer systems (Skyttberg, et. al., 2016), and then more recently to handheld mobile device-based systems (Chahal, et. al., 2020). Latest technology advancements such as Industry 4.0 and Healthcare 4.0 have enabled this evolution. Following this backdrop, designing a Smartphone-based CDSS is the focus of this study.

The introduction of mobile CDSSs to healthcare is not simple. A recent scoping review (Ulapane & Wickramasinghe, 2021) has listed some of the major issues encountered in the past five years in attempts to introduce mobile technologies to healthcare as follows: complexity and performance-related issues in the used technologies; difficulty to validate the efficacy of the introduced technologies; costs involved in introducing new technologies; lack of quality of data (when it comes to the use of Artificial Intelligence (AI)); lack of generalizability of certain techniques and technologies used, lack of expandability and scalability of the introduced technologies; lack of streamlining of the technologies with the clinical workflows; privacy and cyber security-related issues; surveillance capitalism; risks and accountability; policy and legislative challenges; slow adoption of certain technologies in healthcare; perceptions and biases of technology users and potential users; and competence (or lack of it) in technology usage among clinicians. The call for better standardization of mobile technologies in healthcare has also emerged (Lee, et. al., 2018).

The prevalence of diverse issues as noted above, indicates a void in this field. This void comes due to the lack of a systematic approach for the design and development of mobile CDSSs. Motivated by that void, this study attempts to answer the following research question: "How can mobile CDSSs be designed and developed to be of superior fit-for-purpose?"

By answering the aforesaid research question this study makes a twofold contribution: A contribution to theory and a contribution to practice. The contribution to theory comes as a systematic design approach for mobile CDSSs. Our approach extends towards validation and commercialization. Our approach combines the theory of Task Technology Fit (TTF) (Goodhue & Thompson, 1995), the Design Science Research Methodology (DSRM) (Hevner & Chatterjee, 2010), and the input from a commercial software development partner. The contribution to practice is a designed and validated mobile CDSS. It includes a smartphone application and a web-based data analytics platform. This CDSS assists clinicians, specifically doctors, and nurses, to manage surgery patients during perioperative care (i.e., pre-operative and post-operative stages). The CDSS supports with decisions like management of anticoagulant drugs. The specific health focus is prevention of thromboembolism. Thromboembolism is a condition of undesired blood clotting. It is a leading cause of death and complication in surgery patients (Chahal, et. al., 2020). This CDSS has been designed for a leading cancer hospital in Australia.

This paper is arranged as follows: Review of related works; relevant theories; methodology; results; discussion, and conclusions.

2 Review of Related Work

A literature search was carried out surrounding Smartphone-based CDSSs in perioperative care. The following keyword search was done: ("perioperative" OR "surgery") AND "smartphone". The keyword search was done in the Google Scholar database. Google Scholar is accessible to the public free of charge. Almost all academic databases are enlisted in Google Scholar. The search was done between May 1st and May 5th of 2022. The search was limited to items written in English. The items that included the keywords within the item's title were considered. Works published since 2021 were considered to capture the latest results. Twelve articles got retrieved matching the search criteria. Our search is deliberately restrictive and

thus may be incomplete. Our purpose here was to scan the latest literature within the previous year or so for a snapshot of the latest works.

The aims and objectives of the retrieved works were reviewed. We noticed that none of the retrieved works had focused on proposing a systematic design approach. As such, our study contrasts those works. The works (Ahmad, et. al., 2022), (Awaludin, et. al., 2022), (Boaro, et. al., 2021), (Panda, et. al., 2022), (Soangra & Lockhart, 2021), (van den Berg, et. al., 2022), (Voglis, et. al., 2022), and (Wu, et. al., 2022) have all reported some degree of design and development. Their primary focus is the technology solution rather than the design approach. As such, their design approaches are specific for their solutions. Such design approaches can be improved and generalized by grounding on theory. Therefore, our study offers an increment to current thinking as we propose a systematic design approach grounded on theory. Our approach can be replicated irrespective of the health or technology context.

The works (Jones, et. al., 2021), (Kabbani & Kabbani, 2021), and (Lesher, et. al., 2021) were review articles. The need for a systematic design approach is further emphasized in them. Jones, et. al., (2021) concludes a lack of certification, validation and peer review of applications designed for plastic surgery in the UK. Kabbani & Kabbani, (2021) highlights the importance of codesign and cocreation of applications through collaboration with healthcare professionals. Moreover, Lesher, et. al., (2021) has discussed institutional and regulatory barriers to the adoption of mobile health (i.e., mHealth) applications. Such points complement our argument and reemphasize the need for a systematic design approach so that persistent barriers can be overcome and thereby enable smooth and seamless introduction of digital health solutions to healthcare contexts.

3 Relevant Theories

Our attempt is to maximize the fit-for-purpose of mobile CDSSs. A well-known theory to assess fit-for-purpose is the theory of Task Technology Fit (TTF) (Goodhue & Thompson, 1995). We have adopted TTF in this work. Furthermore, our study involves designing an artifact through codesign. Therefore, the Design Science Research Methodology (DSRM) (Hevner & Chatterjee, 2010) is also followed. These theories are summarized in the following subsections.

3.1 The Theory of Task Technology Fit (TTF)

Stated in TTF is that Information Technology (IT) systems are likely to be more usable, desirable, and impactful, if the system's capabilities match the tasks the user must perform (Goodhue & Thompson, 1995). Goodhue & Thompson, (1995) presented a list of factors to measure the influence of TTF on user performance. We have constructed the questionnaire in (TTF Questionnaire, 2022) based on that list. It is tailored for the users of mobile CDSSs. This questionnaire is used for validation of our artifact through user feedback.

3.2 Design Science Research Methodology (DSRM)

DSRM (Hevner & Chatterjee, 2010) is a process for systematically creating an artifact so that the artifact's desirability can be maximized by meeting stakeholder needs. The process includes six steps: (1) Problem identification and motivation; (2) Defining the objectives for a solution; (3) Design and development; (4) Demonstration, (5) Evaluation, and (6) Communication. Research can be integrated at every or any one of the first five steps. Research can target understanding and solving any issues to maximize the artifact's desirability. The landmark publications (Hevner & Chatterjee, 2010), (Hevner & Wickramasinghe, 2018), and (Peffers, et. al., 2007) are useful for more details.

4 Methodology

The DSRM inspired design process we followed is depicted in Figure 1. The participants of the codesign process are listed in Table 1. The various stages of the design process are described in the subsections that follow.

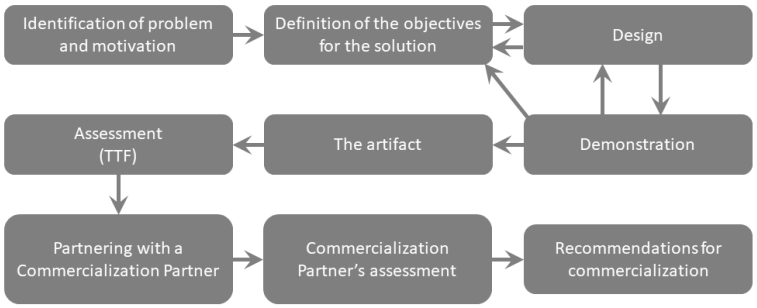

Figure 1: The design process followed

Table 1: Details of the research team

Researcher's code	Description about the participant	Role in the project
C1	Senior Hematologist	Project Lead
C2	Senior Anesthetist	Clinician Facilitator
C3	Senior Anesthetist	Clinician Facilitator
A1	Professor in Digital Health	Principal Investigator
A2	Professor in Behavioral Science	Chief Investigator
A3	Professor in Computer Science	Chief Investigator
R1	Senior Research Fellow in Computer Science	Associate Investigator
R2	Junior researcher in Digital Health	Junior Investigator

4.1 Identification of problem and motivation

This step was conducted between January and June 2020 with the participation of C1, A1, A2 and A3. This step was carried out through drafting and reviewing a proposal for this project. The primary aim came out as to design and develop a mobile CDSS for the target health context (i.e., optimization of perioperative patients to reduce the incidence of thromboembolism). A secondary aim was to commercialize this CDSS, extending it to become a gold-standard for all surgical procedures. A project proposal document was the outcome of this phase.

4.2 Definition of the objectives for a solution

The specific objectives were identified between May and October 2020. These were identified through 1-hour semi-structured virtual meetings that were arranged once a month. Participants C1, A1, A2, A3, R1, and R2 were regular participants and attended all the meetings. Participants C2 and C3 were invited occasionally by the regular participants to obtain specific clinical expertise. Detailed minutes of each meeting were documented. After each meeting the minutes were shared among all participants for consensus. At this stage, the clinician participants C1, C2, and C3, shared with the team the relevant clinical rules to be implemented as the CDSS. The following were defined with consensus as the objectives and deliverables expected from the design phase: (a) A smartphone based CDSS; (b) A database to capture usage data of the CDSS (usage data include data entered to the CDSS and recommendations displayed by the CDSS); (c) A web-based dashboard to enable data display and analytics (this was expected to be a prototype to inspire further developments, specific analytics requirements were not defined at this stage), and (d) Updating certain clinical rules about anticoagulant drug management.

4.3 Design and Demonstration

The Design and Demonstration phases occurred in tandem between October 2020 and October 2021. Participants R1 and R2 led the design and implementation. Participant R2 as one of the first activities translated the clinical rules to editable flowcharts. Examples are available in (CLOTS Dashboard Demo, 2022) and (Ulapane, et. al., 2023). This was done to map clinical rules onto a data structure that is accessible to both clinicians and computer scientists. In our experience, this translation was helpful for liaison between the clinicians and the rest. It also helped in programming the clinical rules into an application. We suggest that translating clinical rules into such more widely accessible data structures is an important intermediate step that helps software implementations of clinical rules. These flowcharts were then shared with participants C1, C2, and C3 to update any clinical rules. Those clinician participants reached consensus among themselves and responded with updates to the clinical rules.

After obtaining the updated clinical rules, the development activities followed. Participant R1 led the software implementation. First, the mobile application was built enabling the app usage data being recorded in a backend database. Secondly, a web-based front-end was developed to enable data display and analytics. The mobile application with data capture facility and the web-based front end combined is the artifact produced by this study. Snapshots of the artifact are available in the Results section. The layouts for the mobile application and the web-interface were deliberately kept simple. Non-cluttered interfaces, preference for push buttons, and using colors of the partnering client hospital's logo were taken as the key design considerations for the mobile application and the web interface. The rationale behind these design considerations was to enhanced user-friendliness through decluttering and adequate functionality. Fancified aesthetics was not prioritized.

Demonstration was done through 1-hour virtual meetings arranged once a month. These meetings were conducted as semi-structured codesign workshops. Incremental progress was demonstrated, and the clinician participants were given the opportunity to provide feedback and express any 'would-like-to-have' sort of wishes. As indicated in Figure 1, opportunity was given for participants to reconsider the original objectives and propose any alterations to them. However, no participant proposed major alterations. Again, detailed minutes were recorded and were shared among the participants after each meeting for consensus. The artifact and the source code were the outcomes of this phase.

4.4 The Artifact

The Smartphone App with data capture facility and the web-based front end combined is the artifact produced by this study. Details are in the Results section.

4.5 Assessment

This phase was carried out between November 2021 and February 2022. The designed application was made available online (e.g., iPhone TestFlight) to download and use. Participants C1, C2 and C3 were asked to download and test. Meanwhile, R2 constructed the questionnaire in (TTF Questionnaire, 2022) based on TTF to be shared with the users of the mobile CDSS to provide feedback. The intention was communicated to C1 to perform a wider assessment, by inviting more clinicians

onboard and asking them to assess the app and provide feedback through the questionnaire in (TTF Questionnaire, 2022). C1 agreed and recruited 7 clinicians inclusive of C1 and C3. These 7 recruits were invited to test the app and then attend a focus group conducted virtually. In the focused group the participants were presented the questionnaire in (TTF Questionnaire, 2022) and were asked to provide qualitative and quantitative feedback. The qualitative feedback was recorded as meeting minutes. The qualitative feedback was also compiled as a report. In the report the feedback was summarized under the main themes of TTF, i.e., (1) Characteristics of the clinician's task involving the technology usage; (2) Characteristics of the technology (i.e., the CDSS), and (3) The impact the CDSS has on the clinician's performance. Several subthemes emerging from the qualitative feedback (inductive analysis) were also highlighted in the report. These findings are summarized in the Results section. This report was then shared with the participants of the focus group for consensus. This report containing user feedback was the outcome of this phase.

4.6 Partnering with a Commercialization Partner

This phase was carried out between March 2022 and August 2022. Different software product development companies were considered as candidates to be recruited as a commercialization partner. The track record of previous work and the experience of the candidates, and any preferences of the partnering client cancer hospital were considered as factors that would weigh our choice of a commercialization partner. A candidate was chosen, and several meetings were held to establish relationship and express our interest. Different plans for commercialization that could be offered by the partner were invited alongside quoted costs. The plans were reviewed by the research participants and the plan that matched the current budget constraints was chosen. Affordable amendments to the plans were also proposed. Then, the relevant contracts and nondisclosure agreements pertaining to intellectual property were signed. Finally, the developed artifact along with the source code (i.e., the outcome of phase 4.3), and the assessment report (i.e., the outcome of phase 4.5) were submitted to the commercialization partner for review.

4.7 Commercialization Partner's Assessment

This phase was carried out between September 2022 and November 2022. The commercialization partner conducted two activities. One activity was assessing the source code. The source code was assessed against several factors, such as industry best practices for quality of the source code (according to the commercialization partner's internally defined criteria that is partly covered by their intellectual property rights), the cyber security aspects, and the possibility to integrate with existing infrastructure of hospitals. The second activity was a replication of the assessment phase (i.e., phase 4.5) with end users, but again, according to an assessment criterion that is defined by the commercial partner. A report was submitted by the partner to the research team at the end of the assessment. The report contained the following: (1) A summary of the findings from the partner's assessment, i.e., code quality and user perceptions; (2) The partner's recommendations along with suggested pathways for commercialization; and (3) Tentative budgets estimates for each commercialization pathway. A couple of follow up meetings were held to clarify any unclear points and to reach consensus. The partner's report following consensus was the outcome of this phase which is consistent with DSRM approaches of getting consensus among all stakeholders/users.

4.8 Recommendations for Commercialization

Currently we are considering the recommendations of the commercial partner and are sourcing funding for pursual. The pathways suggested by the partner for commercialization are depicted in the Results section.

5 Results

Reference (CLOTS Demo, 2021) provides a video demonstration of the CDSS smartphone application. The smartphone application is available in (CLOTS App, 2022) for download and use. Reference (CLOTS Dashboard Demo, 2022) provides documented description about the app functionality and the web interface. Figures 2 and 3 provide snapshots of the artifact. End user feedback obtained from the focus group using the questionnaire in (TTF Questionnaire, 2022) are summarized in Figure 4. The feedback is summarized under the three main themes of TTF listed in subsection 4.5. The themes emerging from the data are highlighted in bolded font.

More discussion about these results is available in our previous work (Ulapane, et. al., 2023). The pathways suggested by the commercialization partner are depicted as a flowchart in Figure 5. Ultimately validation of superior fit-for-purpose is successful commercialization; so, this is a necessary first step in this regard.

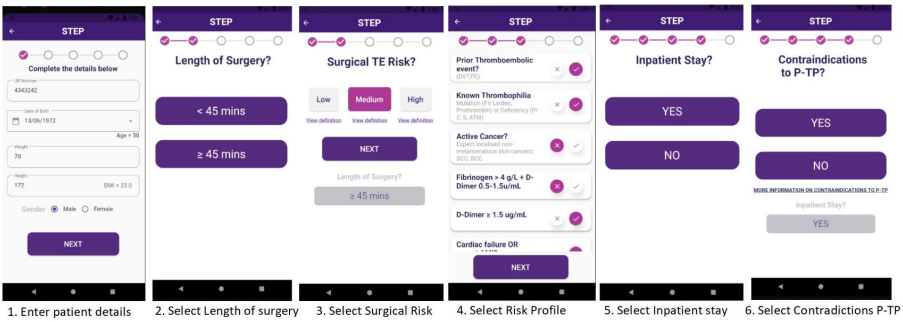

Figure 2: Some screenshots of the smartphone based CDSS app (the font in the figure is legible, please zoom to read)

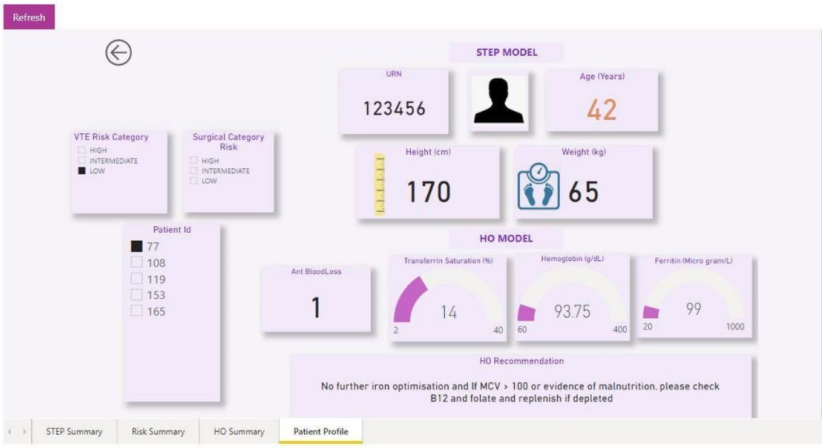

Figure 3: Some screenshots of web interface for data display and analytics (the font in the figure is legible, please zoom to read)

6 Discussion

Our study made a twofold contribution: A contribution to theory and a contribution to practice.

The contribution to theory was a systematic design approach for mobile CDSSs. The approach was applied to design a mobile CDSS to a leading Australian cancer hospital. Key phases of the design process were detailed. The outcomes of each phase were mentioned, and it was emphasized that a successful plan for commercialization is a necessary step for commercialization which in turn is the ultimate evidence of superior fit-for-purpose. Our approach extended the typical analysis of fit-for-purpose to include validation and suggested pathways for commercialization. Our approach combines the theory of Task Technology Fit and the Design Science Research Methodology (DSRM). The pathways for commercialization came as input by a software product development partner.

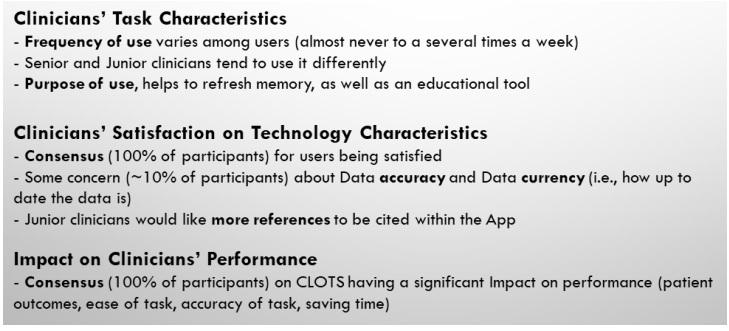

Figure 4: Findings from the TTF questionnaire-based focus group carried out to validate the CDSS (the font in the figure is legible, please zoom to read)

The contribution to practice was a designed and validated mobile CDSS. It included a smartphone application and a web-based data analytics platform. This CDSS was designed to assist clinicians to manage surgery patients during perioperative care. The specific health focus was prevention of thromboembolism. The CDSS can be downloaded from (CLOTS App, 2022) and be used in a smartphone. Key design considerations were discussed in this paper. More details are available in (CLOTS Dashboard Demo, 2022), (CLOTS Demo, 2021), and (Ulapane, et. al., 2023).

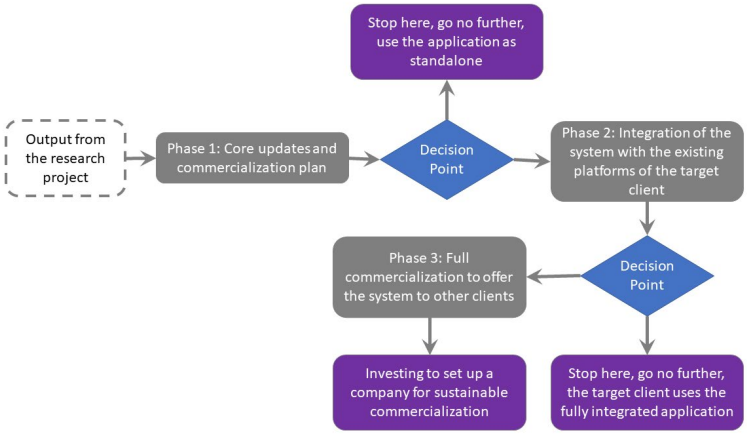

Figure 5: Pathways suggested by the commercial partner to commercialize the CDSS (the font in the figure is legible, please zoom to read)

Two major limitations or challenges were encountered during this study. The first was this being a project conducted during the COVID-19 pandemic. Thus, pandemic measures had to be strictly abided by in all the research activities. This also meant recruiting participants and finding available times being a challenge—the second limitation. This resulted in our participant groups being quite small.

Lessons learned and reflections can be summarized as follows. Making new developments interoperability with existing hospital systems can be challenging. Developing web-based applications instead of mobile applications has some advantages to alleviate the interoperability issue. Policy and regulatory barriers may exist to access health data especially on cyber security grounds.

7 Conclusions

This study reported a systematic design approach spanning from concept to commercialization. The design approach is governed by the Design Science Research Methodology and the theory of Task Technology Fit. The approach was followed to design a smartphone-based clinical decision support system (CDSS) for perioperative patient management. The CDSS was designed for a leading cancer hospital in Australia. The health focus is prevention of thromboembolism in surgery

patients by optimally managing surgery patients during perioperative care. Our design approach and experiences gained are generalizable. They can be resourceful for many health tech developments.

Acknowledgements

This paper is an outcome from the DHCRC-055 project funded by the Digital Health CRC Limited, the Peter MacCallum Cancer Centre, and the Swinburne University of Technology, Australia. Digital Health CRC Limited is funded under the Commonwealth Government's Cooperative Research Centres Program.

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