SWAT 176: Co-designing and pilot testing an infographic to support patients and families through the REMAP-CAP consent process

Objective of this SWAT
To co-design and pilot test an infographic to augment the standard REMAP-CAP consent process.

Study area: Recruitment
Sample type: Patients, Carer/Parent, Trial Team
Estimated funding level needed: Low

Background
Informed consent is essential to the conduct of ethical clinical research and requires clear communication and understanding of a trial's purpose, methods, potential harms and benefits and alternatives to participation.[1,2] This can be challenging for platform trials (also called adaptive trials or multi-arm, multistage designs), which evaluate multiple treatments for a disease at the same time.[3,4] Platform trials allow researchers to identify superior treatments and test new treatments as they emerge, and the treatments offered are constantly changing.[3] The complexities of a platform trial can be difficult to understand, particularly for patients and family members approached for time-sensitive consent.

Ideally, a consent discussion occurs in a calm environment with potential participants in a positive mindset, with ample time to review consent documents before making a decision.[2] This is not always possible when research involves vulnerable populations, such as patients in an intensive care unit (ICU), who have a life-threatening illness, creating increased stress for patients and families.[5,6] The eligibility timeframe for enrolment in ICU-based clinical trials can also be very short, and consent might need to be sought from a patient's substitute decision maker (SDM), adding strain to the consent encounter.[5] Traditional consent forms are long and scientific, requiring significant time and energy to explain and understand, making them challenging to use in stressful, time-constrained situations.[5,7]

Platform trials have been crucial in the timely identification of optimal treatments for individuals with COVID-19 in the ICU;[8,9] including REMAP-CAP (Randomized, Embedded, Multifactorial, Adaptive Platform Trial for Community-Acquired Pneumonia).[10] This is an international trial, which goes beyond the traditional two-arm randomized trial with multiple randomizations with different risk-benefit profiles, response adaptive randomization (where the better performing arm in the trial is preferentially randomized), and international coordination and data sharing.

In Canada, REMAP-CAP is led by a team of researchers and clinicians who developed the Canadian Adaptive Platform Trial in Intensive Care (CAPTIC) research program.[11] This program formed the CAPTIC Patient/Family Partners (PFP), consisting of patients and families with lived ICU experience, to gain their perspectives and uphold the program's commitment to conducting patient-oriented and guided research. The PFP's first priority was to address challenges during the consent process for ICU research and found that the consent documents for REMAP-CAP were difficult to understand because of the trial complexity. PFP believed that use of an infographic may aid in the communication of information about REMAP-CAP for these patients and families who are highly vulnerable and are in a stressful and anxiety-provoking time. It is essential that those with lived experience are involved in the development of such a tool, which can be facilitated through co-design.[12,13]

This SWAT will evaluate this infographic in a single group cohort study.[10,14] It will be jointly coordinated at St. Michael's Hospital (Toronto, Ontario) and McMaster University (Hamilton, Ontario) and take place at up to five Canadian REMAP-CAP sites. St. Michael's Hospital is the site of the REMAP-CAP Regional Coordinating Center in Canada and has a 29-bed mixed medical-surgical ICU, which is the primary catchment area for the REMAP-CAP participants. Additional sites will be selected based on willingness to participate and capacity to implement the intervention. The SWAT will include patients and SDMs or research coordinators involved in consent encounters relating to participation in REMAP-CAP who are able to read, write and speak English and to receive consent documents either in person or by e-mail.

Interventions and comparators
Intervention 1: We will provide patients or SDMs with an infographic to augment the standard REMAP-CAP consent process. The standard consent process includes consent documents provided to the patient or SDM and an explanation/discussion of the study between the patient or SDM and study team. For consent encounters that occur in-person, a hard copy of the infographic will be provided along with the standard consent documents. For remote consent encounters (by telephone or videoconference), an electronic copy of the infographic will be provided along with the standard consent documents.

Index Type: Participant Information

Method for allocating to intervention or comparator
All participants will receive the intervention in this prospective cohort study.

Outcome measures
Primary: We will collect data regarding the feasibility and acceptance of the infographic using patient-centred outcomes. We will collect data from both patients/SDMs and the research coordinators who participate in the consent encounters.

Patient or SDM outcomes: we will collect data using a modified version of the Consent Understanding Evaluation-Revised tool (CUE-R),[15] which we have called “CUE-R 2”. We modified the CUE-R to be used as a self-administered survey, to include both patients and SDMs as potential survey respondents, and to be shorter in length. Modifications were made through consensus among our multidisciplinary research team, including patients or SDMs, REMAP-CAP research coordinators and investigators. The CUE-R 2 will be used as a self-administered electronic survey using LimeSurvey, with participants receiving a unique survey link that will prevent duplicate responses. The CUE-R 2 includes open-ended, closed-ended and Likert-style questions to assess: trial-related knowledge, satisfaction with the consent encounter, satisfaction with information received, confidence in the consent decision, acceptability/ease of use of consent documents, and acceptability/ease of use of the infographic. The CUE-R 2 concludes with demographic questions to characterize our sample.

Research coordinator outcomes: we will collect data using a modified version of a case report form (CRF) used in a SWAT of video-augmented consent for an ICU rehabilitation trial.[16] Feasibility outcomes will include ease of use of the infographic, consent rate and duration of the consent encounter. Additional outcomes will include the number and difficulty of questions asked by the patient or SDM, perception of patient or SDM comprehension, perception of patient or SDM satisfaction, and perception of confidence in the consent decision. Additional feasibility outcomes will include successful implementation of the infographic and reasons why the infographic could not be implemented. Research coordinators will be asked to complete an electronic CRF for each consent encounter within 24 hours, to decrease the potential influence of recall bias.[17] The electronic CRF will also be hosted on LimeSurvey.
Secondary: N/A

Analysis plans
For the CUE-R 2, we will analyze demographic and survey response data using descriptive statistics, including counts, frequencies and means (standard deviations) or medians (1st, 3rd quartiles) for Likert-style questions or if data are skewed. We will narratively summarize text data from open-ended questions. We will calculate survey response rate as the proportion of completed surveys compared to the number of patients or SDMs invited to participate. We will also calculate the proportion of partially- and fully completed surveys. We will analyze research coordinator CRFs using descriptive statistics.

We will assess success of implementation using three metrics: (1) eligible consent encounters (proportion of patients or SDMs identified to receive the infographic compared to total number of REMAP-CAP consent encounters during the study period); (2) receipt of infographic (number of patients or SDMs who received the infographic as a proportion of eligible consent encounters); and (3) feasibility of data collection assessed by the survey response rate.

Data will be analyzed using Stata. Raw data and analysis files will be password-protected and stored on a password-protected computer with a copy of data files kept on the McMaster University secure network. Only research team members will have access to these files.

Possible problems in implementing this SWAT
We do not see any barriers preventing the execution of this SWAT. We have received ethics approval (Unity Health Toronto REB ID #3779) and do not anticipate any harms to patients, SDMs or research coordinators. We also do not anticipate any impact on the host trial, REMAP-CAP.

References

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Publications or presentations of this SWAT design
Supporting Patients/Families through the Research Consent Process in Critical Care (oral presentation). Canadian Critical Care Trials Group Spring 2021 Meeting. Virtual. June 1, 2021.

Supporting Patients/Families through the Research Consent Process in Critical Care (oral presentation). Canadian Critical Care Trials Group Winter 2022 Meeting. Virtual. January 25, 2022.

Examples of the implementation of this SWAT
N/A

People to show as the source of this idea: Zahra Bhimani, Sandra Dalziel, Barbara Dolanjski, Dr. Michelle Kho, Dr. John Marshall, Dr. Srinivas Murthy, Heather O'Grady, Gyan Sandhu, Marlene Santos, Kathy Smith

Contact email address: ogradyh@mcmaster.ca
Date of idea: 19/APR/2022
Revisions made by:
Date of revisions: