Patient-centered perioperative care through mobile application: patient engagement prospective cohort study in elective Cesarean delivery patients

Brief title: Patient-Centred Perioperative Mobile Application

Study Protocol

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Site of Investigation:

IWK Health Centre, Halifax, Nova Scotia, Canada

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1. Research Problem

With increasingly more complex surgical patients and the trend toward decreased hospital stay after operations, continuity of care and prompt management of symptoms and side effects perioperatively are ever more crucial. Our goal is to improve perioperative care with a patient-centred mobile application, starting with a pilot in patients undergoing elective Cesarean delivery. We have completed a research study where we created a prototype based on feedback from patients and anesthesiologists. In this study, we would like to learn about how patients use our mobile application after delivery and how the mobile application can be integrated into daily practice.

2. Background Including Relevant Literature

Perioperative care has been changing in terms of patient population, number of surgeries, and practice setting. With the aging population brings ever more complex surgical patients and increased need for surgeries. According to the Canadian Institute for Health Information (CIHI), comparing 2005-2006 with 1995-1996, the total number of surgeries in Canada rose by 17.3% (1). With increasingly more complex surgical patients and the trend toward decreased hospital stay after operations, continuity of care and prompt management of symptoms and side effects perioperatively are ever more crucial. These changes have necessitated multidisciplinary collaboration and programs such as Enhanced Recovery after Surgery (ERAS) to facilitate comprehensive perioperative care in the outpatient setting. CIHI reports that giving birth is the most common reason for hospital admission, and that CD is the most commonly performed inpatient surgery (2). The average length of stay is 3.3 days (2), which means that most of the recovery process will be at home, giving an opportunity for mobile application to bridge recovery care in the outpatient setting. The Canadian rate of Emergency Room visits within seven days following CD is 8.7% (3), and it may improve outcomes to identify patients with complications earlier before they become serious.

Mobile communication provides an immense opportunity for health care providers to connect with patients in the perioperative setting, presenting an accessible, versatile platform for care and research. Smartphone ownership is prevalent: the Canadian Wireless Telecommunications Association data shows the mobile subscribership to be more than 24 million (4). Despite the wide breadth of subscribers there have been few mobile applications directed at perioperative medicine.

Our aim has been to design a mobile application for perioperative care. While our goal is to eventually build a multidisciplinary perioperative platform that can be easily customized to any surgery at any institution, we have chosen to focus on the obstetric anesthesiology perioperative of cesarean delivery patients due to the technology-savvy nature of this age group and the prevalence of the surgery. We have focused on obstetric anesthesiology as the healthcare provider in this study since there is little existing mechanism for routine surveillance of potential anesthesiology-related complications, such as permanent nerve injury from neuraxial techniques.

Funded by the Dalhousie Department of Anesthesiology, Perioperative Medicine, and Pain Management, we have completed a pilot study "Designing a perioperative mobile application: pilot in anesthesiology postoperative care of cesarean delivery patients". This qualitative, iterative design study involved three cycles of individual structured interviews with patients (total 15) and anesthesiologists (total 9). The interview explored participant perspectives about the role of mobile technology in perioperative care. Participants also interacted with the prototypes and gave feedback. Our previous study was the first completed to explore the use of mobile applications for cesarean

delivery patients. Interviews revealed that mobile technology can play a key role in bridging the gap in the perioperative care of cesarean patients, especially in providing reliable sources of information, identifying and following patients with complications, and research in perioperative outcomes. Our final prototype focused on timely, concise information and self-monitoring. This study has been presented as a poster at the 2017 Canadian Anesthesiologists' Society Conference and is currently at the stage of manuscript preparation.

The objective of this prospective cohort study is to build the mobile application (C-Care) and evaluate its feasibility in providing patient education and reminders for self-monitoring for cesarean delivery patients. We will measure the extent of patient engagement with our application through in-app usage data, as well as receive quantitative and qualitative feedback regarding feasibility. By understanding user behavior and needs through questionnaires and application usage data, we could design more effective and tailored interventions for patients. Results of this study will help further development and implementation of an interdisciplinary mobile monitoring and communication platform for perioperative care.

3. Study Objectives

The primary objective is to measure patient engagement and obtain qualitative feedback on patient experience with the application (please see Methodology for outcomes).

4. Hypothesis to be Tested

No specific hypothesis will be tested.

5. Study Design

Thirty-six patients will be recruited on the day of delivery. After consent, they will receive hands-on guidance to download the application from the mobile Application Stores and an overview of the application. The application contains topics relevant to Cesarean delivery and the recovery process, which the patient could access at anytime. Patient engagement with the application will be monitored (please see Methodology for details) anonymously for 30 days after delivery. On days one to five after delivery, patients will receive a short self-monitoring questionnaire (approximately 1 minute). At the end of two weeks (14 days after surgery), patients will complete an online survey regarding overall satisfaction, potential impact on care, usability and feasibility problems. At any point during the study, patients can email us to report any problems with the application.

6. Sample

6.1 Inclusion and Exclusion Criteria

Inclusion criteria:

Part 1 (screened by asking nurse)

Patient scheduled for elective CD

Age equal or greater than 18

American Society of Anesthesiologists (ASA) Physical Status I-III (i.e. not in life-threatening situation)

Part 2 (screened in person)

Possesses an iOS Smartphone with active data plan and access to WiFi and self-reported use of it on a regular basis (at this stage in development, the mobile application prototype is only available on iOS)

Self-reported proficiency with Smartphone and mobile applications

Reported fluency in English

Exclusion criteria:

- Self-reported physical or psychiatric condition that may impair the ability to use the mobile application, answer questionnaires and surveys, and/or provide insights representative of the general population, such as blindness, under current influence of recreational drugs or alcohol.

6.2 Sample Size and Justification

While there is no specific guidance on the sample size of an iterative feasibility trial, a recent review showed that the median size of feasibility trials is 36 (5). We chose a sample size of 36 since it would provide us with a representative sample of feedback while being feasible (there is on average 10 elective CD per week as a conservative estimate).

6.3 Withdrawals

The participant can withdraw from the study at any time.

7. Methodology
7.1 Overview

Through a patient-driven design process, we have previously created a mobile application prototype for patient education and self-monitoring around the time of cesarean delivery. We have now been building this application to be freely available in the iPhone iOS Application Stores via Optio Publishing. A prototype can be accessed here [hyperlinked]. The developed application will be improved visually and more patient-friendly graphics and language, but will not have major changes in content.

In this prospective cohort study, thirty-six patients will be recruited before their scheduled Cesarean delivery. After consent, a paper demographics questionnaire will be recorded, and patients will receive hands-on guidance to download the application from the mobile Application Stores and an overview of the application. The application contains optional topics relevant to Cesarean delivery and the recovery process, which the patient could access at any time. Each topic takes less than 2 minutes to read through.

Patient engagement with the application will be monitored. This includes the number of topics viewed, time of visit, and number of self-monitoring questionnaires completed. All this data is recorded anonymously within the application for 30 days after delivery.

On the first day after the surgery, patients will receive an email welcoming them to the study with brief instructions about the questionnaires and surveys. On days one to five after delivery, patients will receive a short self-monitoring questionnaire (approximately 1 minute, through the app) to ask about important symptoms. Seven days after the surgery, patients will receive an email thanking them and reminding them of the upcoming survey. At the end of two weeks (14 days after surgery), patients will complete an online survey (open for one week) regarding overall satisfaction, potential impact on care, usability and feasibility problems. After four days, a reminder check in phone call will be performed. Standardized scripts for email and phone contact are found in Appendix 6. At any point during the study, patients can email us to report any problems with the application.

Interim analysis will be performed after the completion of 18 patients. This will consist of ensuring that 50% or more of the patients have logged into the application more than once (the first log in will be orientation by the coordinator). If less than 50% patients logged in more than once, we will pause the study for prototype improvement.

This study will be registered at clinicaltrials.gov.

7.2 Outcomes

Primary outcomes:

From mobile application engagement metrics (within 30 days after delivery)

1. Median number of information topics viewed per participant
2. Median number and percentage of self-monitoring questionnaires completed (out of 5) per participant

3. Median number of total visits to the mobile application per participant

From Survey (Appendix 4, fillable at two-three weeks)

1. Satisfaction score (scale of 0 to 10, 10 being extremely satisfied, 0 being not satisfied)
2. % participants who would recommend the C-Care App to other women undergoing Cesarean delivery.

Secondary outcomes:

From mobile application engagement metrics (30-day)

4. Which topics were viewed the most (rank by topic name and by postoperative day)
5. Which self-monitoring questionnaires were filled the most (rank by postoperative day number)
6. Incidence of important potential anesthetic-related problems entered by the patient (pain, headache, weakness and numbness)
7. Time of the day patient visited site (scatter plot of Nova Scotia time vs. # visits) – one visit = at least one interaction within app, e.g. opening a topic, navigating within app
8. Time (Nova Scotia) of the day patient filled out the questionnaire
9. Number of visits vs. postoperative day
10. Median duration (number of days starting from delivery date until the last day of visit) patient interacted with application within 30 days.

From survey (Appendix 4)

1. % participant who responded "yes" to the question that C-Care App provided them with knowledge about

    a. Cesarean delivery and anesthesia

    b. potential complications to monitor for

    c. the recovery process after Cesarean delivery

2. Anything the patient wanted to change about this application, such as in terms of content, navigation, appearance, and overall experience? (open comment box)
3. If the patient did not use the mobile application, what were the reasons? (open comment box)
4. How could we make the mobile application more helpful for the patient? (open comment box)
5. What do patients think about the name of this App, "C-Care"? Do they have any other suggestions for our name/logo?
6. Any other comments and/or suggestions (open comment box)

Survey design viewable at https://survey.nshealth.ca/TakeSurvey.aspx?SurveyID=724L5mm2

Other qualitative feedback

Patients can email the research team with any feedback, feasibility/usability problems, and suggestions at any time during the study period.

7.3 Eligibility screening and Recruitment

Relevant members of the health care team, including obstetric anesthesiologists, obstetricians, nurses, and resident physicians at the IWK Health Centre will receive information about the study and the patient recruitment process through emails and posters in the work area.

Due to institutional logistical limitations, patients will be recruited day of scheduled delivery, before their surgery. Efforts will be made to contact the patient as early as possible prior to their surgery. A member of the patient's health care team (circle of care) will ask the patient verbally for permission of the research coordinators to discuss with her potential participation in the study. The research coordinator will then screen for whether the patient meets the Part 1 of the eligibility criteria (please see 6.1). The research coordinator will then approach the patient in person to introduce her to the study, as well as complete Part 2 of the eligibility screening. If the patient is eligible, the research coordinator will give the patient full information about the study and answer any questions before obtaining informed, written consent. The research coordinator will use an infographic to help illustrate what the study involves (Appendix 7). If research coordinators are not available, Principal Investigator, Sub-investigator, and/or Supervising Investigator will talk to the patients and obtain informed consent.

All research related discussions, including time to consider research participation, verbal explanation of the consent, time to read the consent and answering any questions that the subject may have about research, all occur before subjects are given any pre-medication. We note that consent for the surgical procedure itself can be obtained by the surgical staff the morning of the operative procedure. The Canadian Anesthesiologists' Society believes that pre-operative consent for clinical research in anesthesia may be obtained after admission to hospital on the day of the scheduled surgery provided that; 1) subjects are not under the influence of pre- medication, 2) risk to the subject and time commitment to the study are not significantly different from routine clinical care, 3) after verbal explanation from the investigator and in the absence of the investigator, subjects are given time to read the information sheet and consider the risks and benefits. Subjects should have an opportunity to raise any further questions or seek clarification on any points concerning the nature of the study, alternatives, risks, benefits, etc, and 4) subjects who feel they are under duress, or require more time to make a decision, should be advised to decline participation in the study (Guidelines on the Ethics of Clinical Research in Anesthesia, www.cas.ca).

If the patient agrees to participate, the research coordinator will proceed to explain more about the study and obtain consent. Patients who have marked functional limitations, or a self-reported physical or psychiatric condition that may impair the ability to participate in the interview process

will be excluded. All participants will be checked that they are able to understand the information about the study presented to them and appreciate their roles, benefits, and risks of participating in this study.

7.4 Honorarium

Participants will receive no reimbursement. There is no cost to participate in the study.

7.5 Duration

Patient engagement data within the application will be collected for 30 days.

8. Data Analysis

Descriptive statistics will be performed. Continuous data will be presented as mean/median and standard deviation as appropriate. Thematic analysis will be performed on the qualitative data.

Interim analysis will be performed after the completion of 18 patients. This will consist of ensuring that 50% or more of the patients have logged into the application more than once (the first log in will be orientation by the coordinator). If less than 50% patients logged in more than once, we will pause the study for prototype improvement.

8.1 Demographics

Patient characteristics to be collected and analyzed include age, gravidity, parity, education level, income, marriage status.

8.2 Quantitative outcomes

From mobile application engagement metrics (30-day)

1. Median number of information topics viewed per participant
2. Median number and percentage of self-monitoring questionnaires completed (out of 5) per participant
3. Median number of total visits to the mobile application per participant
4. Which topics were viewed the most (rank by topic name and by postoperative day)
5. Which self-monitoring questionnaires were filled the most (rank by postoperative day number)
6. Incidence of important potential anesthetic-related problems entered by the patient (pain, headache, weakness and numbness)
7. Time of the day patient visited site (scatter plot of Nova Scotia time vs. # visits) – one visit = at least one interaction within app, e.g. opening a topic, navigating within app
8. Time of the day patient filled out the questionnaire
9. Number of visits vs. postoperative day

10. Median duration (number of days starting from delivery date until the last day of visit) patient interacted with application within one month.

From survey

1. Satisfaction score (scale of 0 to 10, 10 being extremely satisfied, 0 being not satisfied)
2. % participants who would recommend the C-Care App to other women undergoing Cesarean delivery.

3. % participant who responded that the C-Care App provided them with knowledge about

    a. Cesarean delivery and anesthesia?

    b. potential complications to monitor for?

    c. the recovery process after Cesarean delivery

8.3 Qualitative outcomes

From Survey

1. Was there anything you would like to change about this application, such as in terms of content, navigation, appearance, and overall experience? (open comment box)
2. If you did not use the mobile application, what were the reasons? (open comment box)
3. How could we make the mobile application more helpful for you? (open comment box)
4. What do you think about the name of this App, "C-Care"? Do you have any other suggestions for our name/logo?
5. Please note here any other comments and/or suggestions. Thank you for your time! (open comment box)

Qualitative feedback

Patients can email the research team with any feedback, feasibility/usability problems, and suggestions at any time during the study period.

Qualitative analysis will focus on comments on overall usability and identifying key issues and suggestions. Thematic analysis on global feedback, appearance, navigation, and content will be performed.

9. Management of Personal Health Information and Study Data

9.1 Collection of Personal Health Information

Personal health information (PHI) of patients are reviewed during the recruitment process in order to identify potential participants and ensure that they fit Part One of the Inclusion Criteria, which includes

- Patient undergoing elective cesarean delivery
- American Society of Anesthesiologists (ASA) Physical Status I-III (i.e. not in life-threatening situation)

Once the participant fits the above inclusion criteria, only the name of the participant in order for the research coordinator to contact the patient in person regarding the study. Once the patient has consented, her name, phone numbers, email address, date of surgery, age, gravidity, parity, education level, income, and marriage status will be collected.

All data collected will be anonymized so that there will be no PHI during data analysis and publication. Each participant will be identified by a unique code to log in to the mobile application that is randomly generated and the use of the app is blinded to the investigators. There will be no PHI transmitted or stored in the mobile application.

9.2 Measures Taken to Protect Personal Health Information and Study Data

- **Controlled access:** All electronic data will be securely stored on the secure H-drive in a locked office in the Department of Women's & Obstetric Anesthesia at the IWK Health Centre, accessible only by research staff. All study staff will have signed a Non-Disclosure Agreement Form and the IWK Health Centre Confidentiality Form. Paper data (consent forms) will be stored in a locked cabinet in the locked office in the Department of Women's & Obstetric Anesthesia at the IWK Health Centre.

- **Removal of all personal identifiers in electronic data**

- Patients will receive a code to access their mobile application account, thus there will be no personal data collected or stored in the mobile application. The data in the mobile application will be compliant with Canadian privacy laws and encrypted. The application server will be outside of Canada but there will be no identifiable personal information contained on the application: patients will be given a unique 4-digit code to access the mobile application without having to register for any account.

- **The results of the study (prototypes, publications, posters, presentations) will not contain any personal data**

9.3 Storage and Retention of Personal Health Information and Study Data

- All electronic data will be securely stored in a password protected file in a password protected computer on the H-drive in a locked office in the Department of Women's & Obstetric Anesthesia at the IWK Health Centre, accessible only by research staff. Paper data

(consent forms) will be stored in a locked cabinet in a locked office in the Department of Women's & Obstetric Anesthesia at the IWK Health Centre.

- The mobile application will be compliant to Canadian and provincial privacy laws. An encrypted server will be used. The application server will be outside of Canada but there will be no identifiable personal information contained on the application: patients will be given a unique 4-digit code to access the mobile application without having to register for any account.

- The survey will be emailed securely to the participants and their responses will be de-identified and encrypted. Optio publishing (the company developing our mobile application) will not have any access to any identifiable information.

- Relevant paper data will be scanned, de-identified then shredded. All electronic data will be de-identified and kept for further research purposes, for five years after publication or until the end of application development, securely in the H-drive in a locked office in the Department of Women's & Obstetric Anesthesia at the IWK Health Centre. Five years after publication, the data will be deleted permanently in accordance with IWK IT policy.

10. Timeline

Task	Deadline
Ethics approval (minimal risk)	Per REB approval, Aug 2018
Development of iOS mobile application	Completed June 2018
Patient recruitment and data collection	After ethics approval, starting approximately beginning of Aug 2018. The anticipated recruitment would be 5-10 patients per week. The study recruitment data collection period is estimated conservatively to be 3 months (ending approximately end of November 2018).
Analysis, manuscript, knowledge translation	November 2018 – June 2019

11. Budget

Item	Description	Cost
Research coordinator (recruitment, consent, scheduling interviews, interviews and post-interview debriefing)	In Kind from Department of Women's & Obstetric Anesthesia	$0.00
iOS mobile application development (Internal Funding approved, from the Department of Anesthesia, Pain Management)	Optio publishing	$5000
		Total: $5000

12. Ethical Considerations

12.1 Potential Benefits to Subjects and Others

Patients may find the education topics within the mobile application helpful. The questionnaire may alert patients to potentially abnormal symptoms and seek early medical attention. The information gained from this study may be very helpful to other patients and patients may gain personal satisfaction from this.

12.2 Potential Harms to Subject and Others and How They Will be Minimized

This is a minimal-risk study. There is no adverse event, harm, or risk anticipated. In the unlikely event that a participant is distressed, the research team will thoroughly investigate the situation immediately and make the appropriate amendments and referrals, such as family doctor, counsellor, psychologist, and/or psychiatrist.

12.3 Participant Withdrawal

Participants can withdraw from the study at any time. Data with all personal information removed up to that point may be retained for data analysis.

12.4 Alternative Treatments or Procedures

Not applicable.

12.5 Process for Seeking Consent and Assent.

At the pre-op assessment either in the pre-anesthetic clinic or in the hospital, the patient who fits the inclusion criteria will be invited to participate in the study. Please see details in recruitment section above.

13. Appendices List

- **Appendix 1. Patient consent for study**
- **Appendix 2. Demographic information**
- **Appendix 3. Self-check questionnaire (days 1 to 5 after delivery)**
- **Appendix 4. Survey (14 days after delivery, available for 7 days)**
- **Appendix 5: App orientation guide**
- **Appendix 6: Standardized email/phone scripts**
- **Appendix 7: App study infographic**

14. References

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