Use of Continuous Glucose Monitors in Publicly-Insured Youth with Type 2 Diabetes - A Pilot and Feasibility Study

NCT05074667

Informed Consent - English January 13, 2022

IRB Use Only
Approval Date: January 13, 2022
Expiration Date: (Does not Expire)

Please check all that are applicable:

☐ I am an adult participant in this study.

Print your name here:

_____

☐ I am the parent or guardian granting permission for a child in this study (the use of "you" refers to "your child" or "your ward.")

Print child's name here:

_____

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FOR QUESTIONS ABOUT THE STUDY, CONTACT: Sejal Shah MD at 650-721-1811, fax 650-725-8375.

DESCRIPTION: You and/or your child are invited to participate in a research study on the use of continuous glucose monitor (CGM) in youth with type 2 diabetes (T2D). This study will be using the Libre 2 CGM which is FDA approved for use by youth with diabetes. The study will use the CGM according to labeling.

We hope to learn how regularly youth with type 2 diabetes will wear CGM devices. Use of CGM is considered the standard of care here at Stanford for youth with diabetes, meaning that regardless of your participation in the study you (as a Stanford patient) would be offered this device. However, the study is able to provide this device sooner and possibility more regularly than usual to study participants. We hope to see if wearing and using a CGM on a regular basis is achievable and to understand if wearing a CGM may change hemoglobin A1C levels and amount of time blood glucose levels are in the goal range. Additionally, we seek to learn about the experiences of patients with type 2 Diabetes (T2D) with Patient Related Outcome surveys (PROs).

The study is expected to last 1-2 years. The duration of your participation in the study is 1 year. We expect to enroll 30 youth with type 2 diabetes.

You/your child will be asked to wear a Libre CGM daily and change the device every 14 days.

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You/your child will be instructed on how to wear and use the CGM during your/your child's regular clinic visits in the diabetes clinic and how to view your blood glucose readings

You/your child will be asked to upload data from your CGM at each clinic visit, this can be done at home or in clinic.

You/your child should continue to take care of your/ your child's diabetes, including taking diabetes medications as instructed by your/your child's diabetes care team.

We are interested in learning about your experience with Type 2 Diabetes and technology; therefore, we are asking patients/families to complete surveys and questionnaires about this throughout the study. You/your child will be asked to complete questionnaires at 3 time points during the study. These questionnaires are part of the study and not part of regular care in the diabetes clinic at Stanford.

The PROs screening measure consists of four short questionnaires for youth aged ≥ 6 years:

- PROMIS Pediatric Global Health scale (PGH-7) – 7 questions (only for youth aged ≥ 11 years)
- Problem Areas in Diabetes – Pediatric – 11-14 questions (only for youth aged 8-17 years)
- Diabetes technology Questionnaire – 5 questions
- Pediatric Quality of Life Inventory (PedsQL) Diabetes (only for youth < 18 years of age)

The PROs screening measure consists of three questionnaires for parents/guardians:

- Problem Areas in Diabetes – Pediatric – 14-16 questions
- Diabetes Technology Questionnaire – 5 questions
- Pediatric Quality of Life Inventory (PedsQL) Diabetes

PROs questionnaires will be completed at 3 time points during study participation:

- Baseline (at time of CGM start)
- 3 months from Baseline
- 12 months from Baseline

Participation time is estimated to be approximately 20 minutes per time point.

The initial survey is completed electronically using an electronic secure database called REDCap. You will be emailed or texted a link to complete the surveys. During the CGM visit, we will ask that you provide an email or text number (you will be asked which you prefer) that will be the platform for contact for the future surveys. You will have the option of filling out the questionnaires in English or Spanish.

Visits for this study will be done during your/your child's regular diabetes clinic visits. You/your child will be provided with CGM supplies at the first visit and additional CGM supplies half-way between each visit if your/your child's insurance does not provide full, no-cost coverage of the CGM supplies.

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Future use of Private Information

Research using private information and/or specimens is an important way to try to understand human disease. You are being given this information because the investigators want to save private information for future research.

Your/your child's data (Hemoglobin A1C results, glucose data, CGM wear time and medical history and diabetes care plans) will be stored as part of your/your child's medical record. The information collected as part of the study is already collected as part of your/your child's diabetes clinic visit.

Identifiers might be removed from identifiable private information and/or identifiable specimens and, after such removal, the information and/or specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent form.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of such as child abuse and neglect, or harm to self or others.

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RISKS AND BENEFITS: There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with the Protocol Director if you have any questions.

- You/your child will be required to wear the CGM at all times.
- You/your child's CGM glucose data will be shared with our care team from your device to our medical record system and reviewed by your diabetes care provider at your/your child's diabetes clinic visit.
- You/your child will be required to upload your CGM data for a telehealth clinic visit or bring the CGM to your/your child's diabetes clinic visit.
- The study may involve risks to the subject, which are currently unforeseeable
- Survey questions may make study participants uncomfortable
-

The benefits which may reasonably be expected to result from this study are that review of your/your child's CGM glucose data at each clinic visit will provide more information to you/your child and your/your child's diabetes care team which may help manage your/your child's diabetes better. We cannot and do not guarantee or promise that you will receive any benefits from this study.

Your decision whether or not to participate in this study will not affect your employment/medical care.

TIME INVOLVEMENT: Your/your child's participation in this study will take approximately 1 hour for the first visit to learn to use the CGM. You/your child will be asked to wear the CGM and monitor blood glucose levels as recommend by the diabetes care team and attend regularly scheduled diabetes clinic visits every 1 to 3 months. You/your child will be asked to complete surveys at 3 time points during the study, we expect it to take 20 minutes to complete the survey. The duration of the study is 1 year (12 months).

PAYMENTS/REIMBURSEMENTS: You will not receive payment for your participation.

Sponsor
The Maternal & Child Health Research Institute at Stanford University is providing financial support for this study.
National Institutes of Health is providing financial support for this study
Abbott is providing CGM supplies.

PARTICIPANT'S RIGHTS: If you have read this form and have decided to participate in this project, please understand your participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled.

The results of this research study may be presented at scientific or professional meetings or published in scientific journals. However, your identity will not be disclosed**.**
You have the right to refuse to answer particular questions.

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Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

COMPENSATION FOR RESEARCH RELATED INJURY: All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. In spite of all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. You will be responsible for any associated co-payments or deductibles as required by your insurance.

If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

Authorization To Use Your Health Information For Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?

This study will be using the Libre 2 CGM and LibreView which are FDA approved for use by youth with diabetes and are being used according to labeling. We hope to learn how regularly youth with type 2 diabetes will wear CGM devices. We

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hope to see if wearing and using a CGM on a regular basis is achievable. Another goal of this study is to determine how wearing a CGM may change hemoglobin A1C levels and amount of time blood glucose levels are in the goal range. We hope to learn if using and wearing a CGM can help youth with type 2 diabetes take better care of their diabetes and their health. We also seek to understand the impact of having type 2 diabetes and using CGM on patients and parents/caregivers. The participant's individual health information will be used in regular clinical care as part of the participants diabetes clinic visit. We will publish data collected from this study without identifying information. The information in some form will be submitted to the sponsor.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study

Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to:

Dr. Sejal Shah, Center for Academic Medicine, 453 Quarry Road, MC 5660, Stanford, CA 94304

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study, may be used or disclosed in connection with this research study, including, but not limited to: name, medical record number, date of birth, phone numbers, email and home addresses, date of diabetes diagnosis, demographics (age, sex, etc.), Anthropometric measurements (i.e.: height, weight, BMI), other medical conditions, Laboratory results (e.g.: hemoglobin A1c values), date of clinic visits, contacts with the care team,

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insurance type, pump use, CGM use, changes in insulin doses, prescriptions and other medications, and questionnaires.

Who May Use or Disclose the Information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director Dr. Sejal Shah
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary
- Research Staff

Who May Receive or Use the Information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The Food and Drug Administration
- The Maternal & Child Health Research Institute at Stanford University
- National Institutes of Health

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on 12/31/2050 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

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_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
Print Name of LAR

_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

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WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to withdraw your consent and discontinue your participation at any time. Your decision will not affect your/your child's ability to receive medical care for your/your child's disease and you will not lose any benefits to which you/your child would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify (Dr. Sejal Shah) at (650)-721-1811.

- You/your child will not receive CGM supplies through the study
- You/your child will continue to receive medical care for the diabetes clinic
- You/your child may still contact your diabetes care team to review glucose data

The Protocol Director may also withdraw you from the study ability to use CGM devices from the study will be stopped, without your consent for one or more of the following reasons:

- Failure to follow the instructions of the Protocol Director and study staff.
- The Protocol Director decides that continuing your participation could be harmful to you.
- You need treatment not allowed in the study.
- The study is cancelled.
- Other administrative reasons.
- Unanticipated circumstances.
- You/your child is not longer a patient in the Pediatric Diabetes Clinic at Stanford Children's Health

CONTACT INFORMATION:

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Sejal Shah You may contact him/her now or later at 650-721-1811

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Sejal Shah at 650-721-1811.

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Appointment Contact: If you need to change your appointment, please contact the Pediatric Diabetes Clinic at 650-721-1811

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EXPERIMENTAL SUBJECTS BILL OF RIGHTS: As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and
- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you?
____ Yes ____ No

The extra copy of this signed and dated consent form is for you to keep.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Legally Authorized Representative (LAR) Date
(e.g., parent, guardian or conservator)

_____
Print Name of LAR

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_____
LAR's Authority to Act for Participant
(e.g., parent, guardian or conservator)

_____ _____
(If available) Signature of Other Parent or Guardian Date

_____
Print Name of Other Parent or Guardian

_____
Authority to Act for Participant

The IRB determined that the permission of one parent is sufficient in accordance with 45 CFR 46.408(b)

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent

The following witness line is to be signed only if the consent is provided as a summary form and accompanied by a short form foreign language consent.

_____ _____
Signature of Witness Date

_____
Print Name of Witness

(e.g., staff, translator/interpreter, family member)

- *Translated short form must be signed and dated by both the participant (or their LAR) AND the witness.*
- *The English consent form (referred to as the "Summary Form" in the regulations):*
  - *Must be signed by the witness AND the Person Obtaining Consent (POC).*
  - *The non-English speaking participant/LAR does not sign the English consent.*

- *The non-English speaking participant/LAR should not sign the HIPAA participant line*
- *If the participant or the LAR is non-English speaking, the Person Obtaining Consent (POC) must ensure that 1) the LAR's Description of Authority is completed and 2) that any questions or options presented by the consent form are documented and initialed by the POC on the Summary Form, per the participant's wishes, as they are understood during the consent process.*