From Concept to Commercialization: A Double Co-Design Approach

Nalika Ulapane
Swinburne University of Technology, Australia
nalika.ulapane@gmail.com

Abdur Rahim Mohammad Forkan
Swinburne University of Technology, Australia
fforkan@swin.edu.au

Prem Prakash Jayaraman
Swinburne University of Technology, Australia
pjayaraman@swin.edu.au

Penelope Schofield
Swinburne University of Technology, Australia
pschofield@swin.edu.au

Kate Burbury
Peter MacCallum Cancer Center, Australia
kate.burbury@petermac.org

Nilmini Wickramasinghe
Swinburne University of Technology and La Trobe University, Australia
N.Wickramasinghe@latrobe.edu.au

Abstract

A Smartphone-based clinical decision support system (CDSS) has been developed to assist the management of perioperative patients in cancer care. The design process followed a systematic approach guided by design science research methodology (DSRM) and the theory of task technology fit. Our previous work discussed our progress up to the Assessment phase of the CDSS. In this paper, we report on the extension of our codesign work towards commercialization of the CDSS partnering with a commercialization partner. This partnership complemented as a second phase of codesign making our design process more rigorous. Hence an extension to design science research was identified—we name it a double codesign approach. This double codesign approach benefits in making artifacts more rigorous and fit for commercialization. In addition to reporting on our double codesign approach, we also present the different data elements we were able to capture through this CDSS. We discuss the possibilities and barriers we encountered and group the data elements into categories that can be generalized to all CDSSs.

Keywords: Clinical Decision Support Systems, Design Science Research Methodology, Perioperative, Surgery, Task Technology Fit, Smartphone.

1. Introduction

Making clinical decisions is a complicated process that requires cognitive effort. It involves the use of both implicit and explicit knowledge, including observation, information, knowledge, experience, caring, and incidental learning (Banning, 2008). Medical errors can occur due to deficiencies in clinical decision making (Makary & Daniel, 2016), leading to negative health outcomes and increased costs. Therefore, effective, and accurate clinical decision making is crucial for delivering high-quality healthcare.

Technology has been implemented in healthcare to aid clinical decision making, including the use of clinical decision support systems (CDSSs). These systems have evolved from paper-based to computer-based (Skyttberg, et. al., 2016), and more recently to mobile device-based systems (Chahal, et. al., 2020), (Lee, et. al., 2018), (Ulapane & Wickramasinghe, 2021), thanks to advancements in technology such as Industry 4.0 and Healthcare 4.0. Our study focuses on the design and development of a Smartphone-based CDSS for managing perioperative patients in cancer care. This paper reports the extension of our previous work in (Ulapane, et. al., 2023).

In our previous work (Ulapane, et. al., 2023), we discussed the systematic design approach we followed to design our CDSS to maximize its fit for purpose. The phases up to design and assessment were discussed. Our design approach was inspired by the design science research methodology (DSRM) (Hevner & Chatterjee, 2010). We also presented a qualitative analysis of the end-user feedback we received about the CDSS; that analysis was guided by the theory of task technology fit (Goodhue, 1995), (Goodhue & Thompson, 1995).

The CDSS was designed to help optimize perioperative patients in their pre and post-operative stages to reduce the incidence of thromboembolism events. The CDSS was designed to be Smartphone-based to be used by clinicians (i.e., doctors and nurses) at the point of care. As such, going by the Design Science Research Knowledge Contribution Matrix (Gregor & Hevner, 2013), we were designing a 'novel' technological solution, to a 'matured' clinical application. Therefore, our design process differed

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from 'routine design,' and our design process had to include a higher degree of research and learning. Our design thus demanded a multi-staged codesign approach. Up to now, we have followed two stages of codesign, and hence we name our approach a 'double codesign approach'.

In our present paper, we make a twofold contribution. Firstly, we report an extension to the classical design science research approach. As said before, we call our extension a 'double codesign approach'. This resulted through a partnership we made aiming commercialization of our CDSS. Through this contribution, we attempt to answer the following research question, RQ1: "How can Smartphone-based CDSSs be designed to be fit-for-commercialization?" Secondly, we identify and group the different data elements we were able to capture through our CDSS and go on to discuss the possibilities and barriers we encountered. The grouping of data elements we present can be generalized to all CDSSs. Through this second contribution, we attempt to answer the following research question, RQ2: "What aspects of clinical practice can be captured as data through a Smartphone-based CDSS that assists perioperative care?"

The rest of this paper is organized as follows: Section 2 gives an overview of relevant theoretical concepts. The methodology used is described in Section 3, and the results are summarized in Section 4. Sections 5 and 6 discuss the results and implications of this study and provide concluding remarks.

2. Synopsis of Relevant Theories

Our objective has been to design and develop a Smartphone-based CDSS in such a way that its fit-for-purpose is maximized. The theory of Task Technology Fit (TTF) by Goodhue & Thompson (1995) is a well-established method for assessing fit-for-purpose and was adopted in this study. According to the theory of TTF, IT systems are more likely to be usable, desirable, and impactful if their capabilities match the tasks users must perform (Goodhue, 1995), (Goodhue & Thompson, 1995). A questionnaire based on TTF was constructed and used to validate our artifact (i.e., the CDSS) through user feedback. This questionnaire is available in (TTF Questionnaire, 2022).

Additionally, our study involves designing an artifact (i.e., the CDSS) through codesign, so the Design Science Research Methodology (DSRM) (Hevner & Chatterjee, 2010) was also followed. The DSRM is a process for systematically creating an artifact to meet stakeholder needs and maximize desirability. The process includes six steps: problem identification and motivation, defining objectives for a solution, design and development, demonstration, evaluation, and communication. Research can be integrated at any of the first five steps to understand and solve issues to maximize the artifact's desirability. More details can be found in publications in (Hevner & Chatterjee, 2010), (Hevner & Wickramasinghe, 2018), and (Peffers, et. al., 2007).

3. Methodology

The methodology we present in this section answers our RQ1 mentioned in the Introduction. The design process we followed, inspired by the DSRM, is shown in Figure 1. Our methodology has two codesign phases. The process up to the Assessment phase (see Figure 1) is the first codesign phase. Since we aimed at commercialization, it was important to take our CDSS a step further and make it fit for commercialization. For this, we partnered with a commercialization partner and pursued a further Assessment phase (see Figure 1). These next steps that occurred through this partnership complement as a second codesign phase. Thus, we call our method a 'double codesign approach,' and it is an extension to the tradition design science approach. Our second codesign phase resulted in further validating the output from the first codesign phase and suggesting pathways for commercialization. The participants in the codesign process are listed in Table 1. These participants got together as members of a research project. The initiation of this project was discussed in (Ulapane, et. al., 2023). Various stages of the design process are described in the subsections that follow.

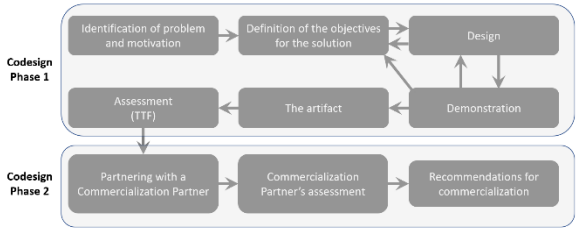

Figure 1. The design process that was followed (the font is legible, please zoom to read).

Table 1. Details of the participants in codesign.

Participant'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

3.1. Identification of Problem and Motivation

This step was carried out between January and June 2020. Participants C1, A1, A2 and A3 participated in drafting and reviewing a proposal for the project. The primary goal was to design and develop a Smartphone-based CDSS to help clinicians of a leading cancer hospital in Australia (i.e., the client hospital that partnered with this work), to optimize perioperative patients by managing their pre and post-operative procedures such that the incidence of thromboembolism surrounding surgery is minimized. A secondary goal was to commercialize the CDSS and make it the gold standard for all surgical procedures. The outcome of this phase was a project proposal document.

3.2. Definition of the Objectives for a Solution

Between May and October 2020, specific objectives were identified through monthly 1-hour semi-structured virtual meetings. Regular participants C1, A1, A2, A3, R1, and R2 attended all meetings while C2 and C3 were occasionally invited for their clinical expertise. Detailed minutes were documented and shared among participants after the meetings for consensus. During this phase, the clinicians C1, C2, and C3 also shared relevant clinical rules to be implemented in the CDSS. The objectives and deliverables for the design phase were defined by consensus as follows:

1) A smartphone based CDSS.

2) A database to capture CDSS usage data, including data entered and recommendations displayed.

3) A web-based dashboard for data display and analytics, intended as a prototype for further development, with specific analytics requirements not yet defined, and

4) Updates to certain clinical rules regarding anticoagulant drug management.

3.3. Design and Demonstration

The Design and Demonstration phases took place simultaneously from October 2020 to October 2021, led by participants R1 and R2. R2 translated clinical rules into editable flowcharts (decision trees), as can be seen in (CLOTS Dashboard Demo, 2022) and (Ulapane, et. al., 2023), to make them accessible to both clinicians and computer scientists. This translation facilitated communication between clinicians and the rest of the team and helped in programming the clinical rules into a software application. We recommend translating clinical rules into widely accessible data structures as an important intermediate step to help with software implementation. The flowcharts were shared with clinicians C1, C2, and C3 so that they can input the desired updates to the clinical rules.

After receiving the updated clinical rules, software development activities began under the leadership of participant R1. A Smartphone application was built to have the facility of recording the app usage in a backend database. This database was then linked to a designed web-based front-end to enable data display and analytics. The combination of the mobile application with data capture and the web-based front-end is the artifact produced by this study. Snapshots of the artifact are available in the Results section. The layouts for both the Smartphone app and the web-based frontend were kept simple, with non-cluttered interfaces, push buttons, and colors from the partnering client hospital's logo as key design considerations to enhance user-friendliness through decluttering. Aesthetics were not prioritized.

Demonstration of the developments took place through monthly 1-hour virtual meetings conducted as semi-structured co-design workshops. Incremental progress was shown, and clinician participants provided feedback and expressed any desired features. As shown in Figure 1, participants had the opportunity to reconsider the original objectives and propose changes, but none did. Detailed minutes were recorded and shared among participants for consensus after each meeting. The artifact and source code were the outcomes of this phase.

3.4. The Artifact

The artifact produced by this study is the combination of the Smartphone App (available in Android and iOS) with data capture and the web-based front-end. More details can be found in the Results

section. According to the classification by March & Smith (1995), our artifact is an 'instantiation' of complex form that combines 'constructs,' 'models,' and 'methods'. The Smartphone App was designed to be used by clinicians (i.e., doctors and nurses) in the hospital who would manage patients in their perioperative phase. More information about the app is available in (CLOTS App Overview, 2022) and (CLOTS Demo, 2021). The data entered to this Smartphone-based CDSS is recorded in a backend database, and the web-based interface was designed to enable the display and post analytics of that data recorded in the database.

3.5. Assessment

Between November 2021 and February 2022, the designed application was made available online for download and testing by participants C1, C2, and C3. R2 created a questionnaire based on the Technology Task Fit (TTF) model for users to provide feedback. The questionnaire is available in (TTF Questionnaire, 2022) for interested readers. Participant C1 recruited 7 clinicians, including C1 and C3, to test the app and attend a virtual focus group where they were presented with the TTF questionnaire, and were given the opportunity to provide qualitative and quantitative feedback. These participants included doctors (anesthetists, hematologists, junior clinicians) and nurses. The feedback was recorded as meeting minutes and compiled into a report summarizing the main themes of TTF:

1) Characteristics of the clinician's task involving technology usage.

2) Characteristics of the technology (i.e., the CDSS), and

3) The impact of the CDSS on clinician performance.

Several subthemes emerging from the qualitative feedback were also highlighted in the report; these themes and feedback are summarized in the Results section. The report was shared with focus group participants for consensus and served as the outcome of this phase. This phase marked the end of codesign phase 1.

3.6. Partnering with a Commercialization Partner

This phase marked the beginning of codesign phase 2. Between March and August 2022, various software product development companies were considered as potential commercialization partners based on their track record, experience, and any preferences of the partnering client cancer hospital. The commercialization partner was expected to help drive the prototypical artifact produced by us to a standardized product that can be commercialized in Australia. A candidate company was chosen, and several meetings were held to establish a relationship and discuss interests. The partner provided different commercialization plans with quoted costs and the research participants chose the plan that fit their budget constraints, while proposing affordable amendments. Contracts and nondisclosure agreements pertaining to intellectual property were signed and the developed artifact, source code, and assessment report were submitted to the partner for review.

3.7. Commercialization Partner's Assessment

Between September and November 2022, the commercialization partner conducted two activities:

1) Assessing the source code against the commercialization partner's IP-protected criteria based on industry best practices for quality, cybersecurity, and interoperability with hospital infrastructure, and
2) Replicating the assessment phase (i.e., the phase described in subsection 3.5) with end users according to the commercial partner's IP-protected assessment criteria.

The partner submitted a report to the research team summarizing their findings on code quality and user perceptions, providing recommendations and suggested commercialization pathways with tentative budget estimates. Follow-up meetings were held to clarify any unclear points and reach consensus. The partner's report following consensus was the outcome of this phase, consistent with DSRM approaches of obtaining consensus among the stakeholders/users.

3.8. Recommendations for Commercialization

We are currently considering the commercial partner's recommendations and seeking funding to pursue them. The commercialization pathways suggested by the partner are shown in the Results section.

4. Results

4.1. The CDSS Smartphone Application

A video demonstration of the CDSS smartphone application is provided in (CLOTS Demo, 2021). A documented description of the app's functionality is available in (CLOTS Dashboard Demo, 2022). The application is based on flowchart-based decision flows

(decision trees). Some examples to these decision flows are provided in (CLOTS Dashboard Demo, 2022) and (Ulapane, et. al., 2023). The application has four models to support with the following four activities surrounding surgery:

1) Calculating the risk of surgery related thromboembolism for a patient.

2) Managing antithrombotic drugs, pre and post-surgery.

3) Warfarin reversal, and

4) Hematinic optimization.

Some snapshots of the Smartphone application are provided in Figure 2. More details about functionality are provided in (CLOTS Dashboard Demo, 2022). The data entered in this application are recorded in a backend database for post analytics. The data flow from the application towards the database and from the database towards the application is discussed further in the Discussion section as part of answering the second research question (RQ2) of this paper.

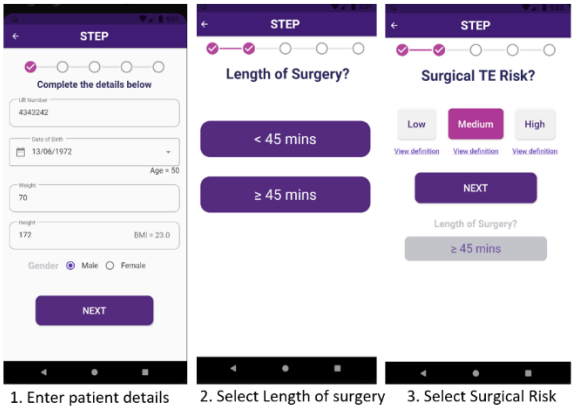

Figure 2. Some screenshots of the CDSS application (the font in the figure is small, zooming might help reading, please also refer to (CLOTS Dashboard Demo, 2022) for more details).

4.2. End User Feedback from Clinicians

The end user feedback obtained from the focus group discussed in subsection 3.5 using the questionnaire constructed for the work based on the theory of TTF can be summarized as follows.

Clinician's Task Characteristics:

- Frequency of use varies among users (almost never to several times a week).
- Senior and Junior clinicians tend to use the system differently.
- Purpose of use differs as well: helps to refresh memory, as well as an educational tool.

Clinicians' Satisfaction on Technology Characteristics:

- Consensus (100% of participants) for users being satisfied.
- Some concern (~10% of participants) about Data accuracy and Data currency (i.e., how up to date and accurate the data is).
- Junior clinicians would like more references to be cited within the app.

Impact on Clinicians' Performance:

- Consensus (100% of participants) on the CDSS having a significant impact (i.e., on patient outcomes, ease of task, accuracy of task, and saving time).

The questionnaire is available at (TTF Questionnaire, 2022) for interested readers. The feedback is summarized above under the three main TTF themes listed in subsection 3.5. These results were discussed in more detail in (Ulapane, et. al., 2023) and hence not elaborated further in the present paper.

4.3. The Data Analytics Dashboard

Provided in Figure 3 is a snapshot of one aspect of the web-based data analytics dashboard. This dashboard is linked with the database which records the data entered in the Smartphone application. Hence the display and analytics of the data entered through the Smartphone application is enabled through this web-based dashboard. The data flow from the database towards the dashboard and from the dashboard towards the database is discussed further in the Discussion section as part of answering the second research question (RQ2) of this paper.

Figure 3. A screenshot of one aspect of the web interface for data display and analytics (the font in the figure is small, zooming might help reading, please also refer to (CLOTS Dashboard Demo, 2022) for more details).

4.4. Suggested Pathways to Commercialize

In our perspective, successful commercialization is the ultimate validation of fit-for-purpose of any solution including digital health interventions. Shown in Figure 4 is a flowchart depicting the pathways suggested for our CDSS by the commercialization partner. What is suggested is a three-phased pathway with decision points at the end of Phase 1 and Phase 2, to decide whether to proceed further in the commercialization pipeline.

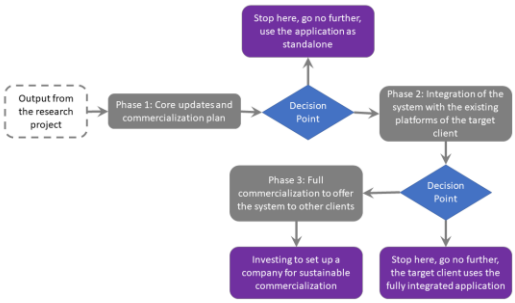

Figure 4. Pathways suggested to commercialize the CDSS (the font in the figure is small, please zoom to read).

5. Implications of Results and Discussion

Our first research question, RQ1, was answered in Section 3. In our attempt to answer the second research question, RQ2: "What aspects of clinical practice can be captured as data through a Smartphone-based CDSS that assists perioperative care?", this discussion is structured as follows. First, we present the data flow architecture between the Smartphone app and the database that collects the data entered to the app. Secondly, we would present the data flow architecture between the database and the Web-based dashboard. Following this introductory discussion, we then go on to discuss the data elements we were able to capture. Finally, we discuss a few options that we explored for analytics and sense-making through the data.

5.1. Data Flow between the Smartphone App and the Database

In more general terms, our CDSS has the components such as the user interface, knowledgebase, models, and so on (Reuter-Oppermann, et. al., 2022). The data flow of our CDSS is depicted in Figure 5, and it was designed to occur across the following five steps (labelled in Figure 5) that happen in sequence:

1) The clinician enters the necessary data to the Smartphone App.
2) The data is transferred to a dedicated backend server.
3) The relevant decision support recommendations are sorted algorithmically.
4) The relevant recommendations are transferred to the clinician's Smartphone.
5) The relevant recommendations are displayed to the clinician of the Smartphone screen.

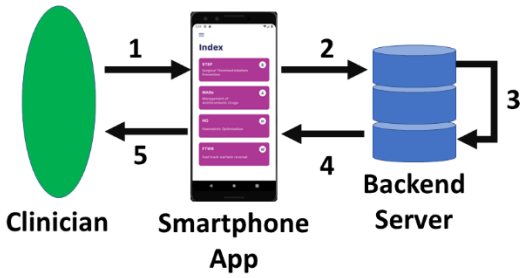

Figure 5. The data flow between the Smartphone App and the Database.

5.2. Data Flow between the Web Interface and the Database

The data flow is depicted in Figure 6, and it was designed to occur across the following five steps (labelled in Figure 6) that happen in sequence:

1) The analyst enters a query (or a request) to the Web-based interface.
2) The query is transferred to a dedicated backend server.
3) The data relevant to the query are sorted algorithmically.
4) The relevant data are transferred to the Web-based interface.
5) The relevant data are displayed on screen to the analyst.

Figure 6. The data flow between the Web Interface and the Database.

5.3. Data Elements that can be Captured through a Smartphone-based CDSS

For more general appeal we discuss in this subsection about the data elements that 'can' be captured through a system such as ours as an addition to discussing only what we 'did' capture. We

identified three main categories of data captured by our system, and our categorization can be generalized for most, or perhaps all CDSSs that could collect data. We deduced the categories as follows.

First, we looked at the main stakeholders who would be using a CDSS like our one. As it could be seen from the previous sections, the main stakeholders who would be using this CDSS are the clinicians (i.e., doctors and nurses) working in cancer care. As such, we labelled our first category of data as "Data about clinicians".

Secondly, we looked at the different types of data the clinicians would be handling with our CDSS. The clinicians would be entering certain details about the patients they care for to obtain decision support recommendations. Through brainstormed logical deduction, we broke down this data to fall within the following two categories:

1) Data about the patients (more details about this category are provided later with examples), and

2) Data about the procedure or clinical workflow relevant for a patient in question (more details provided later).

As such, we identified three main categories of data used with our CDSS, and we argue that our categorization of data is logical in some sense, and generalizable to most, or perhaps all CDSS. We discuss more about the categories of data we identified in the following subsections.

5.3.1. Data about clinicians: In the co-design discussions held as described in subsection 3.3., several points were identified as possible data elements to be collected about clinicians. These included unique identifiers of clinicians (e.g., an employee identification number), unique identifier for the device (e.g., a Smartphone) a clinician uses, clinician's email address and/or phone number, and the clinician's specialty (e.g., whether they are a doctor or a nurse, and their clinical specialty), and tracking each clinician's CDSS usage activity (e.g., login times, decision pathways pursued by each clinician, and recommendations viewed by each clinician).

Then, debate among the codesign participants followed across several meetings do decipher how and what to collect. Through the debates it was realized that tracking and collecting data about clinicians would require at least a clinician login. This meant a clinician being asked to enter a username and a password at least to login to use the CDSS.

While implementing such a login function and tracking and collecting all such data as mentioned above is entirely possible, further discussions revealed whether tracking clinicians to that extent is necessary for a CDSS like ours. While we realized that there may be some other systems that would benefit from such clinician tracking functionality, for our CDSS, we realized that this would be excessive. Our debates also revealed that having a clinician login upfront would in fact come as an additional step for clinicians and might slow down clinician's access to the CDSS. The codesign participants thus came to consensus that having a login system upfront for a Smartphone-based CDSS would be unattractive to clinicians, and thus it was decided to not implement that in our design, and as such, in our implementation we decided to not collect any data about the clinicians and grant them open access to the CDSS with minimum obstacles to use.

Our decision in no way suggests that a clinician login and ensuing clinician tracking is not possible or something that should not be done. While implementing a login and tracking clinician activity is entirely possible, we realized that this functionality is not a necessity for our CDSS. Yet, we report on that point as we went through that deliberation, and keep that point open for others to consider and make use of if they realize they would benefit from clinician tracking.

5.3.2. Data about patients: Data about patients was entirely different to our experiences of tracking clinician data. Several data elements about a patient were necessary for certain decision pathways. For our system, these data elements were comprised of patient demographic data, such as the date of birth (this enables calculation of age), patient height and weight (these enable the calculation of the BMI), and patient's sex. Furthermore, for some decision pathways, data about the patient's medications (e.g., any anticoagulant drugs a patient might be using) are required for our system. Also, for some pathways some specific test results about a patient are also required, for example a blood hemoglobin level or serum creatinine. As such, we identified three subcategories within the cohort of data about patients. We labelled them as follows:

1) Demographic data.
2) Medications.
3) Test results.

We agree that there could be other ways of classifying patient data, and we also agree that there can be more or different subcategories depending on any specific medical conditions or clinical scenarios for which a CDSS might be designed for. But for our system, these subcategories were sufficient, and we argue that our categorization is generalizable for many CDSS.

In terms of implementation, we enabled the collection of all such patient data, and in addition, we enabled the collection of a unique patient identifier number (known as the UR Number) as well to enable tracking of individual patient details. The CDSS App interface for collecting a patient's demographic data inclusive of a unique identifier number is provided in Figure 7 as an example to how we collected the data through the App.

Regarding the patient data collection, we also deliberated whether to enable a connection between the CDSS and the electronic medical record (EMR) of the hospital. Such a connection with the EMR would enable some data retrieval about patients from the EMR and writing some data to the EMR if need be. This functionality was again debated in our codesign workshops. Our debates revealed that enabling such a connection with an EMR is again entirely possible, however, that was too risky in terms of data integrity and data usage since our CDSS is available on a smartphone, and the connection of Smartphones to a hospital EMR can have several security loopholes that might enable theft of manipulation of data in an EMR. As such, we decided against EMR connection, and we did not implement that functionality for our system. However, we remind that the possibility exists to connect a Smartphone CDSS with a hospital EMR in case it is seen as valuable, but we also emphasize considering the risks associated with that. In our case, we decided against that connection.

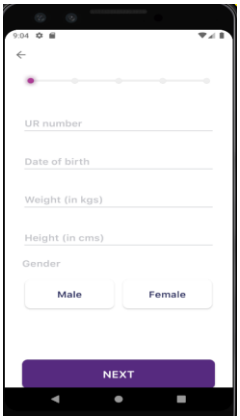

Figure 7. CDSS App interface to enter demographic data of a patient (font in the image is legible, please zoom to read).

5.3.3. Data about the procedure/clinical workflow: The third aspect we considered were the different decision pathways a clinician might have pursued through this CDSS, along with the recommendations they might have viewed. Since we collect a patient identifier (i.e., a UR number, see Figure 7), we resorted to recording these decision pathways under the patient UR numbers. This meant, for each patient, the different decision pathways a clinician might have explored will be recorded in our backend database under the UR number of a patient. An example decision pathway available in our CDSS is depicted in Figure 2; there are hundreds of such decision pathways in our systems depending on the different options the clinician chooses respective to each patient. If we implemented a clinician login and a clinician tracking, we could have recorded the decision pathways explored by each clinician also. We mention that as a possibility for completeness, however as we did not implement a clinical tracking functionality, we did not record the decision pathways under each clinician. Instead, we recorded the decision pathways under the unique identifiers of patients. As such we concede that there are two options to choose from when it comes to recording the decision pathways or the clinical workflows included in a CDSS like ours. They are, to record the decision pathways under clinician identifiers, or to record the pathways under patient identifiers. As a third option, we can also report that collecting the decision pathways under total anonymity, that means, collecting them without linking to a patient or a clinician is also possible if someone sees that option as sufficient.

5.4. How can the data be made sense of?

We identified three ways to make sense of the recorded data. They were:

1) Tabular visualization of the data (an example is shown in Figure 8).
2) Visualizing profiles of individual patients (an example is shown in Figure 9).
3) Cohort analytics making use of aggregate data (an example is shown in Figure 10).

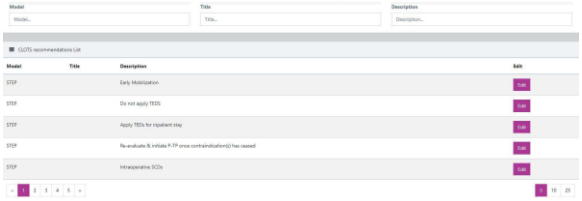

Figure 8. Tabular visualization of data (the font in the figure is small, zooming might help reading, please also refer to (CLOTS Dashboard Demo, 2022) for more details).

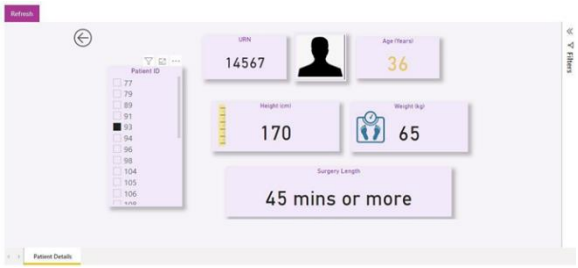

Figure 9. Individual patient profile (the font in the figure is small, zooming might help reading, please also refer to (CLOTS Dashboard Demo, 2022) for more details).

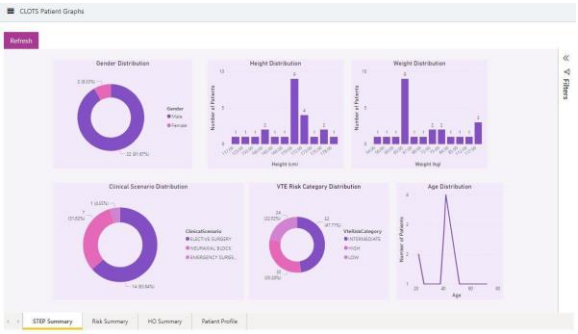

Figure 10. Cohort analytics (the font in the figure is small, zooming might help reading, please also refer to (CLOTS Dashboard Demo, 2022) for more details).

The analytics and visualization options we implemented in our system are indicative only and are certainly not the 'only' options viable. There can be many more analytics and visualization options desirable subject to the domain of application. Our indicative results are suggestive that much more is implementable if desired, and even machine learning can be coupled with such systems to help with a degree of automated and/or semi-supervised and/or augmented sense-making (Wickramasinghe, et. al., 2021).

However, when collecting data through a CDSS with no link to an EMR as for this system, it should be noted that there is no guarantee that the patient data the clinicians might have entered to the CDSS is accurate. There is the chance of clinicians entering data that is not related to real patients to explore the CDSS, sometimes for educational and exploratory purposes. Through our end-user assessment focus groups, we discovered that some clinicians in fact use the CDSS for educational purposes with non-real data. As such it must the remembered that data captured through Smartphone CDSS like ours are not always interpretable as 'actual evidence.' The data collected through such a CDSS must be interpreted as indicative only, and through post analysis of course any correlations and/or trends with the data patient data recorded in EMRs can be identified. Analyzing the synergy or a fusion of multiple modalities of data collected pertaining to a healthcare facility, for example, one modality being an EMR and another modality being a CDSS, has the potential to reveal unique trends or correlations between the practices of clinicians and other indicators such as patient outcomes, and such synergetic analysis will be a domain open for exploration as future work.

5.5. What were the limitations of this study?

This study encountered two major limitations or challenges. The first was conducting the project during the COVID-19 pandemic, which required strict adherence to pandemic measures in all research activities. As a result, the second issue ensued as the difficulty in recruiting participants and finding available times, resulting in small participant groups.

The lessons learned and reflections from this project can be summarized as follows: Ensuring interoperability between new developments and existing hospital systems can be challenging. Developing web-based applications instead of mobile applications may help alleviate this issue. However, policy and regulatory barriers may exist when accessing health data, particularly on cyber security grounds.

Some other limitations include the following: the study focuses only on Australia; biases of participants due to small population sizes, and the lack of reference groups for comparison.

7. Conclusions

This paper made two major contributions: A contribution to theory; and a contribution to practice.

For theory, the paper proposed an extension to DSRM. This consists of two codesign cycles. We called it the 'double codesign approach.' This enables ensuring better artifact fit for commercialization. Moreover, our method combined the theory of Task Technology Fit (TTF) and DSRM to construct a systematic approach to design and develop digital health solutions. Our proposed approach showed how TTF can provide a structured and rigorous approach to inform the DSRM cycles, ensuring solutions that are rigorous, useful, and fit for purpose. Our combined approach of TTF and DSRM is robust and has broad appeal and is extended towards commercialization as well. Our approach can be used to guide the design of information systems in any domain. Moreover, we elaborated on the data collection we were able to do with our Smartphone-based CDSS. This data collection exercise was quite a unique and insightful

experience by itself. The possibilities and barriers that were encountered were discussed along with the opportunities for sense-making using such data.

For practice: we have developed and continued to improve a Smartphone-based CDSS to help clinicians reduce thromboembolism in oncology surgery patients. The CDSS provides high-quality, timely decision support in line with a value-based care approach. The impact of this contribution on clinical outcomes and its support for value-based healthcare cannot be overstated. We also presented some of the domain-specific perspectives obtained through end-user clinicians who assessed the CDSS. Detailed discussion about these end-user perspectives were published before in (Ulapane, et. al., 2023).

Our future work will continue to pursue the commercialization of this CDSS, since for ultimate impact, any digital health solution needs to be commercialized to reach patients and clinicians for superior healthcare delivery to ensue.

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