Informed Consent Form for Participation in a Research Study

Study Title: Can We Improve Quality of Care in Diabetes Clinic through Patient-Entered Electronic Health Data?

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INTRODUCTION

As a Substitute Decision Maker, you are being asked to provide informed consent on behalf of a person who is unable to provide consent for themself. If the participant gains the capacity to consent themself, your consent for them will end. Throughout this form, “you” means you or your child. We encourage parents to include their child in the discussion and decision making to the extent that the child is able to understand.

You are invited to participate in this study because you are currently being followed at CHEO's diabetes clinic and are under 11 years old. Before agreeing to take part in this study, it is important that you read and understand this document. This consent form provides you with information to help you make an informed choice. Please read this document carefully and ask any questions you may have. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Please take your time in making your decision. You may find it helpful to discuss it with your friends and family.

Taking part in this study is voluntary. You have the option to not participate at all or you may choose to leave the study at any time. Deciding not to take part or deciding to leave the study later will not affect the care you receive at CHEO.

IS THERE A CONFLICT OF INTEREST?

The CHEO Research Institute is receiving payment from the funder to cover the costs of conducting the study.

The investigators have no conflicts of interest to declare related to this study.

WHAT IS THE BACKGROUND INFORMATION FOR THIS STUDY?

International guidelines suggest optimal type 1 diabetes (T1D) care delivery involves 3-4 visits per year with a multidisciplinary team. Evolving technology and innovation in the management of T1D has resulted in the collection of a growing number of details from families during their visits. Much of the physician-patient visit is now spent transferring information instead of focusing on T1D care. This contributes to increased time pressures in clinic and reduces time available for simple direct human interaction which underpins optimal therapy, resulting in potential unmet needs for patients, families, and clinicians alike. One way to increase both efficiency and quality of care, is to allow patients and families to provide information in advance of the visit. While pre-clinic questionnaires are common, having the information incorporated directly into the physician's documentation is not. We wish to assess the effect of a patient-facing, electronic health record-enabled questionnaire to collect clinical information on the quality of care in diabetes management.

WHY IS THIS STUDY BEING DONE?

We developed a novel electronic questionnaire (using MyChart® secure patient portal) that allows families to enter information directly into their medical record at CHEO ahead of the clinic visit. This information can then be reviewed and validated by the clinician during the clinic visit.

The purpose of this study is to evaluate the impact of families' pre-clinic input of data into the medical record on patient-reported quality of care, diabetes control and clinic efficiency.

WHAT OTHER CHOICES ARE THERE?

You do not have to take part in this study in order to receive care in the diabetes clinic.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that approximately 200 participants will take part in this study, from the CHEO diabetes clinic.

This study should take approximately just under 1 year (3 regular visits) to complete.

WHAT WILL HAPPEN DURING THIS STUDY?

1. Assignment to a group

If you decide to participate, then you will be "randomized" into one of the groups described below. Randomization means that you are put into a group by chance (like flipping a coin). There is no way to predict which group you will be assigned to. You will have an equal chance of being placed in either group. Neither you, the study staff, nor the study doctors can choose what group you will be in. After you agree to be in the study, and complete the baseline questionnaires, you will be told what group you are in. You will be in the study for a total of 3 clinic visits (baseline clinic and two follow up clinics). The group options are as follows:

Patient facing Electronic Health Record group (intervention):

If you are randomized to this group, you will be asked to complete the patient-facing electronic health record-enabled MyChart® questionnaire up to 7 days prior to two T1D clinic visits. After each of the clinic visits throughout the study, you will complete 2 post-clinic questionnaires about related to the care you received. At the end of the study, you will be asked to complete a questionnaire about your experience with MyChart pre-clinic questionnaire and workflow. The MyChart pre-clinic questionnaire will be completed electronically through your MyChart account. Post-clinic and post-study questionnaires will be completed electronically at home or on paper if you prefer. There will be no additional study visits required for this study.

Standard of care control group (non-intervention group):

If you are randomized to this group you will receive routine clinical care as usual (no MyChart pre-clinic questionnaire, no post-study questionnaire about MyChart tool and workflow). After each of the 3 clinic visits throughout the study, you will complete 2 post-clinic questionnaires about related to the care you received. Post-clinic questionnaires will be completed electronically at home or on paper if you prefer. There will be no additional study visits required for this study.

2. Post-clinic questionnaires

You will be provided 2 post-clinic questionnaires after 3 consecutive diabetes clinic visits. The purpose of these questionnaires is to collect information about patient perceived quality of care. These questionnaires will be provided electronically or via paper. The information you provide is for research purposes only. Even though you may have provided information on a questionnaire, these responses will not be reviewed by your health care team or study team - if you wish them to know this information please bring it to their attention.

We anticipate these questionnaire will take about 10-15 minutes to complete.

You can choose not to answer questions if you wish.

3. Access to health information

The study team will access your medical records to collect some information about you that has already been recorded from previous visits to CHEO, such as date of birth, sex assigned at birth, date of diabetes diagnosis, hemoglobin A1c values from the previous year, visit type (in person or virtual), and number of "no shows" in the previous year. They will also collect information specific to each clinic visit throughout the study, such as visit type (in person or virtual), type of insulin regimen (pump or injections), blood glucose data, and information provided by your doctor about details of the visit including how efficient they felt the visit was.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you choose to participate in this study, you will be expected to complete the study questionnaires and inform the study team if you stop attending CHEO's T1D clinic.

HOW LONG WILL PARTICIPANTS BE IN THE STUDY?

Your participation in this study will last approximately 1 year (3 regular T1D clinic visits).

CAN PARTICIPANTS CHOOSE TO LEAVE THE STUDY?

You can choose to end your participation in this research (called withdrawal) at any time by letting the research team know without having to provide a reason. A decision not to take part, or a decision to withdraw at any time, will not affect the type or quality of care the youth or parent/guardian will receive at CHEO.

Information that was recorded before you withdrew will be used by the researchers for the purposes of the study, but no information will be collected after you withdraw your permission.

CAN PARTICIPATION IN THIS STUDY END EARLY?

Your participation on the study may be stopped early, and without your consent, for reasons such as:

- The research team decides to stop the study
- The research ethics board withdraw permission for this study to continue

If you are removed from this study, the research team will discuss the reasons with you.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

We do not anticipate any risks or harms by participating in this study.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

If you decide to participate, you may or may not benefit directly/immediately from this study. However, the results of this study may help improve care better for children and adolescents with diabetes in our centre and worldwide.

HOW WILL PARTICIPANT INFORMATION BE KEPT CONFIDENTIAL?

If you decide to participate in this study, the research team will only collect the information they need for this study.

Records identifying you at this centre will be kept confidential and, to the extent permitted by the applicable laws, will not be disclosed or made publicly available, except as described in this consent document.

Authorized representatives of the following organizations may look at your original (identifiable) medical records at the site where these records are held, to check that the information collected for the study is correct and follows proper laws and guidelines.

- The Children's Hospital of Eastern Ontario Research Institute, to oversee research at this location;
- The CHEO Research Ethics Board, who oversees the ethical conduct of the study

Information that is collected about you for the study (called study data) may also be sent to the organizations listed above. Your name, address, or other information that may directly identify you will not be used. The record received by these organizations may contain your date of birth, sex assigned at birth and participant code.

In addition to the information collected in the questionnaires about diabetes care leading up to the visit (for experimental intervention group only) and perceptions of diabetes care quality, this research study is collecting information about the patient's demographic, medical history, visit efficiency, and glycemic measures. This is because these characteristics may influence how people respond to technology and new workflows.

Communication via e-mail is not absolutely secure. We do not recommend that you communicate sensitive personal information via e-mail.

If the results of this study are published, your identity will remain confidential. The data may be published or publicly presented during scientific meetings. However, it will not be possible to identify you. You have the right to consult your study file to verify the information gathered, and to have it corrected if necessary.

Even though the likelihood that someone may identify you from the study data is very small, it can never be completely eliminated.

A copy of the consent form that you sign to enter the study will not be included in your health record/hospital chart.

The data collected for this study will be stored for 7 years.

WILL FAMILY DOCTORS/HEALTH CARE PROVIDERS KNOW WHO IS PARTICIPATING IN THIS STUDY?

Your family doctor/health care provider will not be informed by the study team that you are taking part in the study. You can choose to let your family doctor/health care provider know if you like.

WHAT IS THE COST TO PARTICIPANTS?

Participation in this study will not involve any additional costs to you or your private health care insurance.

ARE STUDY PARTICIPANTS PAID TO BE IN THIS STUDY?

If you decide to participate in this study, you will receive a $10 Amazon gift card for each study visit completed, for a maximum of $30.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You will be told, in a timely manner, about new information that may be relevant to your willingness to stay in this study.

You have the right to be informed of the results of this study once the entire study is complete.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected.

By signing this form, you do not give up any of your legal rights against the study doctor or involved institutions for compensation, nor does this form relieve the study doctor or their agents of their legal and professional responsibilities.

You will be given a copy of this signed and dated consent form prior to participating in this study.

WHOM DO PARTICIPANTS CONTACT FOR QUESTIONS?

If you have questions about taking part in this study, or if you suffer a research-related injury, you can talk to your study doctor, or the doctor who is in charge of the study at this institution. That person is:

Dr. Ellen Goldbloom: 613-737-7600 x 1909

If you have questions about your rights as a participant or about ethical issues related to this study, you can talk to someone who is not involved in the study at all. That person is:

The CHEO Research Ethics Board 613-737-7600 x 3272

SIGNATURES

- All of my questions have been answered,
- I understand the information within this informed consent form,
- I allow access to medical records and related personal health information as explained in this consent form
- I do not give up any of my legal rights by signing this consent form
- I agree, or agree to allow the person I am responsible for to take part in this study.

Signature of Participant/ Substitute Decision-Maker	PRINTED NAME	Date

If consent is provided by Substitute Decision Maker: _____ PRINTED NAME of Participant

Signature of Person Conducting the Consent Discussion	PRINTED NAME & ROLE	Date

The following attestation must be provided if the participant is unable to read or requires an oral translation:

If the participant is assisted during the consent process, please check the relevant box and complete the signature space below:

☐ The person signing below acted as an interpreter, and attests that the study as set out in the consent form was accurately sight translated and/or interpreted, and that interpretation was provided on questions, responses and additional discussion arising from this process.

PRINT NAME of Interpreter	Signature	Date

Language

☐ The consent form was read to the participant. The person signing below attests that the study as set out in this form was accurately explained to the participant, and any questions have been answered.

PRINT NAME of witness	Signature	Date

Relationship to Participant