Title: Continuous Glucose Monitoring in the Intensive Care Unit

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UNIVERSITY OF MASSACHUSETTS MEDICAL SCHOOL

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS IN RESEARCH

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Title: Phase 1 Study of the Dexcom G7 continuous glucose monitor (CGM) in the intensive care unit (ICU) at the UMass Memorial Medical Center

Sponsor: Department of Medicine, Program in Digital Medicine, Division of Diabetes and Endocrinology

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Consent Version: May 7, 2023

You are being invited to take part in a research study. Someone will explain this research to you. This form helps to sum up their explanation.

In this form, "you" generally refers to the person who takes part in the research. If you are being asked as the legally authorized representative, parent, or guardian to allow someone else to take part, "you" in the rest of this form generally means that person.

KEY INFORMATION:

You are being invited to participate in a research study because you have an illness that requires care in an intensive care unit (an ICU) AND you have a **high blood sugar level**, likely as a result of diabetes.

If you have questions or don't understand something, please ask.

Taking part in this research is voluntary and completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled.

The main question this study is trying to answer is if a continuous glucose monitor (often called a CGM) for measuring blood glucose is accurate enough to use to help control blood sugar levels in the ICU.

If you join this research, you will have a CGM placed on your skin. There are no placebos or randomization.

If you agree to participate, you will be asked to let us put a continuous glucose monitor, specifically one called a Dexcom G7, on your arm or leg where it will not interfere with your care. The monitor will stay on for up to 10 days or until you leave the ICU.

You need to know that this is a research study. Because we want to find out how accurate the monitor is, we will not use the blood sugar results it gives us to take care of your high blood sugars during his hospital stay. Managing your blood sugar will be done using the standard ways of measuring blood sugar with fingersticks or by sending blood drawn from a vein to a laboratory. Your participation will not affect your medical care in any way. It will only help us learn if the monitors are accurate in the ICU. If we learn that the continuous monitor is accurate and does not cause any unforeseen problems, we may use it to replace fingerstick blood sugars in the ICU in the future.

When the CGM is taken off by peeling off the adhesive patch, you will not need to do anything further.

Your participation is entirely voluntary. Taking part in this research is completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled. Not participating will not affect your medical care in the ICU in any way.

You may not want to be in this study if you are uncomfortable with:

- Having a blood sugar monitor attached to your skin with an adhesive patch.
- Sharing your information with researchers.

Risks: The risks of having a continuous glucose monitor on your skin are small but they include:

- You might develop a skin rash or irritation from the adhesive patch that keeps the CGM in place. Skin irritation or rash may occur in approximately 10% of persons (1 in 10 people). This will be treated by removing the device.
- You might develop a skin infection at the site of the CGM placement. This will be treated by removal of the device and appropriate antibiotics if deemed necessary by clinical staff.

- ~~The 3/32 inch long needle of the CGM that penetrates the skin could break off. If it does, it will be removed by clinical staff.~~Minor bleeding and bruising may occur.
- The short wire that goes into your skin to measure your blood sugar could break off. This needle is about as thin as two human hairs and about a quarter of an inch long. If it breaks happens, it will be removed by the doctors in the ICU."
- There is a risk that someone could get access to the data we have stored about you. If those data suggest something serious about your health, it could be misused. For example, it could make it harder for you to get or to keep a job or insurance. We believe the chance these things will happen is very small, but we cannot make guarantees..

Benefits: If the continuous glucose monitor proves to be accurate

- There is no direct benefit to you if you take part in this research. Your participation will help us to gain knowledge that may help treat seriously ill persons with diabetes in the future.

Alternatives: If you do not participate in this study, you will receive standard care in the ICU and your blood sugar will be measured the way it is usually done.

~~**Conflict of Interest:** None of the persons involved in this study have any financial interest in the success or failure of the Dexcom G7~~

If you think you might like to participate in this research, please continue reading to learn more about the details of this study.

Commented [JM1]: The deleted text in this section has been moved to the study details section as requested.

STUDY DETAILS

Why is this research being done?

As part of getting you well and out of intensive care, nurses will have to check your blood sugar many times, anywhere from 4 to 8 times a day. Most of those blood sugar checks will be done by pricking your finger with a sterile pin and squeezing out a drop of blood. These "fingerstick" blood sugars have been used for years by persons with diabetes, and at this time these "fingerstick" blood sugars are how diabetes is managed all the time in an ICU. They give your doctors and nurses the information they need to decide on the right therapy including the right amount of insulin that may be needed.

Recently companies have developed a new way to measure blood sugar that uses "continuous glucose monitoring." These are very small devices shaped like a coin, about the size of a dime, with a small ~~(3/32 inch)~~ needle in the middle that is about as thin as two human hairs and a quarter of an inch long. An applicator with a spring in it applies the CGM to your skin, and a band-aid-like patch keeps it in place. CGMs stick to the skin for up to 10 days and measure your blood sugar every 5 minutes. Putting them on involves only one pinprick. They are now approved by the Food and Drug Administration and commonly used at home and in diabetes clinics. They provide a lot more information than fingersticks, and when used together with a phone app can warn about high and low blood sugar.

At this time, however, CGMs are not yet approved to use in hospitals or intensive care units because they have not been tested for accuracy and reliability. This research study is to find out if they are good enough to use in the intensive care unit, and we are asking people like you to help us find that out.

How many people will take part in this research?

About 24 people will take part here at UMass Chan Medical School.

How long will I be in this research?

You will participate in this study for up to 10 days or until you are discharged from the ICU.

What happens if I say yes, I want to be in this research?

While you are a patient in the ICU you will receive standard care for your condition. This research will not affect that care.

While you are in the ICU, we will put a CGM on the skin or your arm or leg. The CGM is called a Dexcom G7 and is about the size of a dime; an adhesive patch will hold it on. Many persons with diabetes use it at home.

The CGM will measure your blood sugar every 5 minutes and send the measurements to an iPhone. After you leave the ICU those CGM readings will be compared with the sugar that were obtained in the course of routine care in the ICU when blood is obtained from a vein, or a drop of blood is obtained by a fingerstick. The research CGM blood sugar readings will not be used by anyone caring for you in the ICU.

We will also keep a record of any problems with the CGM such as it falling off or causing skin irritation.

Will you be collecting any specimens from me?

No.

~~**Could being in this research hurt me?**~~

- ~~Skin irritation or rash may occur in approximately 10% of persons (1 in 10 people)~~
- ~~Minor bleeding and bruising may occur.~~
- ~~The short (3/32 inch) wire that goes into your skin to measure your blood sugar could break off. If this happens, it will be removed by the doctors in the ICU."~~
- ~~Skin infection may occur.~~
- ~~Breach of confidentiality We will take steps to protect your personal information. However, there is a risk of breach of confidentiality.~~

~~Once it is in place, people wearing a CGM are generally unaware of its presence.~~

Will this research help me in any way?

- There is no direct benefit to you from participating in this study.
- There are possible benefits to ICU patients in the future.
  - Your participation will help us to gain knowledge that may help treat seriously ill people with diabetes in the future.
  - Future patients may be saved from the pain of frequent fingersticks.
  - Doctors will have much more information on blood sugar levels that will help them keep blook sugar in the normal range, avoiding both highs and lows.
  - ICU staff will receive alerts if your sugar is going dangerously high or low.

What other choices do I have besides taking part in this research?

- The diabetes care you receive in the ICU will be exactly the same whether or not you take part in this research.

Will it cost me any money to take part in this research?

~~There is no direct cost to you.~~

You or your insurance will not have to pay for tests and procedures that are done for research purposes only.

However, you or your insurance will be billed for all routine medical and diagnostic costs that are part of the standard of care for treating your condition. This may include the cost of tests, procedures, or medicines to manage any side effects. You will be responsible for any deductibles, co-payments, or co-insurance payments that your coverage normally requires.

Will I be given any money or other compensation for being in this study?

You will not be paid for taking part in this research.

What happens if I am injured because I took part in this research?

- If you are injured while in the study, the doctors and nurses in the ICU will attend to that injury.

- The ~~University of Massachusetts~~UMass Chan Medical School does not provide funds for the treatment of research-related injury. If you are injured as a result of your participation in this study, treatment will be provided. You or your insurance carrier will be expected to pay the costs of this treatment. No additional financial compensation for injury or lost wages is available.
- You do not give up any of your legal rights by signing this form.

What are my responsibilities if I take part in this research?

You have no specific responsibilities if you take part in this research.

What happens if I say yes, but I change my mind later?

If you change your mind, the CGM will be removed. This will not affect your care because the CGM data collected in this study is not used for making patient care decisions.

Can I be removed from the research without my approval?

You can be removed from the research for the following reasons.

- The CGM has to be removed due to malfunction or adverse skin reactions.
- The CGM has to be removed because you need an MRI imaging study.

How will my information be stored and when will it be destroyed?

We will remove your name and any other information that could directly identify you from your data. We will replace this information with a code number. We will create a master list linking your code number to your name. We will keep this list separate from your data.

We will keep electronic health information and research data on secure computer networks. These computer networks have many levels of protection.

There is no limit on the length of time we will store your data. We will destroy the master list of identifiers as soon as the analysis of the data is complete.

It is possible that we might use the research data in future research. We may also share data with researchers and companies that are not part of UMass Chan. In these cases, we will not share your name or other information that identifies you directly, and we will not come back to you to ask you for your consent.~~It is possible that we might use the research data and specimens in future research. We may also share data and specimens with researchers and companies that are not part of UMass Chan. In these cases, we will not share your name or other information that identifies you directly, and we will not come back to you to ask you for your consent.~~

Who has access to my information?

Your medical record will contain a copy of this form. Other doctors, nurses, and third parties (like insurance companies) may be able to see this information as part of the regular treatment, payment, and health care operations of the hospital. We may also need to disclose information if required by law.

Monitors, auditors, the Institutional Review Boards, and regulatory authorities will be granted direct access to your original medical records for verification of clinical trial procedures and data. These individuals have been trained to protect confidentiality.

Your authorization does not have an expiration date. If you change your mind, you have the right to revoke your authorization in writing or using the contact information at the beginning of this form. If you revoke your authorization, you will not be allowed to continue to participate in the study. We will not collect any new information about you. However, information that we have already collected will stay in the study database and cannot be removed to maintain the integrity of the research. Your information may still be used and disclosed if you have an adverse event.

You do not have to sign this authorization. If you choose not to sign, it will not affect your treatment, payment, or enrollment in any health plans, or affect your eligibility for benefits. You will not be allowed to participate in the research study.

We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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.

Who can I talk to?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed on the first page.

This research is being overseen by an Institutional Review Board. An IRB is a group of people who perform independent reviews of research studies. You may talk to them at (508) 856-4261 or irb@umassmed.edu for any of the following:

Your questions, concerns, or complaints are not being answered by the research team.

You cannot reach the research team.

You want to talk to someone besides the research team.

You have questions about your rights as a research participant.

You want to get information or provide input about this research.

Signature Block for Capable Adults

Your signature documents your consent to take part in this research.

Signature of adult research participant	Date
Printed name of adult research participant	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

Signature Block for Adults Unable to Consent

Documentation of assent is not required. Your signature documents your permission for you or the individual named below to take part in this research.

Signature of adult incapable of consent's legally authorized representative	Date
Printed name of the legally authorized representative	
Explain representative's relationship to, and authority to act on behalf of, the research participant	
Printed name of research participant	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

- Your participation is entirely voluntary. Taking part in this research is completely up to you. You are free to say no or to leave the research at any time. There will be no penalties or changes in the quality of the health care you receive, and you will not lose any benefits to which you are otherwise entitled. Not participating will not affect your medical care in the ICU in any way.