A Patient Portal Intervention to Address Diabetes Care Gaps: A Usability Study

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Informed Consent Document

May 4, 2021

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Institutional Review Board
Informed Consent Document for Research
Principal Investigator: William Martinez, MD, MS
Version Date: May 4, 2021
Study Title: My Health At Vanderbilt Diabetes Care Gaps Usability Study
Institution/Hospital: Vanderbilt University Medical Center

The following information is provided to inform you about the research project and your participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:

The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

What is the purpose of the study?

The purpose of the study is to find out what you think about a new feature in the My Health at Vanderbilt (MyHealth) app. The new feature alerts you when it is time for certain types of diabetes care. The new MyHealth feature also lets you request the care via the app. This care includes A1C blood tests, urine protein tests, diabetes eye exams, and pneumonia shots. You will receive a confirmation message once your request is processed. The message will let you know what to do next to get the diabetes care you requested. Your primary care doctor will be the authorizing doctor and will receive your results.

Time Commitment:

You will complete three email surveys over the three months you are in the study. Each survey takes about 20 minutes to complete. At the end of the study, you might also be invited to do an interview with someone from our team. The interview will take about 30 minutes.

Potential Risks:

The time it takes to be in the study might be difficult for you. You might not like giving your opinions and giving feedback. You do not have to answer any question you do not want to answer. There is a risk of loss of privacy. All efforts, within reason, will be made to keep the personal information in your study record confidential.

Potential Benefits:

You might learn when it is time for certain types of diabetes care. You might learn why certain types of diabetes care are important. You might receive diabetes care that can help prevent health problems.

Potential Costs:

You are responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. The diabetes care you request via using the new MyHealth feature is considered usual care. These costs will be billed to you and/or your insurance.

To be in the study, you will need a smartphone or tablet that can run the MyHealth app. You will NOT be paid for costs related to your smartphone or tablet use or internet access.

Detailed Information:

The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to be in this study because you receive care at Vanderbilt University Medical Center (VUMC) and have diabetes. You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

Procedures to be followed and approximate duration of the study:

The study will last about 3 months. You will be asked to complete surveys, use the new MyHealth feature, and provide feedback. There are three parts to this study: enrollment, using the new feature, and follow up. Some participants will also be invited to do a follow-up interview with someone from our team. The interview will help us better understand your experience using the new feature. Below is a breakdown of activities in each part of the study.

Enrollment:

You will complete your first survey.You will be given access to the new MyHealth feature and instructions on how to use it.You will have access to the new feature for 3 months.

After You Use the New MyHealth Feature:

After using the new MyHealth feature for the first time, you will complete a survey about your experience.

Three-month Follow-up:

You will complete your final survey.You might also be invited to do a follow-up interview with someone from our team. We will do interviews over the phone or Zoom video conference.

We will email you each survey at the appropriate time. Each survey takes about 20 minutes to complete. We will track how you use the new MyHealth feature. We will get information about your health problems, medicines, lab tests, and vaccines from your medical record. We will use this information to make sure you are eligible to be in the study. We will also use this information to describe the medical history of the people in the study.

Expected costs:

You are responsible for paying for the routine care for receive for your health conditions. This includes the diabetes care you request using the new MHAV feature. These costs will be billed to you and/or your insurance.

You have the right to contact your insurance company to discuss the costs of your routine care (non-research) before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you. You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program.

To be in the study, you will need a smartphone or tablet that can run the MyHealth app. You will NOT be paid for costs related to your smartphone or tablet use or internet access.

Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:

The time it takes to be in the study might be difficult for you. You might not like giving your opinions and giving feedback. You do not have to answer any question you do not want to answer. There is a risk of loss of privacy. All efforts, within reason, will be made to keep the personal information in your study record confidential.

Unforeseeable risks:

Because this feature of MyHealth is new, there may be risks that we do not know about at this time.

Good effects that might result from this study:

The benefits to science and humankind that might result from this study.You being in the study might help our team make tools to help people with diabetes take care of their health.

The benefits you might get from being in this study. You might learn when it is time for certain types of diabetes care. You might learn why certain types of diabetes care are important. You might receive diabetes care that can help prevent health problems.

Study Results:

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 the end of the study, the Web site will include a summary of the results. You can search this Web site at any time.

Compensation for participation:

You may be paid up to $140 total for being in the study.

Enrollment:

$30 for finishing your first survey

After You Use the New MyHealth Feature:

$10 for using the feature for the first time$30 for finishing a survey you get after you use the feature for the first time

Three-month Follow-up:

$30 for finishing the follow-up survey$40 if you are invited for an interview and you finish the interview

After your finish a survey or interview, you will fill out a form and a prepaid debit card or check will be mailed to your home address.

Circumstances under which the Principal Investigator may withdraw you from study participation:

You may be withdrawn from the study if:

Our team finds that you are not eligible orYou do not finish the enrollment questionnaire orYou are not willing or able to use the MyHealth app on a mobile deviceIf you are withdrawn from the study for any reason, we will let you know and give you a reason.

What happens if you choose to withdraw from study participation?

You can withdraw from the study at any time by contacting our study team. The contact information is below. If you withdraw from the study, it will not affect the medical care you get at Vanderbilt. If you withdraw from the study, our study team will stop collecting data about you. However, the data we collected before you withdrew from the study will stay in your study record.

Contact Information.

If you should have any questions about this research study or possibly injury, please feel free to contact William Martinez, MD, MS at 615-669-3160 or email the study team at MHAVStudy@vumc.org.

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality:

All efforts, within reason, will be made to keep your personal information in your research record confidential but total confidentiality cannot be guaranteed. We will have a record of your name on this form. We will remove your name and other identifiers from your surveys, interviews, medical record information, and information about how you use of the new MyHealth feature. Instead, we will identify you with a number (for example 001). A document linking your number to your name will be kept separately. We will record study interviews to use to make a written record. Then, we will delete the recording. When we report the results of the study, we might include quotes from you. If we quote you, we will never give your name or any other identifying information about you. All study data will be stored on secure, password protected, computer servers.

This study may have support from the National Institutes of Health. If so, your study information is protected by a Certificate of Confidentiality. This Certificate allows us, in some cases, to refuse to give out your information even if requested using legal means.

It does not protect information that we have to report by law, such as child abuse or some infectious diseases. The Certificate does not prevent us from disclosing your information if we learn of possible harm to yourself or others, or if you need medical help.

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:

Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name or other identifiers. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing (“disclosure”) such data must follow federal privacy rules. By signing the consent for this study, you are agreeing (“authorization”) to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Vanderbilt University Medical Center may share the results of your study and/or non-study linked questionnaire and interview responses, as well as parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the VUMC Institutional Review Board, Vanderbilt University, and National Institutes of Health. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private.

The sponsor and/or Vanderbilt may give or sell your health data, without identifiers, to others or use it for other research projects not listed in this form. The sponsor, Vanderbilt, Dr. William Martinez (Principal Investigator) and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

Authorization to Use/Disclose Protected Health Information

What information is being collected, used, or shared?

To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?

The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?

You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?

Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?

You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

The Principal Investigator's mailing address is:

William Martinez, MD, MS

Vanderbilt University Medical Center

Division of General Internal Medicine

2525 West End Avenue, Suite 450

Nashville TN 37203

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any

health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read and understood the informed consent document. All my questions have been answered, and I freely and voluntarily choose to participate.

◯ Yes
◯ No

Please sign below to indicate that you read and understood the consent document, and that you voluntarily accept to participate in this study.

_____

Please print your FIRST name:

_____

Please print your LAST name:

_____

Please provide your date of birth:

_____

Please provide us with your phone number so we can contact you:

_____

Please provide us with your email address so that we can contact you:

_____

Thank you for your interest in this research study.

Please advance to the next page and download or print a copy of your consent form and keep it for your records. Please note you must certify your information on the next page (by clicking on the certify box) and then click 'Submit' in order to be enrolled in the study.

We will contact you within one week to provide further instructions.

Thank you for your consideration. You will not be enrolled in the study.

Please close your web browser and do not continue to the next page.

Thank you for your time.