



PATIENT INFORMED CONSENT FORM

TITLE: Development of a Patient-Oriented Care Transitions Bundle for Critically Ill Patients in the Intensive Care Unit (ICU)

SPONSOR: Canadian Foundation for Healthcare Improvement (CFHI)
Critical Care Strategic Clinical Network (CCSCN)
Department of Critical Care Medicine, Cumming School of Medicine, University of Calgary, Critical Care Medicine, Alberta Health Services

INVESTIGATOR: Dr. Thomas Stelfox Telephone: [REDACTED]

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form for your records.

BACKGROUND

Critically ill patients treated the intensive care unit (ICU) are the sickest patients in the hospital. When patients are moved from the ICU to a hospital ward or discharged directly home, it can be a risky time in their healthcare management. These transitions in care can expose patients to harmful events, such as problems with medications, long waits to be seen by clinicians outside of ICU (doctors, nurses and other specialists) and consequently disappointment about their care while in hospital. Because of these possible risks, it is important to provide patients and their families (family includes immediate family, relatives or friends) with information that can help them during transitions in care and with their next steps in the recovery process.

In Calgary ICUs, there is currently no fixed process for involving and informing patients, such as yourself, and families about what to expect when transitioning out of ICU. Instructions that clinicians (e.g., nurses, nurse practitioners, doctors) may give to patients and families are usually given only verbally and not in writing. We plan to change this process in the current study by introducing a **patient-oriented transition in care bundle**. The bundle consists of (1) a written summary describing the patient's stay in the ICU and what might happen after ICU (transfer location, symptoms, medications, appointments); and (2) a review and conversation between the patient and/or family member and an ICU clinician about the information in the summary.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of the current study is to determine whether we can improve the ICU transition experience of patients and family member's by engaging them more in the preparation process. This includes providing important information in writing about your condition and health management and an opportunity to discuss the information with an ICU clinician prior to leaving the ICU.

You have been invited to participate in this study because you are currently waiting to transition from the ICU to another hospital unit or home. As a participant in this study, we will assess your satisfaction with the transition process and your confidence in understanding your health condition, what to expect when leaving the ICU, and how to manage your care after ICU.

WHAT WOULD I HAVE TO DO?

1. **Potentially participate in the transition in care bundle** that we are evaluating. Participation will depend on whether a member of our study team is one of the clinicians (e.g. nurse, nurse practitioner, doctor) on your ICU care team. Participation will involve preparing an ICU summary with the clinician before you transition from the ICU. The clinician will complete most information in the summary before sitting down with you to discuss the information. During this time, information may be added to the summary based on your conversation. You may be asked to repeat back, in your own words, what was discussed to ensure the clinician explained things clearly and all your questions were answered.
2. **Complete a questionnaire.** A study team member will contact you within **one week** after your ICU transition to complete a questionnaire about your transition experience. At this time, you may still be in the hospital. If that is the case, we will contact you on your unit. If you have been discharged from the hospital, we will contact you by telephone. The questionnaire will ask you to rate your understanding of and satisfaction with the transition process. It will take approximately 10-15 minutes to complete with a member of our team.

As part of our evaluation of the new ICU transition process, the study team will want to know if you visited the emergency department or were readmitted to the hospital in the month after leaving the ICU. For this purpose, we are asking for your permission to collect your Medical Record Number. This will allow us to access the hospital electronic medical record rather than call you for another telephone survey.

WHAT ARE THE RISKS?

There are no real risks participating in this study. Some people may find answering questions or participating in the education part of the transition summary review frustrating or tiring. We will

offer you breaks as needed. You may not want to answer some of the questions on the questionnaire because they are personal, or because of other reasons. You may refuse to answer any question or discontinue participation at any time without penalty or any impact on your current or future treatment. In addition, there may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers.

WILL I BENEFIT IF I TAKE PART?

If you agree to participate in this study there may or may not be a direct benefit to you. You may gain a better understanding of your health condition and post-ICU management; of course, this cannot be guaranteed or promised. The study results may benefit future patients with experiences and health conditions similar to yours by: i) increasing knowledge about health conditions they may have; and ii) increasing understanding of how best to encourage patient involvement in the transition in care process. Finally, the results from this study will help inform a larger study which will aim to implement this new process in all Calgary ICUs.

DO I HAVE TO PARTICIPATE?

Participation in this study is voluntary. You may refuse participation or withdraw from the study at any time by notifying the study team. Your choice to refuse participation or to withdraw from the study will not have any consequences on your current or future health care. If new information becomes available that might affect your ability to participate in the study, you will be informed as soon as possible.

The research team has the right to withdraw you from the study if you abuse the study staff, verbally or physically.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

You will neither be paid nor have to pay anything to participate in this study.

WILL MY RECORDS BE KEPT PRIVATE?

Your records will be kept private and all the information that you provide will be held in strict confidence. Your information will be coded with a unique randomly generated patient identification number rather than with your name. Your data will be kept confidential. It will be password protected and held in Alberta Health Services systems. Only the study investigator and the secondary sponsor, Alberta Health Services, will have total access to the information that you provide to us. The only information that will become publicly available will be the combined data from all the participants in the study. Information that identifies you will be released only if it is required by law.

The University of Calgary Conjoint Health Research Ethics Board (CHREB) has reviewed and approved this study. The CHREB will have access to your study data for quality assurance purposes. When the study is completed, the deidentified data will be held in a database for future use by other researchers. However, any future use of this research data is required to undergo review by a Research Ethics Board.

IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?

In the unlikely event that you suffer injury as a result of participating in this research, no compensation will be provided to you by the University of Calgary, Alberta Health Services or the Researchers. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a participant. In no way does this waive your legal rights nor release the investigators or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your healthcare. If you have further questions concerning matters related to this research, please contact:

Dr. Thomas Stelfox; [REDACTED]

Or

Rebecca Brundin-Mather [REDACTED]

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

[REDACTED]
Participant's Name

[REDACTED] Nov 6/19
Signature and Date

[REDACTED]
Investigator/Delegate's Name

[REDACTED] Nov 6/19
Signature and Date

[REDACTED]
Witness' Name

[REDACTED] Nov 6/19
Signature and Date

The University of Calgary Conjoint Health Research Ethics Board (CHREB) has reviewed and approved this study. A signed copy of this consent form has been given to you to keep for your records and reference.



FAMILY / CAREGIVER INFORMED CONSENT FORM

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Department of Critical Care Medicine, Cumming School of Medicine, University of
Calgary Critical Care Medicine, Alberta Health Services

INVESTIGATOR: Dr. Thomas Stelfox

Telephone: [REDACTED]

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In Calgary ICUS, there is currently no fixed process for involving and informing patients and family members, such as yourself, about what to expect when transitioning out of ICU. Additionally, instructions that clinicians (e.g., nurses, nurse practitioners, doctors) may give to patients and families are usually only given verbally and not in writing. We plan to change this process by introducing a **patient-oriented transition in care bundle**. The bundle consists of (1) a written summary of the patient's stay in the ICU, current health condition and what might happen after ICU (transfer location, symptoms, medications, appointments); and (2) a review and conversation between the patient and family member and an ICU clinician about the information in the summary.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of the current study is to determine whether we can improve the ICU transition experience for patients and family members, such as yourself, by engaging them more in the preparation process. This includes providing important information in writing about your loved one's condition and health management and an opportunity to discuss the information with an ICU clinician prior to leaving the ICU.

You have been invited to participate in this study because your loved one is currently waiting to transition from the ICU. As a participant in this study, we will assess your satisfaction with the transition process and your confidence in understanding your loved one's health condition, and how to manage his/her care after ICU.

WHAT WOULD I HAVE TO DO?

1. **Potentially participate in the transition in care bundle** that we are evaluating. Participation will depend on whether a member of our study team is one of the clinician on your loved one's ICU care team. Participation will involve preparing an ICU summary with the clinician before your loved one transitions from the ICU. The clinician will complete most information in the summary before sitting down with you to discuss the information. During this time, information may be added to the summary based on your conversation. You may be asked to repeat back, in your own words, what you discussed to ensure the clinician explained things clearly and all your questions were answered.
2. **Complete a questionnaire.** A study team member will contact you within **one week** after your loved one's ICU transition to complete a questionnaire about your experience. At this time, your loved one may still be in the hospital. If that is the case, we will contact you on his/her unit. If your loved one has been discharged from the hospital, we will contact you by telephone. The questionnaire will ask you to rate your understanding of and satisfaction with the transition process. It will take approximately 10 to 15 minutes to complete with a member of our study team.

WHAT ARE THE RISKS?

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or
Rebecca Brundin-Mather [REDACTED]

If you have any questions concerning your rights as a possible participant in this research, please contact the Chair, Conjoint Health Research Ethics Board, University of Calgary at 403-220-7990.

[REDACTED]
Participant's Name

[REDACTED] Nov. 6, 2019
Signature and Date

[REDACTED]
Investigator/Delegate's Name

[REDACTED] Nov. 6, 2019
Signature and Date

[REDACTED]
Witness' Name

[REDACTED] Nov 6 2019
Signature and Date

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