

Appendix E: Take-home Naloxone: A Qualitative Study of Accessibility

St. Michael's

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STUDY INFORMATION SHEET

Study Title: Take-home Naloxone: A Qualitative Study of Accessibility

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Introduction

You are being asked to consider participating in this research study. This information sheet provides details about the study purpose, procedures, and the potential benefits and risks associated with your participation in this study. Before agreeing to participate, it is important that you read and understand the information contained within this letter. All research is voluntary. If you have any questions or concerns, please feel free to contact the research coordinator, Dana Shearer (contact information provided above). Please make sure all your questions have been answered before providing consent to participate in the study.

The purpose of the study

The purpose of the study is to examine experiences of naloxone access (including what makes it easier and harder to get naloxone) among individuals who take opioids, and to identify strategies to improve accessibility to naloxone. In this study, we are particularly interested in learning more about your beliefs about naloxone as well as your experiences of getting and/or using naloxone.

Study description

This study will involve interviews with approximately 40 individuals who use (or have used) opioids and have knowledge of and/or experience with naloxone. The information we will collect from all of these interviews will then be to help us understand people's views of naloxone and experiences getting naloxone kits.

You have been asked to participate in this study as you have been identified as someone with an important perspective to share on this issue. The interview should last approximately 45-60 minutes in length and is designed to get a better understanding of your beliefs about naloxone as well as your experiences of accessing and/or using naloxone.

To ensure we have captured your responses accurately, our interview with you will be audio recorded and then typed up. An experienced researcher from the Applied Health Research Center at St. Michael's Hospital in Toronto will be conducting the interview and analyzing the results.

Results

The results of this study may be presented at a scientific conference or published in a scientific journal. If you are interested in obtaining the results of the study, you can contact the study's Principle Investigator. We expect that the results of the study will be available in September 2019.

Some scientific journals may require us to make your de-identified study data available to the journal, its reviewers, or to other researchers. You will never be personally identified in any publication, report, or presentation that may come from this study.

Direct quotes from your responses may be used in reports or publications, but the quotes will not be attributed to you or contain any information that could be used to identify you.

Confidentiality and Privacy

All persons involved in conducting this study are committed to respecting and protecting your privacy. In accordance with both privacy laws and policies at St. Michael's Hospital, we will make every effort to keep your study information private and confidential.

For the purpose of this study you will be given an anonymous participant code. All data in this study pertaining to you, including the audio recordings and transcripts from your interview, will be labeled with this code. While there will be a list which connects you to your study code, this document will be stored securely and separately from the study data itself.

Any identifying information (e.g., people's names, institutions, etc.) that you do happen to mention in the interviews will not be transcribed. Should you reveal any other details that might be used to identify you indirectly, this will be paraphrased so as to capture the essence of the ideas you have expressed while still protecting your identity. Having said that, we would suggest that you not to disclose any information you deem to be particularly sensitive or which may be used to identify yourself or others.

All hard copy data (e.g., transcripts) related to you will be stored securely within locked filing cabinets at St. Michael's Hospital. The audio file and any other digital files pertaining to you will be stored on password protected computers and drives. The audio-recording of your interview will be destroyed 6 months after publication of the study results. The interview transcripts and all other hard copy and digital study data will be stored at St. Michael's Hospital for a maximum of 5 years, after which time they will be destroyed.

During the course of this research, access to your study data will be limited to the study investigators and their delegates, a professional transcriptionist (external to St. Michael's Hospital), and the Providence St. Joseph's and St. Michael's Healthcare Research Ethics Board for the purposes of monitoring the study. Such access will be used only for the purpose of verifying the authenticity and accuracy of the information collected for the study, without violating your confidentiality to the extent permitted by applicable laws and regulations.

Potential Harms

While every effort will be made to safeguard your privacy, there is always a risk that information may be inadvertently released within a study of this nature, or that you may be identified indirectly by virtue of the things that you say during the course of the interview. However, given the strict procedures we have put in place to deal with these very possibilities (see Confidentiality and Privacy), we anticipate the risks to be very low.

Potential Benefits

We do not anticipate direct benefits that you can expect to receive as a result of participating in this research. However your insights may advance knowledge in an understudied area that may be of personal interest to you.

Participation and Withdrawal

Participation in this study is completely voluntary. If you choose not to participate, this decision will remain confidential. You can withdraw from the study or stop the interview at any point in time, or decline to answer any specific questions without consequence. If you withdraw from the study before the study results have been analyzed, all of your information will be securely destroyed upon your withdrawal. However, if this data has already been distributed for analysis, this may not be possible. Your decision not to participate, to stop participating, or to refuse to answer particular questions will not influence the treatment you may be receiving, the nature of the ongoing relationship you have with your physician and/or members of your medical team, or the nature of your relationship with St. Michael's Hospital either now, or in the future.

Costs and Payments

Your participation in this interview will not involve any additional costs to you. As a token of our appreciation, you will receive a \$25 gift card.

Next steps

If you have any questions or are interested in participating in this research and would like to book an interview, please contact the study coordinator Dana Shearer by phone at 1-888-316-3776 or email at shearerd@smh.ca. Your agreement to participate in the study will be audio recorded prior to conducting the interview, and will constitute your official and informed consent to take part in this study. As such, please make sure that you have reviewed, and fully understand, all of the information contained in this sheet before making your decision. Also, keep a copy of this document for your records.

In no way does your consent waive your legal rights nor release the study investigators or involved institutions from their legal and professional responsibilities.

Remaining questions or concerns

If you have any remaining questions about this study please call the research coordinator Dana Shearer at 1-888-316-3776 or study co-investigator Dr. Cheryl Pritlove at 416-864-6060 ext. 77143. If you have any questions about your rights as a research participant, you may contact Dr. David Mazer, Chair, Providence St. Joseph's and St. Michael's Healthcare Research Ethics Board., at 416-864-6060 ext. 2557.

Thank you!