

Crossing the Divide

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11/28/2022

HS IRB #: 2022-1338

Lead Researcher: Dr. Meghan Brennan; (608) 263-1545

Version: 11/28/2022

**University of Wisconsin-Madison
Consent to Participate in Research
and
Authorization to Use Protected Health Information for Research**

Study Title for Participants: Crossing the Divide

Formal Study Title: Crossing the divide: piloting an integrated care model to bridge rural-urban healthcare systems and reduce major amputations among rural patients with diabetic foot ulcers

Lead Researcher: Dr. Meghan Brennan, MD, MS

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Where Lead Researcher works: Department of Medicine; Division of Infectious Disease

Invitation

We invite you to take part in a research study about caring for rural people with diabetic foot ulcers. We are inviting you because you have developed a diabetic foot ulcer, are a patient at a rural clinic involved in the study, and your primary care provider is participating in the study.

The purpose of this consent and authorization form is to give you the information you need to decide whether to be in the study. It also explains how health information will be used for this study and requests your authorization (permission) to use your health information. Ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. When we have answered all your questions, you can decide if you want to be in the study. This process is called "informed consent."

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Why are researchers doing this study?

We are doing this research because over 2 million Americans develop a diabetic foot ulcer each year, and rural patients with diabetic foot ulcers are more likely to undergo a major amputation or die than urban patients. Our study has two specific purposes: 1) to see if an intervention based on national guidelines helps provider(s) care for rural patients with diabetic foot ulcers, and 2) to help us figure out how best to work with rural patients and their providers to study this disease.

This study is being done at the University of Wisconsin-Madison (UW-Madison) and three rural Wisconsin clinics. A total of about 45 patients will participate in this study.

Funding for this study is provided by the National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases – 1R01 DK132569-01

What will happen in this study?

If you decide to participate in this research study, you will be receiving treatment from your regular healthcare team. They will use our integrated care model. The integrated care model maps out the different actions your provider can take in managing your foot ulcer and is based on national guidelines. Your provider will use the map to determine what next steps are appropriate in caring for your foot ulcer, which we anticipate will help reduce major amputations compared to usual care. Your primary care team will be able to modify these guidelines so that they best suit your particular needs. The integrated care model also includes tools that your primary care clinic can use to communicate with specialists so that, if you need a referral to a specialist, you may be seen more quickly. It will also help your provider be sure that the specialist has all the important information to help care for you. The study team will monitor your medical chart to see how these tools affect your care.

In addition to this initial meeting to review the study and sign informed consent, you will also receive a phone call after 3 months to discuss your ulcer, which should take about 10 minutes. Other than that, you will not need to contribute any additional time beyond your regular clinic appointments that you are already attending.

Protected health information (PHI) used in this study

Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, like

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your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Information currently in your medical records as well as information added to your medical records during the course of this study. This information could include your medical history, diagnoses, medications, test results, exam details, and specialty referrals. We will be focusing on information related to your foot ulcer, diabetes, and cardiovascular health. We will get this information from your health care providers and the electronic medical record.

How long will I be in this study?

You will be part of the study for about 3 months. At the three-month mark, you will receive a short phone call to discuss the outcome of your ulcer, which should take about 10 minutes.

How is being in this study different from my regular health care?

If you take part in this study, the main difference between your regular care and the study is that your primary care provider will be following an integrated care model based on national guidelines of care to streamline the care process. If you require specialty care, the integrated care includes a checklist to help your primary care provider collaborate with the specialist and get you seen in a timely manner. Your provider may deviate from the model based on their best clinical judgment, so that you will always receive care tailored to your needs.

Do I have to be in the study? What if I say “yes” now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide now to take part, you can choose to leave the study at any time.

Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with healthcare providers at

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your primary care clinic, UW-Madison, UW Health or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) does not have an end date. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the research.
- If you take back your authorization, information that was already collected may still be used and shared with others, but the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study.
- To take back your authorization, you will need to tell the researchers by writing to the Lead Researcher, Dr. Meghan Brennan, at 1685 Highland Avenue, Madison, WI 53705.

What are my other choices if I do not take part in this study?

You do not have to be in this research study to get care for your diabetic foot ulcer. If you decide not take part in the study, you have other choices. For example:

- you may choose to get the regular care for diabetic foot ulcers

Will being in this study help me in any way?

- Being in this study may reduce your risk of amputation due to a diabetic foot ulcer by helping your clinicians provide care that follows national guidelines. Even if the study does not help you directly, your participation in this study may help other people in the future by helping us find out how well the integrated care model works and improving it.

This study is not a substitute for your regular medical care. You should continue to see your regular medical providers.

What are the risks?

All studies have possible risks. However, this study has minimal risk. We do not anticipate any additional risks associated with this study beyond those associated with regular care. The risk of amputation due to diabetic foot ulcer will be the same or reduced compared to usual care. There is a risk that your information could become known to someone not involved in this study.

Will being in this study cost me anything?

- There will be no cost to you for any of the study activities or procedures.
- You or your insurance company will have to pay for all costs for medical care related to participation in this study, including co-payments and deductibles. You will have to pay for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may have to pay, you should contact your insurance company.

Will I be paid or receive anything for being in this study?

- We will pay you \$100 at study enrollment and another \$100 at study completion after the 3-month follow-up phone call. You will receive \$200 in total if you enroll in and complete the study.

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services, as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, contact your regular health care provider.
- Call the Lead Researcher, Dr. Meghan Brennan, at 608-220-8488 to report your sickness or injury if it is related to your foot ulcer.

Here are some things you need to know if you get sick or are injured because of this research:

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- If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
- Your health insurance company may or may not pay for this care.
- No other compensation (such as lost wages or damages) is usually available.
- UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
- By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

How will researchers keep my research information confidential?

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. The study has a Certificate of Confidentiality from the National Institutes of Health. A Certificate of Confidentiality prohibits researchers from disclosing information that may identify you in a legal proceeding or in response to a legal request without your consent. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials and the National Institutes of Health responsible for monitoring this study.

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Who at UW-Madison can use my information?

- Members of the research team
- Offices and committees responsible for the oversight of research
- Personnel who schedule or perform medical tests or procedures, handle accounting and billing, or do other tasks related to this study

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Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections
- The study sponsor, The National Institutes of Health
- A de-identified dataset, which will not contain any of your personal information, may be available to other researchers requesting this data for research purposes such as independently verifying our findings.

Will information from this study go in my medical record?

- A medical record may be created for you if you do not already have one. None of the information we collect for this study will go in your medical record, but your medical record might say that you participated in this study. A copy of this consent and authorization form might go in your medical record.

What if I have questions?

If you have questions about this research, you can ask a research coordinator administering this consent or you can contact the Lead Researcher, Dr. Meghan Brennan, at (608) 263-1545. If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

Optional study activities

This part of the consent form is about additional research activities that you may be asked to take part in. This includes interviews to help us better understand how to approach people like you to participate in the study. The interviews will also help us understand how to make participation as easy as possible for people like you. This information will be used to improve the study procedures. Things to know about these activities:

- They are optional. You can still take part in the main study even if you say “no” to any or all of these activities. Also, if you say “no” to the main part of the study, you may be contacted to participate in a recruitment interview because we want to hear from a diverse group of people—those who agree and decline—in order to improve the recruitment process.

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- These activities will not help you directly. We hope the results will improve recruitment and retention strategies for this and future studies.
- We will not put information learned during the interviews into your medical record. We will let you know how we use information from the interviews to improve the recruitment and retention processes.
- Taking part in the optional activities will not cost you anything. You will be reimbursed for your time if you choose to participate in an interview.

Agreement to participate in the research study

You do not have to sign this form. If you refuse to sign, however, you cannot take part in this research study.

If you sign the line below, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

Printed Name of Research Participant

Signature of Research Participant

Date

Signature of Person Obtaining Consent and Authorization

Date

****You will receive a copy of this form****