PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Title of Study: <u>All providers Better Communication Skills program' (ABCs) interprofessional provider education Randomized Controlled Trial</u>

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Sponsor: Health Canada

You are being invited to participate in a research study conducted by Dr. Hsien Seow because you are health care provider, a medical trainee, or an administrator/coordinator involved in health care. A novel virtual educational program is being provided and evaluated across Canada to build serious illness communication skills for health care providers. All enrolled participants in this study will be offered the full education intervention.

To decide whether you want to be a part of this education and research study, you should understand what is involved and the potential risks and benefits. This form gives detailed information about the research study. Once you understand the study, you will be asked to indicate this by typing your name in the designated box on the online consent form, if you wish to participate. Please take your time to make your decision.

The investigators on this study have no conflicts of interest.

WHY IS THIS RESEARCH BEING DONE?

Difficult conversations are common in caring for patients living with a serious illness and patient-centered communication is essential to care for these individuals. High quality communication benefits patients, families and clinicians. Proficiency in a variety of communication tasks is now a requirement within competency-based medical education in Canada.

The ABCs program is a formal communication curriculum developed by a large interdisciplinary team of palliative and end-of-life care clinicians, researchers, and educators, based on years of teaching advance care planning and goals of care discussions workshops. The ABCs adopts a blended format (i.e., participants engage in both asynchronous online modules and synchronous workshops) that has relevance to learners and clinicians at all levels of training and practice. The ABCs program is intended to fill a current gap in standardized education in proficient serious illness communication for all providers.

WHAT IS THE PURPOSE OF THIS STUDY?

The overall goal of this study is to establish an effective communication skills curriculum for health care providers and administrators, that can be delivered remotely and that addresses difficult conversations with patients with a serious illness. Through this study, we will conduct a rigorous evaluation of the ABCs program to assess the process and measure the effectiveness of this training for impacting provider competency and behavior change in serious illness communication. The overall intended impact of the program is to improve clinician satisfaction and confidence for having conversations with patients and families about serious illness, and ultimately, increase access to early palliative care by empowering more health care providers to offer this care.

WHAT WILL MY RESPONSIBILITIES BE IF I TAKE PART IN THE STUDY?

To participate in this education program, you need to provide informed consent and complete the program registration form, an online survey, and a simulated encounter with a standardized patient.

The total time commitment (including enrollment activities) for ABCs program is about 12 hours over a year. This includes: 7 online modules and 3 interactive virtual workshops of about one hour each.
3 virtual simulated encounters with a standardised patient (15 minutes each)
3 on-line surveys (20 mins each)

The on-line surveys will ask you about your confidence in serious illness communicating and your satisfaction with the teaching format. Select participants that complete the ABCs program may be invited (voluntary) to participate in a short virtual interview about your experiences with the program and / or an additional follow-up simulated encounter with a standardised patient and survey (6 months after training).

WHAT ARE THE TWO STUDY GROUPS IN THIS RANDOMIZED CONTROLLED TRIAL? WILL I RECEIVE ACCESS TO THE FULL EDUCATION PROGRAM?

Please note that this education is only being offered as part of a randomized controlled trial research study. All participants will receive the full ABCs program education regardless of the study group they are in.

If you enroll in this study, you will be randomly assigned to one of two groups: Group 1 will begin the education in February, Group 2 will begin the education in September (see the information sheet for the schedule of activities). You will have a 1 in 2 chance of being in a given group.

Neither you, the study staff nor the investigators can influence which group you enter. Regardless of your group assignment, you will be asked to complete the simulated encounters and surveys at the times indicated in the following program schedule.

Course Content	Important Dates
Registration, Consent, Simulated Patient Encounter 1 & Baseline Survey	Oct 1, 2024- Jan 15, 2025
Modules and Workshops	Learning Group 1: Feb 3 - May 30, 2025 Learning Group 2: Sept 8 - Dec 30, 2025 *Learners will be randomly selected to **either** Learning Group 1 or Learning Group 2
Simulated Patient Encounter 2 & Survey	May 12 - July 30, 2025
Simulated Patient Encounter 3 & Survey	Dec 15, 2025 - Feb 20, 2026

HOW WILL CONFIDENTIALITY OF THE SURVEY AND INTERVIEW DATA I PROVIDE BE ENSURED?

We will collect you name and email address from the registration form (stored on a secure McMaster University server) to create you a Moodle account for accessing the ABCs education materials, booking your simulated encounters, and completing the study surveys.

Your responses to questionnaires will be collected according to a unique coded identifier and stored in secured databases. No personal or identifying information will be collected in the study surveys or interview, nor will IP addresses be collected. Survey data will be stored on a Moodle learning management system

(hosted by Lingel Learning, accredited Moodle partner) in encrypted formats, housed on Canadian servers. This platform is compliant with Canadian and International security standards. Privacy and security information can be found here for Moodle: https://moodle.com/security-privacy/

Some participants that indicate (on the final survey) that they are willing to participate in a virtual interview may be contacted to share their experiences regarding the ABCs education and impact. These interviews will be conducted via McMaster University Zoom and the audio data recorded. Recordings will be assigned a unique identifier and housed securely within the McMaster University server. Only study personnel will be able to view the files. The de-identified audio files will be uploaded to McMaster Zoom for transcription. The transcription files will not contain any personally identifying information.

The risk of privacy breach for data collected is minimal. Some survey 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 identifiable information (e.g., name). If identifiable information is shared, we will remove it when analyzing data. As indicated, you may choose not to answer any question.

As mentioned, the ABCs education and study will use the McMaster Zoom platform, which is an externally hosted cloud-based service. A link to their privacy policy is available here:
https://explore.zoom.us/docs/doc/PIPEDA_PHIPA%20Canadian%20Public%20Information%20Compliance%20Guide.pdf

Participants agree not to make any unauthorized recordings of the content of ABCs webinar, education, simulated encounter, or other data collection sessions in Zoom.

While the Hamilton Integrated Research Ethics Board (HiREB) has approved using the platform to collect data for this study, there is a small risk of a privacy breach for data collected on external servers. Please talk to the study coordinator or investigator if you have any concerns.

HOW WILL SIMULATED ENCOUNTERS BE CONDUCTED AND RECORDED? HOW WILL CONFIDENTIALITY OF THESE DATA BE PROTECTED?

Simulated encounters where you will have a conversation with a seriously ill (standardized) patient will be conducted virtually through a McMaster University Zoom link. You will be able to sign up for these encounters at times of convenience for you. Only you and a standardized patient will participate in the encounters. The 3 simulated encounters will be video- and audio-recorded for evaluation later. Recordings will be assigned a unique identifier and housed securely within the McMaster University server. Only study personnel and evaluators (assessing the encounters) will be able to view the files. Evaluators are health care professionals (physician, nurse, psychologist, social worker) who are university faculty, affiliated with the ABCs program, and that have received extensive training in serious illness communicating. Your name or personal information will not be shared with the evaluators, and they will only have access to the recordings that have been randomly assigned to them. Your communication skills will be scored, and these data stored in a secure and anonymized database with unique study identifiers. No personal or identifying information will be stored with the simulated encounter data. Recordings and any identifiable data will be destroyed as soon as the study is completed. De-identified data will be stored for 10 years and then destroyed.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?
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 in the simulated patient encounters when discussing topics related to end-of-life. You may stop the discussion at any time. You may refuse to answer questions on the questionnaires (or in the interview, if applicable) that make you feel uncomfortable.

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. Choosing not to participate in this study will in no way affect your academic or professional standing.

HOW MANY PEOPLE WILL BE IN THIS STUDY?
It is expected that approximately 300 people will participate in this education program and research across Canada.

WHAT ARE THE POSSIBLE BENEFITS FOR ME AND/OR FOR SOCIETY?
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 a serious illness. You may find this experience useful for your overall practice or health service delivery. If you complete the program, you will be provided with feedback on your final simulated encounter and a certificate of program completion. Your participation may help other health care providers and trainees by validating the ABC educational resources for future use.

IF I DO NOT WANT TO TAKE PART IN THE STUDY.
The education program and research are voluntary and you can choose not to take part. If you no longer wish to participate in this educational program and research please contact the study coordinator, Kayla McMillan at mcmilk3@mcmaster.ca or the study investigator, Dr. Hsien Seow at seowh@mcmaster.ca

WHAT INFORMATION WILL BE KEPT PRIVATE?
Your identifiable data will not be shared with anyone except with your consent or as required by law. All personal information such as your name will be removed from the data and will be replaced with a number. A list linking the number with your name will be kept in a secure place, separate from your file. Your personal information (name and email address) and your Moodle account will be deleted once the study is completed. The data, with identifying information removed, will be securely stored electronically on the Principal Investigator's McMaster University Teams account held on a secure server at the university.

It is possible that representatives of the Hamilton Integrated Research Ethics Board, this institution and affiliated sites, and the sponsor may consult your original (identifiable) research data to check that the information collected for the study is correct and follows proper laws and guidelines.

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.

CAN PARTICIPATION IN THE STUDY END EARLY?
If you volunteer to be in this study, you may withdraw at any time. You have the option of removing your data from the study *OR* information provided up to the point where you withdraw will be kept unless you request that it be removed. You may also refuse to answer any questions you don't want to answer on the surveys and remain in the study. The investigator may withdraw you from this research if circumstances arise which warrant doing so.

WILL I BE PAID TO PARTICIPATE IN THIS STUDY?
You will receive $100 in Amazon gift cards for completion of the full education program, specifically $25 for completing each of the 2nd and 3rd (final) simulated patient encounters and surveys.

You may also be asked (voluntarily) to complete a simulated encounter and survey six months after the education intervention and / or to participate in a short virtual interview, for which you would receive $25 (gift card) for each activity.

WILL THERE BE ANY COSTS?
Your participation in this research project will not involve any additional costs to you.

WHAT HAPPENS IF I HAVE A RESEARCH-RELATED INJURY?
There is no expected risk of research-related injury. However, if you indicate agreement with the information in 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 sponsor(s) from their legal and professional responsibilities.

IF I HAVE ANY QUESTIONS OR PROBLEMS, WHOM CAN I CALL?
If you have any questions about the research now or later, please contact the study coordinator, Kayla McMillan at mcmilk3@mcmaster.ca or the study investigator, Dr. Hsien Seow at seowh@mcmaster.ca

CONSENT STATEMENT

Participant:

I have read the preceding information thoroughly. I have had an opportunity to ask questions and all of my questions have been answered to my satisfaction. I agree to participate in this study. I understand that I can download a copy of this form. By agreeing to participate in this study, I do not give up any of my legal rights.

Name	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.