Barriers and Facilitators to Optimal Anticoagulation Management: A Focus Group Study Protocol

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Abstract

Background: Oral anticoagulants (OACs) require high-quality management given their frequent use amongst seniors, clinically important benefits and common, serious drug-related harm. Improvement in OAC management has been proposed as a means to improve health outcomes and health care sustainability. The objective of this focus group study is to identify barriers and facilitators to optimal OAC management from the perspective of patients, caregivers and healthcare providers.

Methods: We have planned a multi-site qualitative study based on a qualitative descriptive approach with two patient/caregiver focus groups and two health care provider groups to be held in Southwestern Ontario, Canada. The desired sample size is 32-40 participants (based on 8-10 people per focus group). **Discussion:** The findings from these focus groups will be used to inform our intervention in a follow-up randomized trial, "Coordinated Oral Anticoagulant Care at Hospital eDischarge" (COACHeD) which aims to improve OAC management and bridge knowledge gaps in this area.

Trial registration: This is a sub-study of Improving Anticoagulant safety at Hospital Discharge: A Randomized Trial with ClinicalTrials.gov Identifier: NCT02777047.

Keywords: Anticoagulants; Barriers; Facilitators; Management; Focus group; Protocol.

Background

Anticoagulants are the top cause of medication-related serious harm, regarding emergency department visits, hospitalizations and fatalities [1, 2]. More than 7 million prescriptions are dispensed annually for oral anticoagulants (OACs, including warfarin, dabigatran, rivaroxaban, apixaban and edoxaban) in Canada [3]. The frequent chronic utilization of OACs in addition to their ability to lower adverse clinical event rates (stroke, embolism, death) along with their high potential for causing major harm (primarily bleeds, which can be fatal) are all drivers of the need to prioritize the safe and effective use of these drugs. Each adverse drug event requiring a hospital visit approximately doubles the cost of care in the subsequent six months [4]. All investigations, root cause analyses and national patient safety inquiries into anticoagulation safety problems cite clinician difficulties with keeping track of exactly what the patient is taking compared to what they should be taking [5-7]. More complex problems include: identifying individual patient risk factors for benefit versus harm, drug interactions and contraindications, dosing adjustments over time and around procedures, monitoring and reversal strategies, and poor adherence by patients [8-12].

In preparation for a randomized trial to test an intervention to improve the coordination of care of patients on OACs, we completed a literature review to identify the main barriers that our intervention should address. We were surprised that we couldn't identify any focused study or systematic review outlining overall barriers and facilitators to optimal oral anticoagulant therapy management in the modern era of both warfarin and direct-acting oral anticoagulants (DOACs).

Our research team's collective clinical experience suggests barriers to optimal anticoagulation management might largely be described in themes of provider and patient/caregiver communication, knowledge and behavior.

Focus group studies are a useful qualitative research design to encourage meaningful, detailed responses to clinical questions, particularly around management or process issues. Focus groups provide a rich understanding of people's experiences and perspectives that are not obtainable from quantitative or short answer questionnaires [13]. Focus groups are also a recommended method for data collection in qualitative descriptive studies[14].

Our objective in this focus group study is to explore barriers and facilitators to optimal OAC management, from the perspectives of patients, caregivers, and healthcare providers.

Methods/Design

Study Identification

The research protocol was approved by Hamilton Integrated Research Ethics Board as an amendment to the randomized clinical trial (Improving Anticoagulant Safety at Hospital Discharge: Coordinated Oral Anticoagulant Care at Hospital eDischarge. (COACHeD). See Additional file 1 for the research ethics board (REB) approval.

Study design and Setting

This is a multi-site qualitative study - consisting of several focus groups using a semi-structured process. We plan to conduct one each of patient/caregiver and healthcare provider groups in 2 cities (Hamilton and Kitchener-Waterloo) in Ontario, Canada.

Recruitment of Participants

We will recruit patients who are currently taking OACs, or have previously taken OACs but are not currently taking them or have refused OAC therapy, as well as caregivers for those who require assistance to manage their medications. Patients and caregivers will be selected from the practice lists of co-investigators and colleagues aiming for balance in current users, ex-users, and refusal

to start OAC with a range in age as well as the type of follow-up (organized OAC clinic versus, specialist clinic, primary care.

The inclusion criteria for patients are: 1) Age 18 or older; 2) Ability to read and speak English or with a close caregiver who can translate; 3) Currently taking OACs or were taking OACs in recent past (maximum 2 per group) or refused OAC therapy (maximum 1 per group); 4) Provide consent to participate.

A member of the research team will be introduced to patients by someone in the patient's circle care. After this introduction, the research team member will provide the patient with an overview of the study and ask if they are willing to participate in the study. The informed consent process will occur at the beginning of the focus group discussion.

Separate focus groups will be run with a multidisciplinary mix of healthcare providers who prescribe, dispense, or manage OAC therapy will be held. The email participation invitation will be sent out to different clinics in each city. For the healthcare providers, the inclusion criteria are 1) Physicians, nurses, pharmacists who currently manage patients on OACs. Exclusion Criteria are 1) patients less than 18 years of age; 2) Individuals who don't provide informed consent.

Providers will include primary care and secondary care providers with a mix of community and hospital base, within our investigators' extensive network of colleagues.

We plan to recruit approximately 12 individuals per focus group meeting, with a goal of 8 to 10 participants at each discussion which should allow for in-depth discussion of the issues.

Data collection

Before the beginning of each focus group, the facilitator and the research assistants will introduce themselves to the participants and have some informal discussions – these interactions are intended to help make the participants feel comfortable and familiarize with the facilitator [15]. Participants

will also be asked to complete a brief demographic form (Additional file 2, Part 1). Before the formal discussion begins, the facilitator will review the consent form and describe processes for ensuring participant anonymity as well as outline some ground rules for the discussion.

The focus group facilitator will be positioned within a circle with the participants, and the note-taker and assistant will sit outside of the circle and observe the focus group. The details of the physical setting and the Focus Group Set-up Guide can be found in are shown in **Table 1**.

Table 1. Focus Group Set-up Guide

I. PURPOSE. To describe in detail the process for conduction our focus group discussions for the OAC Management Focus Group Study.

II. RATIONALE. We plan to perform focus group discussions with two groups of participants: Patients taking or previously taking oral anticoagulants or their caregivers and healthcare professionals that are involved in prescribing, managing or dispensing OACs. The goal of these focus groups is to explore barriers and facilitators to optimal oral anticoagulation management.

III. SUPPLIES AND MATERIALS

- REB approval letter
- Study protocol for the focus group
- Consent forms
- Focus Group Guide
- Enrolment form
- 2 Digital recorders
- Spare batteries
- Name-tags with numbers
- Notepad
- Pens
- Clipboard

IV. OUR DEFINITIONS

- **Focus group discussion** (FGD): a qualitative method to draw out opinions from a group of people brought together in person in a social setting to facilitate participation.
- **Facilitator:** the research team member who will run the group discussion, ask questions and manage group dynamics. The facilitator will also be responsible for setting ground rules.

- **Note-taker:** the research assistant responsible for keeping the record of all participants, their demographic details, the critical points of the discussion (including the level of participation by each participant and observations on group dynamics).
- **Assistant:** another research assistant who will be responsible for all of the logistics related to the focus group including organizing the venue, the layout of the room, informing participants about the date and location of the FGD and provision of refreshments.

V. REVIEW OF FGDs

A. Role of facilitator

- The facilitator will introduce themselves, the note taker, the assistant, and the study objectives. They will relay information on what participants can expect from the FGD.
- The facilitator will review ground rules for the discussion with the participants and answer any questions they have about the ground rule.
- During the FGD, the facilitator will guide the discussion by posing questions from the discussion guide or follow-up questions based on the emerging discussion. Questions should be neutral and should not lead the respondents to confirm a viewpoint.
- The facilitator will not show any judgment on the responses or opinions of group members, and state that there is no ‘right' or ‘wrong' answers.
- The facilitator will balance the discussion, giving all participants a chance to speak, and not letting any individual dominate the conversation.
- Group answers to questions will be followed with probes to clarify comments.
- At the end of the FGD, the facilitator will open the floor for concerns, questions or anything else related to the topic that has not yet been discussed. The FGD will end by thanking respondents for participating.

B. Role of note-taker

- The note-taker will record demographic details of each participant on the enrolment form as each participant arrives, seating and numbering them.
- The note-taker will take notes on the note-taker form, including the seating plan and context of the FGD.
- The note-taker should record information on non-verbal communication during FGDs including ambiance, laughter, and expressions.
- It is critical to capture as much of the FGD as possible in writing in case of audio record failure.

C. Role of research assistant

- The assistant is responsible for ensuring minimal distraction for the participants and hosting the FGD and facilitator/note-taker team.
- The assistant will welcome and seat participants as they arrive.
- The assistants will give each participant a tent card with study identification number (Study ID) on it, which will facilitate the communication within the focus group.
- The assistant will deal with latecomer(s). The latecomer will be asked to join the group quietly after getting the consent form signed, and a written ground rule will be given.
- The assistant is responsible for making arrangements for refreshments.

D. Dynamics of an FGD

- The facilitator and participants should respect each idea and contribution.

- When experiences and comments are shared, the facilitator will assess whether they are general or specific. Regarding a specific experience, the respondent should be given a chance to explain their position.
- General ideas will be assessed in each FGDs conducted to check the prevalence of ideas.
- There is no wrong answer in FGD.
- When an individual participant discusses their own experience, the facilitator will pick an aspect of the experience to question the group about to the group to see how their opinions compare.
- The facilitator will focus on bringing all participants, including the quiet ones, into the discussion. Dominant participants will be silenced with a sensitive approach if necessary (e.g., "Thank-you; what does the group have to say about her/his opinion?")
- The experience of all participants is equally valid, but it is the experience of the group, not of an individual, that the FGD aims to explore.

VI PROCEDURES

A. Performing the FGDs

- At the time of participants arrive, the note-taker should ask them their name, ask them to sign the attending form, and then complete the baseline and demographic form.
- The note-taker will check whether each participant has already signed a consent form. If they have not, the note-taker will get consent forms, talk through it with the participants and then ask them if they would like to consent. The note-taker will then ensure the consent form signed by the participants.
- The note-taker will then give the participant a tent card with their first name on it, and lead them to their seat.
- Once all the participants are in places, the note-taker will record everyone's seating positions.
- After all the participants have arrived, the facilitator will welcome everybody and give a brief introduction to the FGD using the script below as a guide.

Script for welcoming participants to the FGD

"*Hello everyone and thank you for coming this evening*

My name is xxx; I work as a research coordinator at McMaster University. Introduce other team members.

We are working with a research team who want to learn more about the barriers to, and facilitators for, optimal management of oral anticoagulants which is the topic we will be discussing this evening.

The discussion will last approximately 90 minutes and will be digitally recorded. The recording of our discussion tonight will be transcribed by a professional transcriptionist, and the transcript will be de-identified. Only the research team will have the right to access the transcript, and if we present or publish data from this discussion, it will be completely de-identified."

- *Before we begin, I'd like to establish a few 'ground rules' for our discussion tonight:* If not mentioned by participants, the facilitator should add the following rules:
    - Respect everyone's opinions – there are no right or wrong answer
    - Turn mobile phones off

- Give everyone in the focus group a chance to talk and do not interrupt or talk to someone
- Confidentiality – do not repeat or discuss with anyone outside the group anything that is mentioned here.

- After the ground rules have been settled, the facilitator will begin the FGD using the focus group guide.
- If/when latecomers arrive; the assistant will complete the enrolment form, give them a tent card with their name on it and show them to a seat, as the note-taker will be recording the content of the discussion.
- Participants will be allowed to leave the discussion briefly for a washroom break, but the facilitator will aim to have no more than one participant absent from the discussion at any one time.
- If a participant, at any time point, wishes to leave the group altogether, the facilitator will allow this but their contributions prior to withdrawal stay with the transcripts.
- At the end of the FGD, the facilitator will thank the participants, state again for how confidentiality will be maintained and how the information will be used and by the research team.

B. Immediately after the FGD

- Once all the participants have left, the facilitator, note-taker, and assistant will meet to discuss the FGD.
- All data information (the audio files, attending signed form, and note-taker form) will then be taken to the research office for transcription and storage.

We will use a detailed Focus Group Guide for each of the Healthcare provider and the Patient/Caregiver focus groups. This consists of questions and probes to help develop the discussion and to ensure each topic is covered (see details in the Tale 2 and Table 3).

Table 2. Focus Group Topic Guide- Healthcare Providers.

Domain	**Topic**
Introduction	I'd like to begin by asking everyone to introduce themselves by name, and also describe their clinical specialty.
Management of anticoagulants	**Health care provider's perspective anticoagulant management** 1) We'd like to ask you begin by thinking about the patients you see who have the best adherence to taking the oral anticoagulants as prescribed. Why are these patients doing well with taking their oral anticoagulants? <u>Probes:</u> • Patient-level factors (socio-economic status, ability to be compliant, willingness to be compliant, challenges accessing medical care including distance/transportation).

	• Support system • Think of one patient you provide care for who is doing well – what things contribute to their success with taking the oral anticoagulants? 2) What other behaviors do you believe are important for patient self-management of oral anticoagulants? 3) Based on your clinical experience, what aspects of healthcare provider management do you believe influence the management of oral anticoagulants? Probes: patient follow-up 4) Summarize discussion about facilitators for adherence to oral anticoagulants. Anything else to add about facilitators for adherence to oral anticoagulants? 5) Next, we'd like to ask you to think about which patients are not adhering to their oral anticoagulants. Why do you think these patients are not doing well with taking their oral anticoagulants? Probes: patient-level factors (socio-economic status, ability to be compliant, willingness to be compliant, challenges accessing medical care including distance/transportation, risk of falling • Need for more regular blood tests. • Adjusting/determining the correct dose, dietary restrictions. • Patient fear of risks associated with oral anticoagulants • Drug side effects • Drug interactions • Support system Think of one patient that you provide care for who is having a difficult taking their anticoagulants as prescribed – what challenges do they deal with? 6) What are some of the difficulties that as clinicians, you experience with managing oral anticoagulant medications in your patients? Probes: • Adequate time and resources for patients to be informed? • Knowing if the patient is taking what they should be taking/prescribed to take? If yes, why is this difficult? • Challenges related to identifying individual patient risk factors for benefit versus harm? • Dose adjustments over time and around procedures – monitoring and reversal strategies • Issues around legal liability? • Issues around having different professions working together inter-professionally? (I.e., concern about other healthcare providers stepping on physician's toes/taking over their scope of practice; concern about the ability of other professions to manage patients taking oral anticoagulants?)

	Think about one of the patients where you are had a very difficult time managing their oral anticoagulants – what made it difficult? 7) What would things help you to manage your patients' use of oral anticoagulant medications more successfully? <u>Probes:</u> • patient level factors • system level factors 8) Summarize discussion re: challenges to oral anticoagulant medication adherence. Anything else to add to the challenges to oral anticoagulant medication adherence?
Education	**For the next part of the discussion, we would like to focus on patient education about oral anticoagulant medications.** 1) Can you begin by telling me how patients are educated about oral anticoagulants? <u>Probes:</u> • Discussions during visits for medical care, pamphlets • How do you educate the patients you provide care to about oral anticoagulant medications? • Do you believe patients receive enough education about 1. Their medical condition and the risk of stroke/blood clots; 2. The role of oral anticoagulant medications in lowering risk for stroke/blood clots; 3. The risks associated with taking oral anticoagulants (primary bleeds); 4. The importance of being compliant when taking oral anticoagulants • Do you think there is every any reluctance on the clinician's part to educate patients about the risks associated with taking oral anticoagulants? • Is the education they receive relevant to them? (I.e., in the language they can understand and tailored to the patient experience?) 2) In your experience do you believe that most patients or their caregivers understand enough about oral anticoagulant medications? <u>Probes:</u> • why or why not 3) What are some of the challenges to educating patients about oral anticoagulants that need to be addressed? 4) Summarize discussion about OAC education. Are there any other ways that patient education about oral anticoagulant medications can be improved?
Communication	**For the last part of the discussion, we would like to focus on the role of communication in the management of oral anticoagulant medications.** 1) What types of communication are typically involved in the management of oral anticoagulants? <u>Probes:</u> • Face-to-face

	• Phone calls • Emails • Texts to and from patients • With other clinicians/healthcare providers • Communications from labs 2) Have you experienced any communication barriers related to the management of oral anticoagulants? <u>Probes:</u> • the communication breakdown with patients/caregivers • communication breakdown between clinicians involved in patient's care (i.e., one clinician prescribes a medication that will interact with oral anticoagulants b/c they aren't aware the patient is taking oral anticoagulant) 3) Have you experienced any factors that make it easier to management oral anticoagulants in patients? 4) How do you think communication-related to oral anticoagulant medications can be improved?
Closing	We are now approaching the end of our discussion. Is there anything else anyone would like to add to the management of oral anticoagulant medications? Thank you for sharing your experiences, your perceptions and your time.

Table 3. Focus Group Topic Guide- Patients/Caregivers

Domain	**Topic**
Introduction	I'd like to begin by asking each of you to introduce yourself by name, describe if you are a patient or a caregiver and share your experience with blood thinners (currently taking them, took them in the past, or refused to take them).
Anticoagulant Knowledge	**For the first part of the discussion tonight, we'd like to talk about your knowledge about blood thinners.** 1) Can you start by describing why you are taking blood thinners, or if you have taken them in the past or refused to take them, why your doctor suggested that you take them? 2) Next, can you describe some of the benefits of taking blood thinners? 3) And now can you please talk about some of the potential harms associated with taking blood thinners? 4) For those who have refused to take blood thinners, can you tell us why you refused to take them? 5) For those of you who are taking blood thinners or are a caregiver for someone who takes blood thinners, can you describe if you can take them the way the doctor has prescribed them for you? **If yes,** why are you (or the person you provide care for) able to take blood thinners the way your doctor prescribed them? <u>Probes:</u> • What things make it easy to take blood thinners?

	• Motivation • Comfort level with blood thinners • Trust in doctor • Support from family/friends • Support from health care providers/clinic (including follow-up via phone or at visits) • Clinic/lab easy to get to • Reminders: calendars, alarms on phones, dockets, blister packs, et al. • Routine Have you ever thought about stopping your blood thinner medication? If yes, why have you thought about stopping your blood thinner medication? If yes, why haven't you stopped taking your blood thinner medication? For those of you did stop taking blood thinners would you willing to share with us the reasons why you stopped taking them? **If no,** why aren't you (or the person you provide care for) able to take blood thinners the way your doctor prescribed them? <u>Probes</u> • What things make it difficult for you to take blood thinners? • Lack of motivation (including knowledge) • Discomfort with blood thinners (INR testing, potential risks including risk of falling) • Dose adjustments over time and around procedures – monitoring and reversal strategies • Side effects experienced from taking blood thinners • Blood thinners interact with other medications • Lack of trust in doctor • Lack of support from family/friends • Lack of support from health care providers/clinic (including no follow-up or limited follow-up via phone or at visits) • Challenges with getting to lab/clinic/doctor (distance, transportation, working hours, physical mobility challenges) What do things you think would make it easier for you to take blood thinners as prescribed? <u>Probes:</u> • Communication from healthcare team (face-to-face, phone calls, emails, texts). Probe re: preferred method of communication; if/how communication might make it more difficult rather than easier? Have you talked about any of the challenges you experience with taking blood thinners with your doctor or healthcare team? Why or why not?

	Does your doctor know you aren't taking your blood thinners as prescribed? Why or why not?
Education	**For the second part of the discussion, we would like to talk about education about the use of blood thinners.** 1) Can you tell us about the education you received about/information about blood thinners? <u>Probes:</u> • What did you learn about? • Your medical condition and the risk of stroke/blood clots • The role of blood thinners in lowering risk for stroke/blood clots • The risks associated with taking blood thinners (primary bleeds) • The importance of taking blood thinners as prescribed (being compliant) • Who? • When? • How? (pamphlets, discussion, website/video) • How often? • Was the education presented in language that you could understand? 2) Do you feel you know enough about the blood thinner that you are taking or that your doctor recommended to you? If no, what things would you like to know more about? 3) Do you have any suggestions about how we could improve the way patients and caregivers are educated about blood thinners? <u>Probes:</u> • Who? • When? • How? (pamphlets, discussion, website/video) • How often? • What kind of information is shared? • Language used?
Communication	1) What communication (face-to-face, phone calls, email) would you think helps to ensure the medication you are taking are managed in the best possible way? 2) What communication would make management more difficult? 3) Are there any suggestions you have that could improve this?
Closing	We are now approaching the end of our discussion. Is there anything else anyone would like to add to their experience with blood thinners that we have not talked about? • Summarise • Thank participants • Provide extra information and contacts to participants

Each participant will be given a unique study identification number (Study ID). This will be used in the enrollment and demographic forms. Participants will introduce themselves and be asked to identify themselves each time they speak during the focus group discussion. The transcriptionist will assign each focus group participant a unique subject number to track their conversation through the transcript and ensure their anonymity.

A Note Taking Form (see Additional file 2, Part 1) will be used for all focus group discussions, which will be completed by the note taker. Also, a digital recording will be made of the discussion. The note taker will draw a map of participants and record which participant made which contributions. The note taker will also make notes on the non-verbal behavior during the interview as well as notes about the setting and atmosphere of the interview.

After each focus group discussion, the facilitator, the note-taker, and the research assistant will meet to discuss the group dynamics during the discussion and share any surprising or important observations to include in future focus group discussion and data analysis. The facilitator will then complete the focus group debriefing form (See Additional file 2, Part 2).

Data processing and data analysis

Demographic data will be summarized using descriptive statistics. We will use NVivo (v10.0 QSR International, Australia) to manage the qualitative data for analysis.

The transcripts from the focus groups and the researchers' field notes will be analyzed using conventional content analysis [16] to identify themes through a qualitative descriptive approach[14]. The conventional content analysis is an analytic method often used with studies that aim to describe a phenomenon[16]. The method is based on an inductive approach to coding, where codes are developed directly from the data rather than through the use of preconceived categories. In our study, the analyst will review the focus group transcripts in their entirety to understand the

context of the discussion, then will complete line by line coding of the transcripts, highlighting words in the text that capture key thoughts or concepts. The analyst will develop labels for codes based on the highlighted words in the transcripts. A preliminary list of codes will be developed. Two other members of the research team will be asked to review a few transcripts and the preliminary list of codes, and through consensus, the list of codes for the coding will be decided upon. The analyst will code the remaining transcripts, noting any new codes in the study audit trail[17] and ensuring new codes are applied to previously coded transcripts. When coding is complete, research team members will review coding reports and then meet to organize the codes into meaningful categories based on their relationships to each other. We will ensure there is an exemplar from the data for each code and category. The categories of codes will then be organized into higher level clusters[18]. The analyst will record all decisions related to the coding and analysis process in a study audit trail [17]. The research team will assess data saturation through a review of all transcripts, coding reports and by examining the audit trail.

Discussion

To understand the barriers to and facilitators for optimal OAC management from the perspectives of patients, caregivers, and providers, we have decided to use the qualitative description method using focus groups for data collection. Qualitative description allows for a comprehensive summary of an experiences or phenomenon in everyday terms [14]. The minimal level of interpretation with this analytic method results in an analysis which yields a description of the participants' experience that is close to their own words [19]. We selected focus groups for data collection because they typically obtain a broad range of information about events or experiences[14] and can be useful for encouraging discussion with participants who otherwise might feel they have nothing to say[20].

We recognize some limitations inherent in our design choices. Our study will be conducted in the Hamilton and Kitchener-Waterloo area, representing two regional health networks in Ontario. Thus generalizability of our findings to other geographic areas, particularly remote rural areas, may be limited due to differences in local practice and health system organization. [21, 22]. Also, focus groups may not be appropriate for tapping into individual biographies or narratives but focus groups are more suitable to study experiences and attitudes [23].

This study is meant to complement several ongoing quantitative studies, including systematic reviews of OAC management and analysis of Ontario's linked healthcare administrative databases to determine (directly or indirectly) barriers and facilitators to optimal OAC management. These, in addition to the focus group study, will inform our randomized trial which will evaluate care coordination intervention to improve the quality of OAC management, currently in the planning stages. The barriers and facilitators identified in the present study will optimize the care coordination intervention.

Upon completion, the results of this focus group study will be submitted to a peer-reviewed biomedical journal for publication and presented at several conferences.

List of abbreviations

OACs: Oral anticoagulants; DOACs: direct-acting oral anticoagulants; REB: research ethics board.

Declarations

Ethics approval and consent to participate

This study was approved by the Hamilton Integrated Research Ethics Board (HiREB) with Project number of 2017-1639 and Tri-Hospital Research Ethics Board (THREB) with an approval number of 2017-0635. Informed consent will be obtained from all relevant participants.

Consent for publication

Not applicable

Competing interests

The authors declared no potential conflicts of interest concerning the research, authorship, and publication of this article.

Funding

This is a sub study of a randomized clinical trial which is funded by the Canadian Institutes of Health Research (CIHR) under Award Number 365834.

Authors' contributions

AH is the principal investigator of the COACHeD study, Improving Anticoagulant Safety at Hospital Discharge: Coordinated Oral Anticoagulant Care at Hospital eDischarge. All authors contributed to the conception, design of the study, and the editing and final approval of the protocol.

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Additional file 1. Ethic approval from Hamilton Integrated Research Ethics Board (HiREB) and Tri-Hospital Research Ethics Board (THREB).

HiREB

Hamilton Integrated Research Ethics Board

Amendment Approval

February 14 2017

HiREB Project #: 2017-1639

Local Principal Investigator: Dr Anne Holbrook

Project Submission Title: IMPROVING ANTICOAGULANT SAFETY AT HOSPITAL DISCHARGE: A RANDOMIZED CONTROL TRIAL

Document(s) Amended with version # and date:

Document Name	Document Date	Document Version
Barriers and Facilitators OAC Management focus group approval letter Schulman draft jan27 17 SS	Jan-27-2017	1.0
Healthcare Provider Consent Form 31 Jan 17	Jan-31-2017	1.0
Patient Consent form- Jan 31 17	Jan-31-2017	1.0
Protocol only- Barriers and Facilitators to Optimal Anticoagulation Management Jan 31 17	Jan-31-2017	1.0
Protocol Summary of changes note Addition of 4 new co-investigators Dr. S. Gilck, Dr. Joanne Ho, Dr. Deborah Siegal and Dr. Jean Eric Tarride.	Feb-07-2017	1
Recruitment Poster- Jan 31 FINAL	Jan-31-2017	1.0
SJHH outpt letter signed anne B 31-1-17	Jan-31-2017	1.0

Research Ethics Board Review:

[X] Amendment approved as submitted
[ ] Amendment approved conditional on changes noted in "Conditions" section below
[ ] New enrollment suspended
[ ] Study suspended pending further review

Level of Review:

[ ] Full Research Ethics Board
[X] Research Ethics Board Executive

Dr. Mark Inman, MD, PhD
Chair, Hamilton Integrated Research Ethics Board

The Hamilton Integrated Research Ethics Board (HiREB) represents the institutions of Hamilton Health Sciences, St. Joseph's Healthcare Hamilton, and the Faculty of Health Sciences at McMaster University and operates in compliance with and is constituted in accordance with the requirements of: The Tri-Council Policy Statement on Ethical Conduct of Research Involving Humans; The International Conference on Harmonization of Good Clinical Practices; Part C Division 5 of the Food and Drug Regulations of Health Canada, and the provisions of the Ontario Personal Health Information Protection Act 2004 and its applicable Regulations; For studies conducted at St. Joseph's Healthcare Hamilton, HIREB complies with the health ethics guide of the Catholic Alliance of Canada

TRI-HOSPITAL RESEARCH ETHICS BOARD (THREB)

(A shared service for Cambridge Memorial Hospital, Grand River Hospital and St. Mary's General Hospital)
Grand River Hospital, Rm. K415, Kaufman Building, 835 King Street West, Kitchener, Ontario, N2G 1G3
Tel: (519) 749-4300 ext. 5367 Fax: (519) 749- 4282

September 27, 2017

CERTIFICATE OF A PPROVAL
THREB #2017-0635

Dr. Anne Holbrook
c/o Sarah Laferriere
50 Charlton Ave E G624
Hamilton, ON L8N 4A6

Dear Dr. Anne Holbrook,

Barriers and Facilitators to optimal Anticoagulation Management: A Qualitative Study GRH

Study Identification Number: THREB #2017-0635

1. THREB Application for Review received September 18, 2017.
2. Administrative approval received September 6, 2017. GRH

Initial Approval Date: October 2, 2017
Anniversary Date for Renewal: October 2, 2018

Thank you for your application requesting approval of the above research study. The Chair of the Tri-Hospital Research Ethics Board (THREB) has reviewed your request by Delegated Review and has approved it.

If there is a contract or data sharing agreement, the study may not commence until those documents have been finalized.

The study is to be reviewed in one year, before the next "Anniversary Date."

Approval is granted to conduct the research project in accordance with the above protocol.

Requirements for ongoing approval include:

a. Annual progress reports for review and continued approval of the study by THREB
b. Submission of any changes in the protocol, informed consent documents, information sheets, questionnaires, recruitment posters or other study materials;
c. Timely reporting of all local serious adverse events;
d. A final report, upon completion of the study, submitted within three months.

Additional file 2. Focus Group Notes and Debriefing

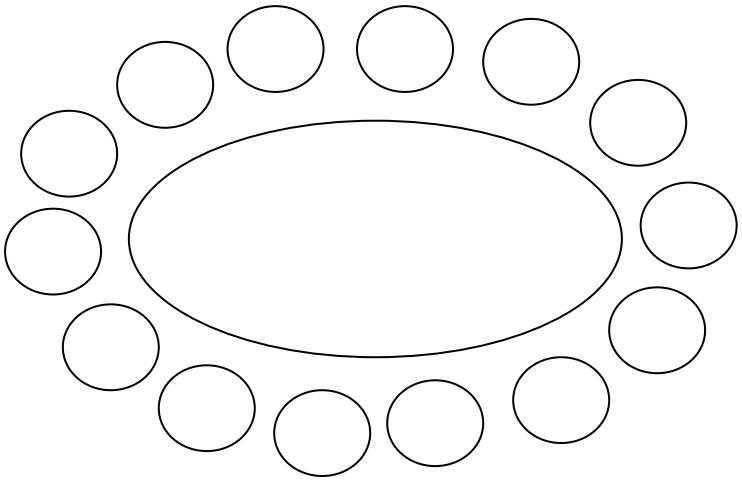
Part 1: Focus Group Notes

IDNO: |__|__|__|__| **Facilitator Initials:** |__|__|__| **Note-taker Initials**: |__|__|__|
Participant sub-group: (circle): Healthcare Providers/ Patient-Caregiver
Audio: |__|__|__| **Location:** (circle one): Hamilton/Kitchener-Waterloo
Group number: |__|__| **Date**: |__|__|/|__|__|/|__|__| **Time** start ___:___ end ___:___

Meeting place description: *detail and description, e.g. size and accessibility, and how this could affect the discussion; interruptions during the discussion*

Participants and Seating: *Note invitees who did not attend*

Seating diagram:



Group dynamics: *general description – level of participation, dominant and passive participants, interest level, boredom, anxiety – and how these relate to the different topics discussed*

Impressions and observations:

Running notes (detailed notes following the discussion, as near verbatim as possible, including identification of all contributors):

Part 2: Focus Group Debriefing

IDNO: |__|__|__|__| **Facilitator Initials**: |__|__|__| **Note-taker Initials**: |__|__|__|

Participant sub-group: (circle): Healthcare Providers/ Patient-Caregiver

Audio: |__|__|__| **Location**: (circle one): Hamilton/Kitchener-Waterloo

Group number: |__|__| **Date**: |__|__|/|__|__|/|__|__|

1. What were the main issues or themes that struck you during this focus group?

2. What new information did you gain through this focus group compared to previous focus groups in this study?

3. Was there anything surprising to you personally? Or that made you think differently about this research question?

4. What messages did you take from this focus group for intervention design?

5. How would you describe the general atmosphere and engagement of the focus group?

6. How would you describe the group dynamics? For example, were there dominant individuals (what was the result and what were their IDNOs)? Did all participants contribute? Did you feel there was pressure to adhere to dominant viewpoints (what topics)?

7. What else was important about this focus group?