

LETTER OF INFORMATION / CONSENT

Title of Study: The ABCs of Serious Illness: piloting a serious illness communication training curriculum among internal medicine residents.

Investigators:

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You are being invited to participate in a research study conducted by Dr. Megan Smith-Uffen because you are an internal medicine resident at McMaster University enrolled in an oncology rotation. This is a student research project conducted under the supervision of Dr Hsien Seow. Dr. Smith-Uffen is a resident in the Internal Medicine Program at McMaster University. This research will be completed as a part of the research curriculum for that program. The study will help the student learn more about the topic area and develop skills in research design, collection and analysis of data, and writing a research paper.

In order to decide whether or not you want to be a part of this research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study, which will be discussed with you. Once you understand the study, you will be asked to sign this form if you wish to participate. Please take your time to make your decision. Feel free to discuss it with your friends and family and the research team.

The investigators on this study have no conflicts of interest.

WHY IS THIS RESEARCH BEING DONE?

Difficult conversations are common in medical practice and patient-centered communication is essential to care for individuals with serious illnesses. Residency training is a time to build strong communication skills. Proficiency in a variety of communication tasks is now a requirement within competency-based medical education (CBME) in Canada. Currently, educational resources are limited, and residents have indicated a desire for more education on end-of-life communication skills. A formal communication curriculum could fill a gap and help to standardize teaching and evaluation.

Virtual care has been quickly adopted within oncology practice in the context of the COVID19 pandemic. How best to teach communication skills in the context of virtual care is unclear. To mitigate current challenges, we have developed electronic learning modules (ELMs) to create a novel virtual training curriculum entitled “The ABCs of Serious Illness”.

WHAT IS THE PURPOSE OF THIS STUDY?

The overall goal of this study is to establish an effective communication skills curriculum for internal medicine residents that can be delivered remotely and that addresses difficult conversations with patients. Currently, the ELMs focus on oncology. In the future, the curriculum will be expanded to encompass multiple specialties. This project will explore whether the ABCs of Serious Illness oncology ELMs increase self-efficacy and address self-reported weaknesses in communication training for internal medicine residents at McMaster University completing an oncology rotation. This work will provide information to better understand whether a virtual learning curriculum can address identified needs for communication training among internal medicine residents.

WHAT WILL HAPPEN DURING THE STUDY?

If you volunteer to participate in this study, we will ask you to do the following things:

You will be asked to complete a series of online ELMs. There are five modules, each should take 20-30 minutes to complete. There will be content to read and example videos to watch. Links the modules will be sent to your email. You have protected time in your oncology rotation schedule (labelled “Reading” on the schedule sent to you by the oncology administration) to complete the modules. The total expected time to complete the curriculum is ~2.5 hours over the 4-week rotation. You will be asked to complete a pre- and post-curriculum written survey (estimated time to complete is ~5-10 minutes each) and a post-curriculum virtual semi-structured interview (~20-30 minutes).

Surveys will ask about your confidence in end-of-life communicating and your satisfaction with the teaching format. The interview will explore your answers in the surveys. You will be able to sign up at times of convenience for you. Only you and a research assistant will participate in the interview. Information about the platforms used, data collection and data privacy is below.

ARE THERE ANY RISKS TO DOING THIS STUDY?

There are no medical risks to you from participating in this study. Taking part in this study may make you feel uncomfortable. You may become uncomfortable when learning

about and discussing topics related to end-of-life. You may refuse to answer questions on the surveys or in the interview that make you feel uncomfortable. You may stop the interview at any time or take a break. The information collected with this study will not impact on your formal evaluation. Your program director will not have access to your results. If you choose to take part in this study, you will be told about any new information which might affect your willingness to continue to participate in this research. You can withdraw (stop taking part) in the study at any time up until the end of the virtual interview. I describe below the steps I am taking to protect your privacy.

ARE THERE ANY BENEFITS TO DOING THIS STUDY?

We cannot promise any personal benefits to you from your participation in this study. However, possible benefits include improving your confidence and communication skills for end-of-life communication and other difficult conversations with patients with cancer. You may find this experience useful for your overall training goals in residency. Your participation may help other residents by validating novel educational resources for future use. There are no medical benefits to you from your taking part in this study.

WILL I BE PAID OR REIMBURSED FOR BEING IN THIS STUDY?

You will receive a 50\$ gift certificate to your choice of Tim Hortons, No Frills, Shoppers, Metro, or Amazon to compensate you for your time in this study.

WILL THERE BE ANY COSTS?

Your participation in this research project will not involve any additional costs to you.

HOW MANY PEOPLE WILL BE IN THIS STUDY?

It is expected that 15 participants will enter this study. These participants will be internal medicine residents from McMaster University enrolled in an oncology rotation.

WHAT INFORMATION WILL BE KEPT PRIVATE?

This study will use LimeSurvey to conduct the surveys. A link to their data protection policy is available here (<https://www.limesurvey.org/support/faq>). Your responses to questionnaires will be collected according to a unique coded identifier and stored in a secured OneDrive database. No personal or identifying information will be collected, nor will IP addresses be collected. Risk of privacy breach is minimal. Some questions have open text response options and information you choose to share may be identifiable, so please bear this in mind. We ask you to avoid including identifiable information (e.g., name) in these answers, if possible. If identifiable information is shared, we will remove it when analyzing data. You may choose not to answer any questions.

This study will use Zoom to conduct the semi-structured interview. A link to their privacy policy is available here (<https://explore.zoom.us/en/privacy/>). An audio recording will be made with the purposes of allowing the research assistant to transcribe the interview. The audio recording will only be started once you have had a chance to ask any questions you have about the interview. The recording and transcriptions will be de-identified and collected according to unique coded identifiers and stored in a secured

OneDrive database. We ask you to avoid vocalizing identifiable information (e.g. name) during the recording, if possible. If identifiable information is shared, we will remove it when saving the audio file, transcribing the interview, and analyzing the data. You may choose not to answer any question. You may choose to end the interview at any time. By signing this consent form (below), you agree not to make any unauthorized recordings of the content of the interview.

Your program directors will not have access to the recordings or study-related assessments. Participation in the study will not influence your formal evaluations or academic standing within your oncology rotation or postgraduate program. Your identifiable data will not be shared with anyone except with your consent or as required by law. For the purposes of ensuring the proper monitoring of the research study, it is possible that a member of any institutional regulatory body may consult your research data. By signing this consent form, you authorize such access.

If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your specific consent to the disclosure. Direct quotes may be used in the publication/presentation of this data. While the Hamilton Integrated Research Ethics Board has approved using the LimeSurvey, Zoom, and OneDrive platforms to collect data for this study, there is a small risk of a privacy breach for data collected on external servers falling outside the control of the research team. Please talk to the researchers if you have any concerns.

WHAT IF I CHANGE MY MIND ABOUT BEING IN THE STUDY?

Participation in the study is voluntary. You are free to refuse to answer any question or to withdraw at any time. Information you provided up to the point where you withdraw will be kept unless you request that it be removed. In the case of your interview data, you may request it be withdrawn up to the completion of the interview, upon which it will be de-identified and transcribed. Your decision to participate in this study or withdraw from it will in no way affect your residency training.

IF I DO NOT WANT TO TAKE PART IN THE STUDY, ARE THERE ANY OTHER CHOICES?

It is important for you to know that you can choose not to take part in the study. You will have access to any other communication skills training experiences that are provided in your residency program. Choosing not to participate in this study will in no way affect your education or evaluations.

WHAT HAPPENS IF I HAVE A RESEARCH-RELATED INJURY?

There is no expected risk of research-related injury. However, if you sign this consent form it does not mean that you waive any legal rights you may have under the law, nor does it mean that you are releasing the investigator(s), institution(s) and/or funding source(s) from their legal and professional responsibilities.

HOW DO I FIND OUT WHAT WAS LEARNED IN THIS STUDY?

The expected completion date for this study is approximately two years. A summary of the results will be submitted to the McMaster University Internal Medicine Program research department in the form of a report. Results will be synthesized into a publication for peer review. Results may be presented at local, national and international conferences.

IF I HAVE ANY QUESTIONS OR PROBLEMS, WHO CAN I CALL?

If you have questions please contact Dr. Smith-Uffen megan.smithuffen@medportal.ca or the research assistant at abcresearchstudy@gmail.com.

CONSENT

I have read the information presented in the information letter about a study being conducted by Dr. Megan Smith-Uffen and Dr. Hsien Seow of McMaster University entitled ‘The ABCs of Serious Illness: piloting a serious illness communication training curriculum among internal medicine residents’.

I have had the opportunity to ask questions about my involvement in this study and to receive additional details I requested.

I understand that if I agree to participate in this study, I may withdraw from the study at any time up until the end of the virtual interview. By signing below, I also agree not to make any unauthorized recordings of the content of interview/data collection session. I will be given a signed copy of this form. I agree to participate in the study.

Name of Participant (Printed)

Signature

Date

Consent form explained in person by:

Name and Role (Printed)

Signature

Date

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HIREB). The HIREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call the Office of the Chair, Hamilton Integrated Research Ethics Board at 905.521.2100 x 42013.