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

5/13/2025

NCT05203471

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

Protocol Number: 2022-1338-CP
Principal Investigator: Meghan Brennan, MD, MS

National Institute of Diabetes and Digestive and Kidney Diseases R01

Protocol Version History

Protocol Version	Version Date	Summary of Revisions Made	Rationale
1.0	09/26/2022	Initial version	Version sent to IRB with initial application
1.1	10/17/2022	Addressed initial IRB comments	Addressed initial IRB comments
1.2	11/17/2022	Addressed full IRB review comments	Addressed full IRB review comments
1.3	12/07/2022	Addressed final IRB review comments	Addressed final IRB review comments
1.4	02/17/2023	Updated amount paid to clinics for participation	After the PI had several clinics decline enrollment, she increased the incentive for clinic participation from $1000/year to $4500 for enrollment.
1.5	07/07/2023	Added information about using the UW Health's Clinical Research Data Service for assistance with recruitment efforts for UW Health site(s)	The research team has had difficulty using HealthLink to identify potential patients at the UW Health Belleville clinic, so are enlisting CRDS for assistance.
2.0	09/18/2023	Additional CRFs and recruitment materials were added, as well as edits/additions to some forms based on specific clinic requests and feedback.	We made some edits and additions based on feedback from our first ICTR DMC meeting, as well as feedback and requests from clinics interested in enrolling in the study. We also had to make some edits based on creation of our REDCap database for this project and usability of that program.

2.1	04/26/2024	Updated Interview guide with edits/ additions to retention interview questions	In preparation for starting retention interviews soon and based on some of the feedback we received in recruitment interviews and PI clinic visits with HCWs, we have updated the questions and added some additional ones.
3.0	06/24/2024	1) Updated “Zoe Boston” with “Devan McClain” (name and contact info) 2) Updated qualitative retention interview inclusion criteria 3) Updates and additions were made to the qualitative retention interview portion of the interview guide	1) Devan McClain has replaced Zoe Boston as research coordinator of the study. 2) We expanded our inclusion criteria and anticipated number of participants for the retention interviews so that we could include key informants from the clinic level, such as administrators. 3) We made some edits/additions after review of the first few retention interviews conducted with patient participants.
3.1	08/28/2024	Increased the number of healthcare worker (HCW) participants and patient participants for qualitative retention interviews by 1 each	A HCW that we’d like to interview was out on medical leave when we were recruiting; she has since returned to work and got back to us expressing interest in participating (and we have the funds to cover additional interviews). We are also increasing our maximum patient participants by one.
4.0	10/14/2024	Changed reimbursement method to Advarra, added patient information letter as a new retention strategy, added qualitative questions to see what patients thought about the new letter	UW policy is mandating switching to Advarra for study reimbursements as of 01/01/2025; initial qualitative interviews of patients suggested we should add a letter to serve as a reminder about the goals of the study and what to expect
5.0	02/06/2025	Updated ratio of active patients to historical controls & removed the date constraint for historical controls; removed Jamie’s work phone number	Per our statistician, with our final number of active patients, we need 135 historical controls for 80% power. We have exhausted our options within the date constraint initially included due to COVID. We think it’s more important to be adequately powered and will include COVID as a limitation. Jamie will no longer have a dedicated UW number as of 2/28/25
6.0	05/05/2025	1) Location of where study files, both paper and electronic, are stored was changed and updated 2) Verbiage was added regarding adding the study’s de-identified dataset to a new UW Box folder for the statistician to access 3) Dr. Brennan’s and Dr. Smith’s information was updated as needed	1) The Health Innovation Program (HIP) recently lost their office space at 800 University Bay Dr, so the paper files and consent forms had to be moved to the PI’s new office at UW MFCB. With those and other recent changes at HIP, Dr. Brennan was informed the HIP servers would potentially be phased out, so she worked with DOM IT to move everything to her UW Restricted ResearchDrive 2) A de-identified dataset will need to be stored somewhere the statistician can access it, so we’re using UW Box

			3) Addresses recently changed due to the Health Innovation Program losing their office space, and Dr. Brennan's title has also changed

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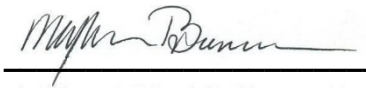
1.0 STATEMENT OF COMPLIANCE

I confirm that I have read this protocol. I will comply with the IRB-approved protocol, and applicable regulations, guidelines, laws, and institutional policies.

I agree to ensure that all study team members involved in the conduct of this study are informed about their obligations in meeting the above commitment.

Name	Signature	Date
Meghan B. Brennan, MD, MS		**02/17/2023**
Principal Investigator		

2.0 LIST OF ABBREVIATIONS

AE	Adverse Event
BAA	Business Associate Agreement
CCC	Clinical Coordinating Center
CFR	Code of Federal Regulations
CHDR	The Center for Health Disparities Research
CMP	Clinical Monitoring Plan
Cooperative	Rural Wisconsin Health Cooperative
CRF	Case Report Form
CTCAE	Common Terminology Criteria for Adverse Events
CTMS	Clinical Trial Management Software
DCC	Data Coordinating Center
DHHS	Department of Health and Human Services
DMC	Data Monitoring Committee
DSMB	Data & Safety Monitoring Board
DSMC	Data & Safety Monitoring Committee
DSMP	Data & Safety Monitoring Plan
eCRF	Electronic Case Report Forms
EDC	Electronic Data Capture
GCP	Good Clinical Practice
HIP	Health Innovation Program
HIPAA	Health Insurance Portability and Accountability Act
ICTR	Institute for Clinical and Translational Research
IND	Investigational New Drug Application
IRB	Institutional Review Board
IT	Information Technology
MOP	Manual of Procedures
NIH	National Institutes of Health
OHRP	Office for Human Research Protections
OnCore	Online Collaborative Research Environment
PCP	Primary Care Provider
PHI	Protected Health Information
PI	Principal Investigator
POC	Point of Contact
REDCap	Research Electronic Data Capture
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
sIRB	single IRB
SMART IRB	Streamlined, Multisite, Accelerated Resources for Trials IRB
SMC	Safety Monitoring Committee
SMPH	School of Medicine and Public Health
SPH	Sauk Prairie Healthcare
UP	Unanticipated Problem

3.0 STUDY SUMMARY

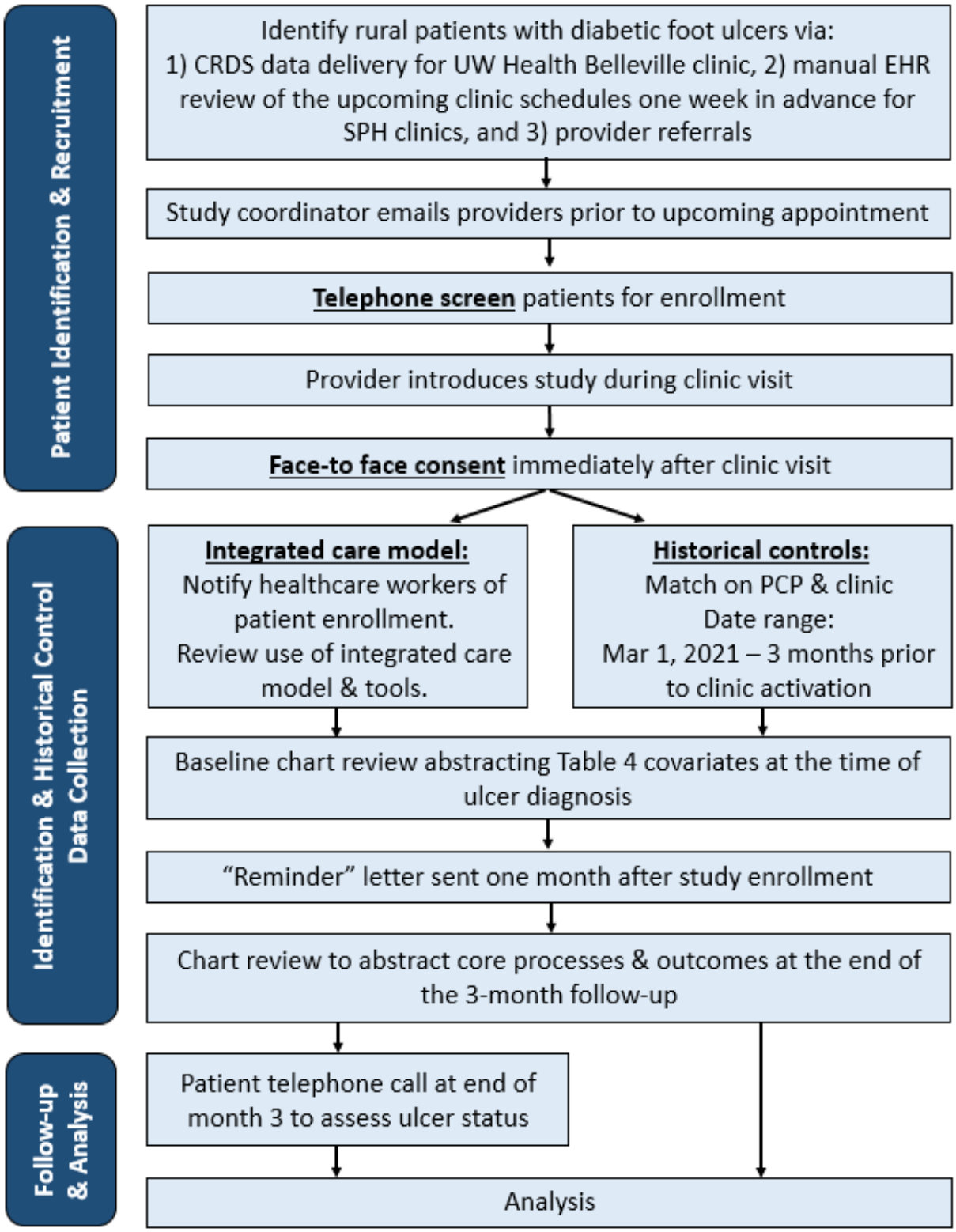
3.1 Synopsis

Full 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
Short Title	Crossing the Divide
Protocol Number	2022-1338-CP
ClinicalTrials.gov Identifier & Summary	NCT05203471 This study is being done to pilot an integrated care model that focuses on improving collaboration between rural primary care providers and urban specialists, particularly infectious disease physicians and vascular surgeons
Number of Sites	This is a single site study conducted in the United States. A total of 3 clinics serving rural Wisconsin with preference for those participating in the Rural Wisconsin Health Cooperative will be identified. Attempts will be made to select one clinic each from a rural advantaged, rural, and rural disadvantaged community.
Main Inclusion Criteria	Healthcare Workers: • Rural providers (primary care providers at UW Health Belleville and wound care and diabetes care specialists at Sauk Prairie Healthcare) and schedulers placing referrals • Employment at a rural advantaged, rural, or rural disadvantaged community clinic selected for participation Patient Participants: • Participating rural provider • Diabetic foot ulcer diagnosis
Main Exclusion Criteria	Healthcare Workers: • Insufficient overlap in work schedules between rural providers and schedulers Patient Participants: • Receiving palliative care • No insurance to cover referral to University of Wisconsin Specialty Clinics
Objective(s)	<u>Primary Objectives</u> • Evaluate the potential of our integrated care model to reduce major amputations by examining its impact on guideline-concordant care processes, including urban specialty referral • Build recruitment and retention strategies for the trial that work across diverse, rural clinics
Endpoints	<u>Primary Endpoints</u> • Completion of 5 vascular and 4 infectious disease care processes, modeled as percent indicated and dichotomously (all relevant completed vs. missing ≥1) • Development and refinement of recruitment and retention strategies that meet our goal targets of 60% and 80%, respectively <u>Secondary Endpoints</u> • Amputation, either major or minor, within 3 months of follow-up

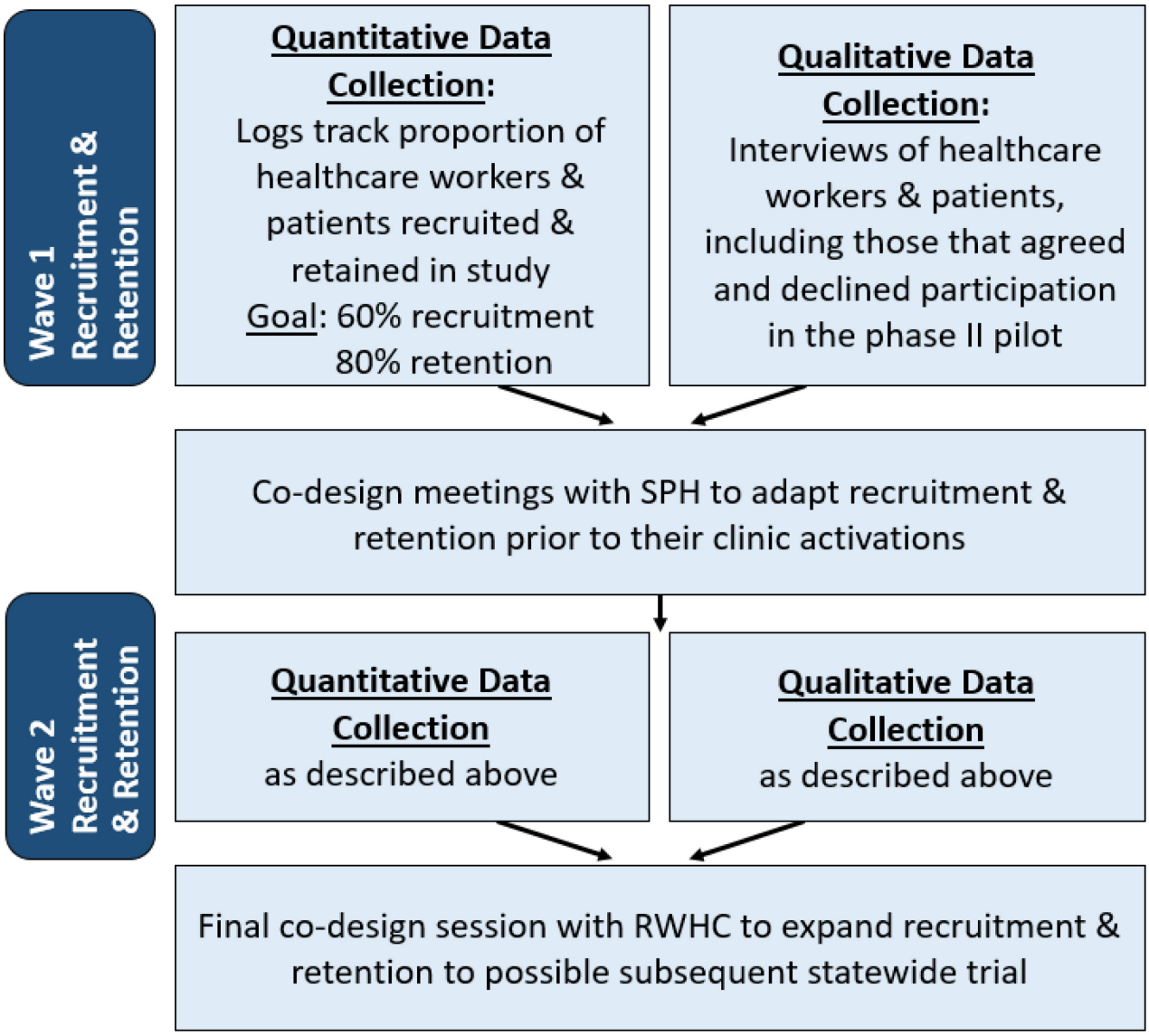
Study Design	This is a phase II pre-post serial cohort design trial with adaptive recruitment and retention strategies. Enrollment will be implemented in two phases; healthcare systems will be enrolled in consecutive 6-month periods.
Study Intervention	A rural integrated care model consisting of a care algorithm for use by rural primary care providers to guide integrated care for patients with diabetic foot ulcers, and a referral checklist for use by rural schedulers to place referrals with urban specialists.
Total Number of Subjects	Up to 45 patient participants will be enrolled in the study with additional historical control patients obtained via chart review (1 active patient participant; 5 historical control patients, up to 180 patients total). Up to 30 healthcare workers will be enrolled (180+30=210 individuals participating in the care algorithm pilot). From the pool of patients and healthcare workers approached for recruitment, we will ask up to 36 individuals, consisting of 18 patient participants and 18 healthcare worker participants, to participate in feedback interviews; this group will be a mix of both those that enrolled in the integrated care intervention study and those that declined participation in the study. These individuals will provide qualitative data needed to build recruitment and retention strategies, meeting our second objective. We are uncertain of the exact mix of qualitative participants who will have consented or not to participate in the care algorithm pilot. Therefore, the total number of subjects is anticipated to be between 190 and 246, including historical controls.
Study Population	Patient participants are adults aged 18+ diagnosed with diabetic foot ulcers and receiving care at a participating clinic. Health workers include primary care providers, other healthcare providers such as specialists, and schedulers employed at a participating clinic.
Statistical Methodology	Although this sample size is not powered to detect differences in major amputation, it does provide adequate power to find a difference in care processes proximal to major amputations. With a fixed sample size of 27 active patients, matched 1:5 pre/post with historical controls, alpha of 0.05, we are powered at >0.90 to detect an absolute increase of 30% (from 20% to 50% completion, measured dichotomously) in the group receiving integrated care.
Estimated Subject Duration	The duration of the study for each patient participant is approximately 3 months.
Estimated Enrollment Period & Study Duration	Study enrollment and follow-up will occur over 24 months with the total expected duration of the trial to be 36 months.

3.2 Schematic of Study Design

Phase II pre-post serial cohort design schematic to test the rural integrated care model



Adaptive recruitment & retention study design to build recruitment & retention strategies that work across diverse, rural clinics



4.0 KEY ROLES

The following is a list of all key personnel and roles:

Principal Investigator	Meghan Brennan, MD, MS Associate Professor of Medicine University of Wisconsin–Madison 4263 UW Medical Foundation Centennial Building 1685 Highland Ave Madison, WI 53705 (608) 220-8488 mbbrennan@medicine.wisc.edu
Participating Sites	Clinic 1: UW Health Belleville Family Medicine 1121 Bellwest Blvd Belleville, WI 53508 Clinic 2: Sauk Prairie Healthcare Diabetes Management Clinic 260 26th Street Prairie du Sac, WI 53578 Clinic 3: Sauk Prairie Healthcare Wound Care Clinic 260 26th Street Prairie du Sac, WI 53578
Data and Safety Monitoring Board	ICTR Data Monitoring Committee University of Wisconsin–Madison *asiedschlag@wisc.edu* (contact: Amy Siedschlag)
Funding Sponsor	National Diabetes and Digestive and Kidney Diseases Institute (NIDDK) Bethesda, Maryland 20892
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5.0 INTRODUCTION

5.1 Disease Background

Over two million Americans develop a diabetic foot ulcer each year, costing >$1.3 billion.[1,2] While other diabetes complications are decreasing, the CDC estimates that, since 2009, all diabetes-related amputations have increased 63%.[3,4] Above-ankle, major amputations increased 29% — the worst rates in more than 20 years.[3,5] The impact is unquestioned: patients with diabetic foot ulcers fear major amputation more than death.[6] Six million patients living with diabetes in rural areas have even poorer outcomes.[7]

Our team and others found that rural patients have 37% higher odds of major amputation and 40% higher odds of premature death than their urban counterparts, even after controlling for other sociodemographics, ulcer severity, and comorbidities.[8,9] Furthermore, baseline rates of diabetes and other amputation risk factors, like smoking, are higher in rural populations compared to urban; these rates are rising in the wake of the COVID-19 pandemic.[7,10-14] We urgently need interventions to assist rural healthcare teams in caring for these high-risk, rural patients with diabetic foot ulcers.

5.2 Current Standard of Care

Many urban, tertiary care centers have decreased the risk of major amputation and death by approximately 40% after implementing integrated care models that focus on centralizing multiple specialists into a single clinic to facilitate side-by-side collaboration.[15] Urban integrated care models work by co-locating multiple specialists in the same clinic and using algorithms to address four physiologic factors: 1) poor glycemic control, 2) vascular disease, 3) mechanical complications, and 4) secondary infection. However, the urban integrated care model has never been adapted to rural, primary care settings until our team partnered with the Rural Wisconsin Health Cooperative to design such a model. The current work aims to pilot our integrated care model for the first time in preparation for a statewide clinical trial of its effectiveness.

5.3 Integrated Care Model to Reduce Amputations from Diabetic Foot Ulcers in Rural Clinics

Our integrated care model promotes cross-setting collaboration without co-location through the utilization of two tools: 1) a care algorithm and 2) a referral checklist. The care algorithm supports rural primary care in providing high quality, local care to most patients. It also addresses obstacles to collaborating with urban specialists by providing *a priori* agreed upon referral criteria including timeframes, clinical indications, and pre-consultation diagnostics for severe disease. The referral checklist will support rural clinic schedulers, who place referrals to urban specialty clinics, by providing schedulers with a list of documents that should be included, reducing barriers of time-consuming triage and disjointed electronic health records.

5.4 Rationale

5.4.1 Integrated Care Model

Adapting the urban model of integrated care to rural settings is a highly promising solution to overcome rural disparities in major amputations. Our systematic review of 33 studies found that integrated care reduces major amputation and death for patients with diabetic foot ulcers by approximately 40%.[15] It uses a coordinated, systematic approach to address four physiologic factors: 1) poor glycemic control, 2) vascular disease, 3) mechanical complications, and 4) secondary infection. Multi-specialist teams average five disciplines and rely on co-location, urban referral pathways, and care algorithms to guide care for shared patients.[15] Multiple professional societies recommend integrated care for patients with diabetic foot ulcers.[16,17] These models have been successfully implemented in major cities spanning four continents.[15] However, integrated care models have never been adapted to rural settings, where co-location with multiple specialists is not feasible.

Among rural patients, poor collaboration with specialists accounts for 55% of excess hospitalizations and 40% of excess mortality, compared to urban residents.[18] This is most salient for high-risk patients requiring vascular surgery or infectious disease input, who face a 90-fold increased risk of major amputation.[19] Using a national Medicare sample of 56,440 patients with diabetic foot ulcers, our team reported that infectious disease physicians are associated with a reduced risk of major amputations (HR 0.83, p<0.001).[20] Others found that vascular surgeons are associated with a 38% reduction in major amputations.[21] However, both specialties almost exclusively practice in urban settings.[22] For rural patients to receive integrated care including input from these limb salvage specialists, teams must collaborate across the rural-urban health system divide.[23]

Our qualitative research highlights that, without a systematic way to provide integrated care, rural healthcare teams struggle to collaborate with urban specialists.[23,24] Our analysis of 44 interviews with rural patients, their caregivers, and healthcare workers emphasized the impact of delayed, poorly coordinated care with urban specialists. Rural-urban healthcare worker collaborations are stymied by: 1) time-consuming referrals, 2) negative interactions, and 3) multiple, disjointed electronic health records.[23]

In preliminary work, our team, in partnership with the Rural Wisconsin Health Cooperative (Cooperative), developed an intervention to address this critical gap. The Cooperative is a nationally recognized consortium of 43 rural health systems throughout the state dedicated to improving rural diabetes care. Together, we co-designed the first integrated care model adapted to the rural setting that promotes collaboration across the rural-urban divide.[23,24] The model streamlines the referral process and overcomes disjointed electronic health records by providing a checklist to be used by rural support staff (clinic schedulers) when faxing critical triage information between clinics. It establishes *a priori*, mutually agreed-upon criteria for timely, urban specialty referrals. We hypothesize that our rural integrated care model will reduce major amputations for rural patients with diabetic foot ulcers. Our hypothesis is based upon 1) implementing a model that directly addresses the most pressing health system barriers identified in our prior work, 2) the documented success of urban integrated care, and 3) the strength of our partnership with rural stakeholders in the co-design and pilot phases of our research.[25,26]

5.4.2 Recruitment and Retention Strategies

Inadequate recruitment and retention into clinical trials are the two top reasons clinical trials fail.[27] Furthermore, rural participants are under-represented in clinical trials, and there is a paucity of data regarding how to improve rural participation.[28,29] Therefore, it is critical that we develop strong recruitment and retention strategies during this pilot to assure subsequent trial success. We will collect quantitative data on the number of recruited patients and 3-month retention over the pilot. To improve these metrics, we will analyze qualitative data from healthcare workers and patients using an existing conceptual model of participant-centered recruitment and retention.[30] Our 2-wave, adaptive design allows us to pilot two iterations of recruitment and retention strategies. Adaptations will be co-designed with the Cooperative prior to activating the second and third clinics and upon completion of the pilot. Using qualitative data to drive improvements in recruitment and retention is a proven approach.[31,32] In one instance, recruitment rates nearly doubled from 35% at the beginning of the pilot to 69% during the definitive trial.[31-33] Our goal is to develop strategies that achieve a recruitment rate of 60% and retention rate of 80%, which would place us in the top tertile of clinical trial performance and ensure an adequately powered statewide trial.[34,35]

6.0 STUDY OBJECTIVES AND ENDPOINTS

Objectives	Endpoints
Primary	

Evaluate the potential of our integrated care model to reduce major amputations by examining its impact on guideline-concordant care processes, including urban specialty referral	A) Completion of 5 vascular and 4 infectious disease care processes, modeled as percent indicated and dichotomously (all relevant completed vs. missing ≥1) B) Amputation, either major or minor, within 3-month follow-up
Build recruitment and retention strategies for the trial that work across diverse, rural clinics	Development and refinement of recruitment and retention strategies that meet our goal targets of 60% and 80%, respectively

7.0 STUDY DESIGN

7.1 General Design

This is a phase II pilot of an integrated care model for treatment of diabetic foot ulcers in rural patient populations and includes adaptive recruitment and retention strategies. The protocol uses a pre-post serial cohort design, where the second and third clinics are activated six months after the first clinic and all clinics complete the trial simultaneously. This design allows: 1) use of refined recruitment and retention strategies when the final two clinics are activated, and 2) dispersion of activation efforts to facilitate completion by small research teams. Subject accrual will occur over 24 months. The design was modified so that clinics 2 and 3 could be activated simultaneously based on 1) our 100% recruitment of healthcare workers from clinic 1, which was greater than expected, and 2) our lower than expected patient recruitment from clinic 1. Having the third clinic activated for longer than initially planned should increase our likelihood of recruiting enough patients into the trial.

The study population will consist of 45 patient participants that develop diabetic foot ulcers during the enrollment period and receive care from participating rural providers (primary care providers (PCPs) at UW Health Belleville and diabetes or wound care providers at Sauk Prairie Healthcare) at rural clinics taking part in the study. Clinic schedulers, in addition to rural providers, will also be enrolled. Patient participants will be eligible only if their rural provider already consented and enrolled in the study. Patient participants will complete screening activities and their rural provider(s) and clinic scheduler will use the integrated care model to assist with care decisions (although rural providers will retain clinic discretion to deviate from the integrated care model to best serve the patient). Study activities include screening, chart reviews, and telephone assessments. Historical control data from up to 180 patients (1:5 active patient enrollment: historical control matching) will be obtained from medical records for comparison. Historical controls will be matched based on clinic and providers but no other factors due to the low overall volume of patients on any one provider's panel with diabetic foot ulcers.

Recruitment and retention strategies will be adapted iteratively during the study. Prior to enrollment of clinics 2 and 3, we will meet with administration and key healthcare workers from SPH to share our qualitative recruitment results from clinic 1 (Belleville) and brainstorm modifications that hold promise for successful recruitment of healthcare workers and patients at SPH's clinics 2 and 3. Data on recruitment and retention will be obtained through interviews with a subset of healthcare workers (e.g., rural providers, schedulers, and administrators) and patient participants, and through tracking of recruitment and retention efforts.

7.2 End of Study Definition

The end of the study is defined as the date of completion of any final follow-up activity or data collection described in the protocol.

8.0 SUBJECT SELECTION

8.1 Inclusion & Exclusion Criteria

8.1.1 Healthcare Workers

Inclusion Criteria
1. Willing to provide informed consent.
2. Willing to comply with study procedures
3. Rural providers (PCPs in Belleville; diabetes and wound care specialists in SPH) and schedulers placing referrals.
4. Employed at a participating rural clinic.
5. For rural providers, confirm understanding that they will retain clinical discretion to deviate from the integrated care model if they think it would best serve the patient.
6. Available for the duration of the study.

Exclusion Criteria
1. Insufficient overlap in work schedules between rural provider and scheduler based on clinic manager determination.

8.1.2 Patients (including Historical Controls)

Eligibility will be determined by inclusion and exclusion criteria below and confirmed by medical record review as necessary.

Inclusion Criteria
1. Able and willing to provide informed consent.
2. Willing to comply with study procedures and be available for the duration of the study.
3. 18 years of age and older.
4. Patient with either type 1 or type 2 diabetes at a participating rural clinic.
5. Develops diabetic foot ulcer during enrollment period.

Exclusion Criteria
1. Receiving palliative care such that referral to urban centers for aggressive limb salvage would be inappropriate (as assessed by their rural provider).
2. Insurance would not cover referral to the University of Wisconsin specialty clinic.
3. Not suitable for study participation due to other reasons at the discretion of the investigators.

8.2 Vulnerable Populations

Pregnant women, those who lack consent capacity, the mentally ill, prisoners, cognitively impaired persons, non-English speaking individuals and children will not be included in this research study.

Employees of the clinics that agree to participate in this study will be enrolled, but these individuals do not have a status relationship with members of the research team that would constitute a vulnerable population.

8.3 Participant Identification

8.3.1 Clinic Identification

The pilot will take place in three rural clinics: UW Health Family Practice Clinic in Belleville, Sauk Prairie Healthcare Diabetes Clinic, and Sauk Prairie Healthcare Wound Care Clinic.

8.3.2 Healthcare Worker Identification

Healthcare workers will be identified through their employment at each of the three rural clinics participating in the study. Lists of eligible employees will be obtained from clinic administrators.

8.3.3 Patient Participant Identification

Following identification of healthcare workers, the medical records of the participating clinics will be reviewed to identify patients with diabetes who are cared for by a participating healthcare worker. Those who develop a diabetic foot ulcer will further be identified by participating rural providers in the course of their normal work flow and referred to the research coordinators. Additionally, the research coordinators will monitor clinic schedules of participating rural providers to identify incoming patients with new foot ulcers.

8.4 Subject Recruitment

A total of 45 patient participants and up to 30 healthcare workers will be recruited from the 3 rural clinic sites in Wisconsin. Recruitment will be staggered so that Clinic 1 will be active for 24 months with a target patient enrollment of 20; Clinics 2 and 3 will be active for 18 months with a target patient enrollment of 25 total. This translates into a targeted rate of enrollment of 4.5 patients per activated clinic every 6 months. The initial recruitment strategy outlined below will be used to recruit patient participants from the first clinic. Recruitment strategies will be iteratively adapted one month prior to enrollment of the second and third clinics, and again at the end of the pilot. Changes to recruitment will be submitted to the IRB prior to implementation, as needed. Specific recruitment strategies are as follows:

8.4.1 Healthcare Worker Recruitment

Approximately one month prior to activating each clinic for patient enrollment, healthcare workers at each respective clinic will receive an email invitation to an informational meeting regarding the study. Up to three emails may be sent in the four weeks prior to the meeting with an opt-out option included in each email. The meeting will take place when patients are not scheduled and include light fare (e.g., pizza). The principal investigator and study coordinator will present details of the study. The email invitation will offer individual recruitment meetings for those interested in participating but unable to attend the dinner meeting. Attendees will be invited to register for a 1:1 interview to improve the recruitment session, regardless of their decision to participate in the pilot as part of purposeful sampling to obtain qualitative data on improving the recruitment process for healthcare workers.

8.4.2 Patient Participant Recruitment

8.4.2.1 UW Health Family Practice Clinic in Belleville

Potentially eligible patients at UW Health Family Practice Belleville clinic will be identified by the Clinical Research Data Service and provided on a weekly basis to the study team so that eligibility can be confirmed before patients are approached at the clinic. Providers can also refer patients directly to the study team. The clinic will be offered the option of introducing the study with information sheets in the waiting areas, such as a table top flyer and bi-fold brochure (see Appendix).

8.4.2.1 SPH Clinics

The study team will review upcoming clinic schedules one week in advance to identify potentially eligible patients using the SPH EHR. A Business Associates Agreement will be in place to formalize UW study team's remote access to SPH EHR. Providers can also refer patients directly to the study team. The clinic will be offered the option of introducing the study with information sheets in the waiting areas, such as a table top flyer and bi-fold brochure (see Appendix).

Telephone Contact: Research coordinators from the University of Wisconsin without clinical ties to the clinic or healthcare worker participants will review primary care provider schedules weekly to identify patients being seen for a diabetic foot ulcer. We anticipate that most patients will be identified very soon after the initial diagnosis, although some delay may occur between diagnosis and identifying these patients by the research coordinators during subsequent follow up. Additionally, rural providers will be able to directly contact the research coordinators when they identify a potentially eligible patient. After checking with the rural providers to ensure identified patients are eligible (i.e. not on hospice, truly have a diabetic foot ulcer), coordinators will telephone potential patient participants, using the preferred contact number listed in the clinic system. Patients will receive up to three calls on separate days and different times (morning, mid-day, and afternoon). If a call is not answered, coordinators will leave a message inviting the participant to return the call. When contact is made, coordinators will offer an in-person face-to-face meeting to review eligibility, provide detailed information on the study, and obtain written consent. The standardized telephone script is available in the Appendix. Patients contacted by telephone, regardless of their decision to further engage in the pilot, will be asked if they are willing to participate in a future interview to improve the recruitment process.

See section 11.0 for additional information on adaptive recruitment strategies.

8.5 Remuneration and Retention Strategies

8.5.1 Retention Strategies

We will request feedback on communication throughout the study to ensure both formal and informal communications are clear and as part of the adaptive design process for retention (i.e. we will use feedback to improve recruitment and retention protocols before activating additional clinic sites and at the end of the study). The following initial retention strategies will be implemented, with revised strategies (in *italics* below) added as developed:

- Our research coordinator will meet weekly with participating healthcare workers to review patient enrollment and assess, but not facilitate, use of the care algorithm/referral checklist.
- Researchers will solicit formal feedback from both healthcare worker and patient participants during planned interviews and preliminary data (e.g. up-to-date recruitment and retention rates) will be shared during the interviews.
- We will invite two research participants, optimally one healthcare worker and one patient, from each activated clinic to participate in the final co-design session with the Cooperative, incorporating on-the-ground patient and healthcare worker perspectives.
- All enrolled patients and healthcare workers will receive emailed or mailed (per participant preference) study updates linking recruitment and retention changes to participant feedback after each adaptation and at the close of the study. Healthcare workers may also receive in-person study updates at standing meetings if that is their clinic's preference.

- *All enrolled patients will be mailed an informational letter describing the study no earlier than 1 month after consent. The purpose of this letter is to remind patient participants about the study, including its purpose, and serve as a way to keep them feeling engaged about the project. This retention strategy emerged from our qualitative interviews to improve study retention. The form letter has been added to the appendix.*

See section 11.0 for additional information on adaptive retention strategies.

8.5.2 Remuneration

Individual healthcare workers will not receive financial compensation for participating in the pilot. Rather, the clinics will be compensated $4500 for their involvement. We doubt this nominal fee (compared to their overall operating budgets) will be enough to risk coercion from clinic managers to healthcare workers to participate. Patient participants who consent will be given $100 upon enrollment and an additional $100 upon completion of the 3-month follow-up. This has been in the form of cash for most of the duration of the study. However, starting in 2025, per UW–Madison policy, stipends for research participation must be paid using the Advarra payments system. Within this system, participants have the choice of a Visa card, direct deposit, or check. Enrollment will be completed in 2024 and payment for completion of the study is paid via mail. Since will be unable to work with the patient participants in person for this payment, and due to the nature of our patient participant demographics (majority elderly, several without email and/or limited access to internet/computers and/or transportation), we will be opting to send payment to all patient participants who complete the study in the form of a Visa card. Patient participants enrolled after 9/23/24 will be notified that although their enrollment payment is in the form of cash, they should expect payment for completion of the study in the form of a Visa card due to university policy changes. Patient remuneration may be revised as part of co-design adaptations.

8.6 Early Termination and Withdrawal

All subjects are free to withdraw from participation in the study at any time upon request via letter as described on the consent form.

The Principal Investigator (PI) may discontinue or withdraw a healthcare worker from the study at her discretion for failure to consider use of the integrated care model with their patient participants, although deviation from the model will be allowed based upon the rural provider's clinical judgement.

Patient participants who sign the informed consent form, receive the study intervention, then subsequently withdraw, or are withdrawn or discontinued from the study will not be replaced.

The following actions will be taken if a patient participant withdraws or fails to return the three month follow-up phone call:

- Before a patient participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant where possible, by completing up to 3 telephone calls. These contact attempts shall be documented in the participant's study file. Participants that do not agree to participate in the follow-up phone call will be asked to provide a reason for discontinuing participation.
- If the patient participant continues to be unreachable, they will be considered to have withdrawn from the study with a primary reason of lost to follow-up. The withdrawn date is the last day of attempted contact.

9.0 INTEGRATED CARE MODEL INTERVENTION

9.1 Integrated Care Model

The integrated care model uses two tools to promote provider collaboration across rural and urban healthcare systems: 1) a care algorithm and 2) a referral checklist.

The care algorithm will be used by rural providers—primary care providers (PCPs) at UW Health Belleville clinic and rural diabetes and wound care specialists at SPH clinics—to guide integrated care for patients with diabetic foot ulcers (see Appendix). It supports rural providers, allowing most patients to be cared for locally and reserving urban specialty referral for those with limb-threatening disease. The algorithm triggers intensive medical management, especially for key gaps in vascular care. The rural providers will retain final clinical decision making autonomy; the algorithm is there as a general guide and clinical support tool with the ability to deviate from the algorithm when it is in the best interests of the patient. The model also supports rural patients by allowing both in-clinic and telemedicine urban specialty consultation. Rural patients and urban specialists jointly decide between in-person and telemedicine consultation for each visit.

The integrated care model's referral checklist will be used by rural schedulers who place referrals to urban specialists (see Appendix). It prompts schedulers to fax appropriate supporting documents (e.g., notes, labs, vascular testing results) with the referral request.

10.0 INTEGRATED CARE MODEL STUDY VISITS AND PROCEDURES

10.1 Healthcare Workers

10.1.1 Screening and Enrollment

10.1.1.1 Informed Consent

For healthcare workers participating in the informational meeting session, the PI and study coordinator will present details of the study to the group. Consent forms will be distributed to the group for review during the session. Participants will have time to ask questions during the group session or after the session is complete. Those willing to participate can sign and date the consent during the meeting. Having the rural providers and schedulers attend the same informational meeting is beneficial because it is efficient. The consents will be turned in without eliciting any formal knowledge of who signed or not, minimizing risk of coercion.

For healthcare workers unable to attend the informational meeting session, the PI or study coordinator will meet with the participant to discuss the study. The consent form will be provided to the subject for review and the PI or study coordinator will give the subject time to review and ask questions. If the subject is willing to participate, they can sign and date the consent form at that time. Immediately following signed informed consent, self-reported demographics will be collected using a standardized form to comply with NIH sponsor requirements.

All healthcare workers will be provided with the option to take the consent form home with them for additional consideration and to contact the study PI or research coordinators with additional questions. The study PI or a research coordinator will review all informed consent documents to ensure that all fields that require a response are completed. Each participant will be provided with a copy of the consent form to keep for their records. Original copies of the consent form will be retained by the study PI and research coordinators.

10.1.1.2 Eligibility Confirmation Screening

After informed consent is obtained from healthcare workers, screening will be performed to ensure an appropriate match between enrolled rural providers and schedulers. Healthcare workers will be excluded if the clinic manager determines there is insufficient overlap in work schedules between rural providers and schedulers. In the event a healthcare worker is excluded, they will be thanked for their interest and offered the opportunity to receive updates on the status of the study. Healthcare workers may also be approached for participation in recruitment and retention interviews.

10.1.2 On-Study and Follow-up Procedures

Healthcare workers will meet with the PI or a research coordinator to discuss the integrated care model in detail. Rural providers will be provided with a copy of the care algorithm and schedulers will be provided with a copy of the referral checklist to review. Healthcare workers will be encouraged to ask questions about the integrated care processes. Once eligible patient participants are identified, rural providers and schedulers will be informed of the patient participant's enrollment in the trial. If a patient is enrolled through a Sauk Prairie Healthcare Clinic (diabetes or wound care clinics), an email will be sent to the patient's PCP informing them of the patient's enrollment in the study. A research coordinator will meet with rural providers and schedulers weekly to discuss the status of the study and answer any questions they may have. The PI will be available as back-up to answer any questions.

10.2 Patient Participants

10.2.1 Study Calendar

The procedures performed at each study visit are listed in the table below.

Procedure	Screening	Baseline visit	Intervention	Telephone contact	End of Study/Early Withdrawal
Visit Window	Identification of Foot Ulcer	Next Clinic Visit		Month 3	
Telephone Screen	X				
Informed Consent		X			
Eligibility		X			
Integrated Care Model			X		
Chart Review		X	X	X	X
Follow-up				X	

10.2.2 Screening and Enrollment

10.2.2.1 Pre-screening

Research coordinators will review the schedules of participating rural providers weekly to identify patients being seen for a diabetic foot ulcer. Additionally, rural providers will be encouraged to contact the research coordinators when they identify a potentially eligible patient. To assist with this process, providers will have access to a bi-fold brochure generally introducing the study and table top flyers to display in patient waiting rooms (see Appendix) For the UW Health Family Medicine Clinic in Belleville, CRDS will also generate a data report to help screen for potentially eligible patient participants. The report will be delivered via REDCap to the study team weekly and cover the upcoming week's schedule. Once identified, telephone screening will be performed for initial eligibility and to schedule the consent discussion. The telephone script to screen for eligibility is available in the Appendix.

10.2.2.2 Informed Consent

Preliminarily eligible patient participants will be invited to participate in an informed consent discussion and formal screening at their next scheduled clinic visit. Potential patient participants are asked to come to the visit immediately after their scheduled clinic visit. The informed consent process will be conducted following all federal and institutional regulations relating to informed consent. The discussion will take place in a private room at the rural provider's clinic. Informed consent will be obtained prior to conducting any study-related activities. Immediately following signed informed consent, self-reported demographics will be collected using a standardized form to comply with NIH sponsor requirements.

The informed consent process will be performed as follows:

- A trained research coordinator will review the informed consent form and discuss the study in detail with the potential research participant.
- A trained research coordinator will explain the study, its risks and benefits, what would be required of the research participant, and alternatives to participation.
- The research participant will be given the opportunity to take the informed consent form home so that they may discuss it with family members, friends, clergy, or others when possible.
- The research participant will have the opportunity to ask questions and have all questions answered by the research coordinator.
- The informed consent document must be signed and dated by the research participant.
- A trained research coordinator will review the informed consent document to ensure that all fields that require a response are complete (i.e., checkbox marked yes or no, etc.) as applicable.
- The research participant will be given a copy of the informed consent form. The original signed and dated informed consent form is kept with the study records.

10.2.2.3 Baseline Visit and Enrollment

Following informed consent, subject eligibility will be confirmed as follows:

A patient participant will be defined as "enrolled" in the study when they meet the following criteria:

- The patient participant has been consented by a research coordinator.
- The patient participant and a research coordinator have completed all screening documentation.
- The PI has verified that the patient participant meets all of the inclusion criteria.
- The PI has verified that patient participant meets none of the exclusion criteria.
- The patient participant completed a clinic visit with the participating rural provider, who considered recommendations outlined in the integrated care algorithm.

Following enrollment, the participant's medical record will be reviewed, and patient characteristic data will be abstracted. This will include sociodemographic data, comorbidities, medications, lab values, and ulcer characteristics. See Appendix for full list of variables.

10.2.2.4 Screen Failure and Re-enrollment

Individuals who do not meet the criteria for participation in this trial (screen failure) because they are determined not to have a diabetic foot ulcer may be rescreened if they develop a diabetic foot ulcer later. Rescreened patient participants should be assigned a new subject ID number when they are re-screened.

10.2.3 On-Study and Follow-up Procedures

10.2.3.1 Integrated Care Model Visit

Integrated Care Model activities will be performed by the rural provider and scheduler following the patient participants' enrollment in the study, as outlined above.

Following the rural provider visit, data on care processes will be abstracted from the participant's medical records. This includes information related to vascular disease care processes, infectious disease care processes, and other care processes. See Appendix for the full list of variables.

10.2.3.2 3 Month Follow-up

Patient participants will receive a follow-up call 3 months after their integrated care model visit (i.e., enrollment) to assess ulcer status and screen for any adverse events. This will be done by a research coordinator. Additionally, data will be abstracted from the patient's medical records. This includes medications, lab values, ulcer characteristics, and details of major or minor amputation, if applicable. If the patient participant is deceased at the time of the 3-month follow-up, information about the participant's death will also be obtained from medical records. See Appendix for the full list of variables. The following is a list of adverse events that will be tracked by the study team:

- Hypoglycemia requiring hospitalization or an emergency room visit
- Adverse reaction to a smoking cessation product
- Muscle aches after starting or changing a statin
- Complication of a revascularization procedure
- Adverse reaction to a wound care product or dressing
- Adverse reaction to an antibiotic prescribed for an infection complicating the diabetic foot ulcer
- Hospitalization for a diabetic foot ulcer (occurs in 30% of patients with diabetic foot ulcers)
- Major (above-ankle) amputation (risk increases with ulcer severity but is 5% in the overall national cohort of patients with diabetic foot ulcers)
- Death
- Patient reported adverse events that the patient attributes to study participation

All serious, unanticipated adverse events, deaths (whether anticipated or not), and major amputations (whether anticipated or not) will be reported to the ICTR DMC within 14 days of the study team becoming aware of these events.

10.3 Historical Control Patient Participants

10.3.1 Screening and Enrollment

Controls will be matched 1:5 with enrolled patient participants based on clinic and primary care provider and identified through a review of medical records. Additionally, CRDS will be used to screen for historical controls at the UW Health Family Medicine Clinic in Belleville, and data will be delivered to the study team through REDCap. Controls will be identified and selected starting from the date 3 months prior to clinic activation and going back in time until the required number is reached. . The 3-month wash-out will avoid contaminating primary care teams with intervention activation events. Patients receiving palliative care, those unable to provide consent, and those who lacked insurance covering referral to University of Wisconsin specialty clinics will be excluded from the control population consistent with prospectively enrolled patient participants.

A waiver of informed consent and HIPAA authorization waiver has been obtained for data abstraction activities for historical controls. This aspect of the study meets the four criteria for a waiver of HIPAA authorization. First, the research involves no more than minimal risk to the historical controls as it consists of a chart review only. Second, the research could not practicably be carried out without the

waiver since a substantial proportion of the historical controls are likely to have died (~20% in our national cohort study were dead within one year). Third, the research could not practically be carried out without using Identifiable Private Information because we need to access their medical records, which contain the most accurate record of what care they received for their foot ulcer. Fourth, the waiver is unlikely to adversely affect the rights and welfare of the subjects due to the procedures we have in place to maintain the confidentiality of all participants, both historical and prospective.

10.3.2 Data Abstraction

Medical records will be reviewed, and similar data collected from prospectively enrolled patient participants will be extracted from historical control patient participants. This includes sociodemographic data, comorbidities, medications, lab values, and ulcer characteristics at baseline and at 3 months post-baseline. Amputation and death data will also be collected, if applicable. See Appendix for the full list of variables.

11.0 ADAPTIVE RECRUITMENT AND RETENTION PROCEDURES

11.1 Interview Procedures (Qualitative Data Collection)

11.1.1 Subject Identification and Recruitment

11.1.1.1 Recruitment Interviews

Up to 9 healthcare workers and 9 patient participants from each clinic will be identified to participate in recruitment interviews (n=18 total participants). We will purposively sample across roles (i.e., rural providers/schedulers), those who consented or declined participation in the integrated care model intervention, and oversample both healthcare workers and patient participants from under-represented minority populations.

A research coordinator not participating directly in recruitment efforts will reach out to patients by telephone and healthcare workers by telephone or email to assess their interest in scheduling an interview. Up to three attempts will be made to reach potential interviewees. If a call is not answered, the coordinator will leave a message inviting the participant to return the call. A scripted telephone invitation and template email to participate in the qualitative portion of this study is included in the Appendix. The method of contact will be determined based on the participant's preferred method of contact as noted when they filled out the Demographics CRF.

Identification and recruitment activities will take place within 3 months of each clinic being activated for the integrated care model intervention.

11.1.1.2 Retention Interviews

Up to ten healthcare workers and ten patient participants will be identified to participate in retention interviews (n=20 total participants). These individuals will be sampled to reflect their experiences across retention adaptations and clinics. In addition to healthcare workers enrolled in the quantitative portion, we will also recruit clinic administrators and staff who helped patient recruitment efforts and support clinic engagement with this study (e.g., help set-up meetings with clinicians, facilitate electronic health record access with the study coordinators, serve as ombudsmen to the larger healthcare system with respect to study activities). We anticipate significant overlap between people who agree to participate in the recruitment and retention interviews. In total, we will not enroll more than 36 people between these two efforts.

A research coordinator not participating directly in recruitment and retention efforts at that clinic will reach out to patients by telephone and healthcare workers by telephone or email to assess their

interest in scheduling an interview. Up to three attempts will be made to reach potential interviewees by phone. If a call is not answered, the coordinator will leave a message inviting the participant to return the call. A scripted telephone invitation and template email to participate in the qualitative portion of this study is included in the Appendix. The method of contact will be determined based on the participant's preferred method of contact as noted when they filled out the Demographics CRF.

11.1.2 Enrollment

A separate informed consent for the qualitative sub-study will be verbally obtained from participants at the time of the interview. An oral consent script will be used to provide details of the interview procedures to research participants including study risks and benefits, what would be required of the research participant, and alternatives to participation. The script is available in the Appendix. Potential research participants will be given time to ask questions and can reschedule the interview if they would like additional time to consider participation. Interested participants will be able to provide oral consent to participate. Oral consent will be documented by the study coordinator in the original interview recording. Oral, rather than written, consent is being used because some interviews will take place by telephone.

11.1.3 Interviews

Interviews will take place at a time chosen by the interviewee and can be conducted in person, via telephone call, or via virtual meeting, based on the participant's preference. Interviews will be audio recorded and transcribed verbatim with the exception that personal identifying information will be removed. Interviews will be semi-structured following our conceptual model of participant-centered recruitment and retention adapted from Chhatre et al. (see Appendix for interview guides).[30] Probing questions will provide depth and detail about how recruitment and retention strategies could be improved. Following analysis of the interview materials (see section 11.3.1 below), a synthesis of the findings will be emailed to interviewees to ensure that the descriptions are salient and credible. Emails will also offer an opportunity for feeding back preliminary data as a means of improving study retention. For participants completing a recruitment interview that declined enrollment in the care algorithm part of the study, the Demographics form will be completed at the end of the interview.

11.1.4 Remuneration

Interviewees will receive $50, with an average interview lasting 30 minutes.

11.2 Recruitment and Retention Data Collection (Quantitative Data Collection)

We will use recruitment and retention data to assess the impact of the initial strategies and subsequent adaptations. We will keep logs of participant recruitment and retention. For healthcare worker (rural providers and schedulers) recruitment, we will record how many healthcare workers at each site: 1) were emailed an invitation to the recruitment meeting, 2) met with the study PI or research coordinator, and 3) consented to participate. Retention for healthcare workers will be defined as not having withdrawn consent to participate in the study and will not be based on their use of the integrated care model, since deviation from the model will be allowed if it is in the best interest of the patients as determined by the participating rural provider. Retention for administrators and other staff not formally consented in the quantitative portion will be defined as willingness of the clinic to continue to support the research endeavors.

For patient participant recruitment, we will record the number of patients who: 1) were contacted by phone, 2) completed the face-to-face appointment, and 3) consented to participate. For patient participant retention, we will log how many patient participants withdrew from the study or were lost to follow up before the 3-month telephone call. Logs will separate data into three distinct groups corresponding to adaptive iterations of the recruitment and retention strategies.

11.3 Recruitment and Retention Data Analysis

11.3.1 Qualitative Data Analysis

We will analyze interview transcripts using directed content analysis, where an existing conceptual model drives an *a priori* coding matrix.[36] The columns of the matrix will be composed of categories derived from the conceptual model.[30] Interview questions are placed in the matrix rows, with supporting quotes populating each cell. We will allow our matrix to be unconstrained.[37] This means that, while the majority of the coding matrix is predetermined, we will add new categories (columns) to reflect emerging facets of the data that may refute, extend, or enrich the conceptual model. We are using an unconstrained model because our intent is to capture all possible strategies to promote recruitment and retention.[36]

Before coding begins, the PI and research coordinators will create a code book to define each category, tailoring definitions to rural recruitment and the current study. Core definitions will be based on those originally published.[30] The group will refine the code book iteratively using emerging data to hone *a priori* codes and define new ones relevant to emerging themes. Two study team members will code all transcripts independently (PI and a research coordinator). First, transcripts will be read for immersion. Second, portions of the transcripts pertaining to barriers and facilitators of recruitment and retention will be highlighted, regardless of whether they represent core concepts in the matrix. Starting analysis in this way prevents researchers from focusing too narrowly on *a priori* codes. Third, highlighted passages will be coded using the predetermined categories. Fourth, any highlighted text that fell outside the predetermined categories will be given a new code and entered into the unconstrained matrix.[36] Independent coders will meet to discuss discrepancies identified using NVivo comparisons of coded text and interpretations of code book definitions. If questions remain, Dr. Pecanac (qualitative co-investigator) will assist with resolution. Once the matrix is complete, researchers (Drs. Pecanac and Brennan) will examine the data in each category and describe how the current process of recruitment is working, how recruitment strategies are impacted by different conditions, and interactions between different strategies.[36,37] Analysis will be shared with the participating clinics and Rural Wisconsin Health Cooperative during a final co-design session to adapt recruitment and retention strategies to meet our target goals of 60% recruitment and 80% retention in a subsequent, wider state trial.

11.3.2 Quantitative Data Analysis

Dr. Sampene will serve as the study's biostatistician and be available to assist with the quantitative data analysis. We will calculate recruitment and retention rates prior to activating the next clinic. We will compare results to our goals of 60% and 80%, respectively.[34,35] We will create recruitment and retention cascade graphics for both healthcare workers and patients to assist with determining which steps in the process have the highest attrition. Subsequent adaptations will focus on these steps. We will use descriptive statistics, such as counts, rates, and percentages, to summarize recruitment and retention during each cycle of adaptation. The denominator for healthcare worker recruitment steps will be the number of healthcare workers emailed to attend an informational meeting. The denominator for healthcare worker retention will be the number enrolled in the study. Retention will be assessed every 3 months until the end of the study, varying across each clinic due to staggered activation. The denominator for patient recruitment will be the number of patients we attempted to contact by telephone. The denominator for patient retention, assessed at the 3-month follow-up telephone call, will be the number of patient participants enrolled in the study. Comparisons of recruitment and retention between adaptations will be performed using ANOVA or chi-square tests, depending on the outcome types for these endpoints. Also, correlative measures will be calculated when such methods are informative.

11.4 Cooperative Co-design for Recruitment & Retention Adaptations

Recruitment and retention strategies have been iteratively adapted prior to enrollment of clinics 2 and 3, leading to protocol changes from version 1.4 to 2.0. At the end of the pilot, a co-design meeting will occur with the Cooperative to further refine recruitment and retention strategies with the goal of preparing for a larger, statewide trial using their network of rural healthcare clinics. Our research study team, led by the PI, will present quantitative and qualitative analysis of the most current recruitment and retention strategies (outlined above). Cooperative participants include clinicians, nurses, administrators, and quality improvement experts. We will invite two patient representatives from each activated clinic to participate. Cooperative members include patients in their meetings specifically to ensure patient-centeredness.

During the co-design session, we will use participatory ergonomics, which is a systems engineering approach where the researchers spearheading the study work side-by-side with stakeholders to design it.[38,39] We used this same approach with the Cooperative to successfully identify health system barriers exacerbating rural disparities in major amputations and design our integrated care model.[23,24] Research coordinators will distribute adaptations to participating healthcare workers at each activated clinic with explanations for the changes linked to their feedback.

All enrolled patient participants will receive a mailed update after each modification and at the close of the study, detailing our findings and adaptations. These steps are critical not only in keeping participants informed of protocol changes but also in providing evidence of responsiveness to their feedback, which has been linked to study retention.[40-43]

12.0 DATA HANDLING AND RECORD KEEPING

12.1 Data Collection

12.1.1 Data Collection

Standardized data collection forms (e.g., source documents, case report forms, standardized assessment forms, etc.) are used to ensure data collected are consistent and compliant with the protocol and IRB application.

Data collection is the responsibility of the research coordinators under the supervision of the Principal Investigator (PI). The PI is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the recorded and reported data.

All data collection forms must be completed in a legible manner; any missing data will be explained. Data entry errors will be corrected with a single line through the incorrect entry and the correct data is entered above/near the correction. All changes will be initialed and dated. Forms will be filled out electronically or using black or blue ink.

Data collection forms are maintained in the subject files and retained as described in Section 12.3: Records Retention.

Data collection will be done through manual chart abstraction by Devan McClain, Jamie LaMantia, and/or Meghan Brennan. These individuals will be granted remote access to all three clinics' electronic medical record. A business associate agreement (BAA) with SPH will be put in place for this purpose. A unique study ID will be assigned to each patient participant. A key linking the patient participant's ID and the study ID will be kept on the HIPAA compliant HIP server and UW Restricted ResearchDrive. A coded dataset will be created on the HIP servers/UW Restricted ResearchDrive and REDCap for analytic purposes and ICTR DMC oversight purposes.

Study data will be documented and monitored in SMPH REDCap. Data will be collected on paper as described above, recorded by either the study participant or research staff, then electronically entered, with confirmation of correct entry, by the research staff via REDCap on research computers. To gain access to the REDCap system, study team members will need to fill out a REDCap account request through ICTR and complete required training using the following link: *https://redcap.ictr.wisc.edu/surveys/?s=DWJFCLFHYL8PKJRT*

Once approved, each user will have their own account. To ensure that REDCap users have access only to data and information that they are supposed to have access to within the application, each user's privileges will be assigned by the study's principal investigator or the study team member that created and manages the REDCap project database. After REDCap entry, source documents will be stored in a locked filing cabinet in Dr. Brennan's office location within the secure UW Medical Foundation Centennial Building, and maintained for the length of time approved by the IRB.

12.1.2 Data Management

All electronic data will be stored on the Health Innovation Program's servers and the PI's/Meghan Brennan's UW Restricted ResearchDrive and/or entered into the SMPH REDCap database. The study team will have access to these application servers for statistical processing; data storage for datasets with personal health information (PHI); backup and recovery; technical, physical, and management security and privacy controls; ongoing review of regulatory agreements and access compliance; remote access to IT resources; and IT helpdesk support. The data will be stored in a location on the servers that will be restricted to approved members of the study team. Additionally, the REDCap database will be used by the ICTR DMC, which is providing oversight for this clinical trial. Printed and signed consent forms and other printed study materials will be kept in a locked cabinet in Dr. Brennan's office location within the secure UW Medical Foundation Centennial Building.

Additionally, a spreadsheet of coded data collected from all study participants will be loaded to a UW Box folder for the statistician to access for data analysis.

12.2 Confidentiality and Privacy

Research participant confidentiality and privacy are strictly held in trust by the participating investigators, their study team, and the sponsor and their agents. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

All research activities will be conducted in as private a setting as possible. Audio recordings of interviews will be obtained using a recording device that is kept in the possession of the research coordinator when in use and in locked rooms limited to essential personnel when not in use. Transcription will be conducted by members of the study team (HIP student hourlies with appropriate IRB and HIPAA training add to the research team roster for this specific purpose, Devan McClain and/or Jamie LaMantia) and individual identifiers will be redacted prior to sharing this information as part of interviews and co-design meetings.

All study team members engaged in the conduct of this project have completed training on the protection of human subjects and the Health Insurance Portability and Accountability (HIPAA) Privacy Rule. In addition, all key personnel (i.e., Principal Investigator, individuals involved in identifying/recruiting subjects, obtaining informed consent, or interacting and intervening with research study participants) have undergone both Human Subjects and Good Clinical Practice (GCP) training.

Information about study participants will be kept confidential and managed according to HIPAA requirements. All study participants will provide informed consent, with prospective patient participants receiving the integrated care intervention also providing consent on a combined consent and HIPAA

authorization form that includes specific privacy and confidentiality rights. Study data will be maintained per federal, state, and institutional data policies.

The investigator(s) will ensure that the identities of study participants are protected by using coded information specific to each participant. The log of participant-identifying information that links participants to their study-specific identification number will be maintained by the investigator and research study team. Hard copy logs and all study records will be maintained in locked rooms and access will be limited to essential study personnel. Electronic study records/files will be stored on HIPAA-compliant Health Innovation Program servers and Meghan Brennan's Restricted ResearchDrive and accessed via networked computers that are password-protected with access provided only to authorized study personnel.

Authorized representatives of the following groups may need to review this research as part of their responsibilities to protect research subjects: authorized representatives of the sponsor, representatives of the IRB, DSMB/DMC, regulatory agencies, and federal oversight agencies. The clinical study site will permit access to such records.

Research coordinators may use e-mail to communicate with research participants, if the participant has agreed to using email in the Informed Consent form. The information contained in emails will be limited to study visit time and date information, general questions, etc. All emails to participants will be sent from UW/wisc.edu accounts; personal, home, or Gmail email accounts will not be used.

12.3 Records Retention

Essential documents will be maintained for a minimum period of 7 years following completion of the study per UW-Madison institutional policy.

12.4 Retention for Future Research: Data and Audio- or Video-Recording Banking

12.4.1 Purpose of Storage

Essential documents will be maintained for a minimum period of 7 years following completion of the study per UW-Madison institutional policy. De-identified data will also be stored so that it can be made available to independent researchers wishing to verify our findings.

12.4.2 Data and/or Biospecimens Being Stored

Only de-identified data will be stored beyond completion of the study. De-identified data will include: a dataset comparing historical patients to those prospectively enrolled in the integrated care model and de-identified qualitative interview transcripts.

12.4.3 Location of Storage

De-identified data will be stored on the Health Innovation Program HIPAA compliant Server (P://), which is housed in a state-of-the-art data center at the Centennial Office Building managed by UW SMPH IT and is connected via fiber optic cable to the Health Innovation Program (HIP) suite at 800 University Bay Drive.

Data will also be stored on Meghan Brennan's UW Restricted ResearchDrive, the University of Wisconsin campus-wide file storage service managed by the Division of Information Technology. This is a secure space with data protection and security features based on the NIST Cybersecurity framework. It includes off-site backups, encryption, and monitoring by the University of Wisconsin Cybersecurity Operations Center.

12.4.4 Duration of Storage

Data will be retained for a minimum of 7 years per UW-Madison institutional policy.

12.4.5 Access to Data, Images, Recordings and/or Biospecimens and Security Measures

Access to identifiable data will be limited to those collecting it, so that they may check and confirm its accuracy, and those transcribing audio recordings of the qualitative interviews. The PI and research coordinators, and Drs. Pecanac and Sampene (co-investigators) will work with de-identified data.

The following measures were put in place to protect confidentiality:

1. Access to identifiable data will be limited to those collecting data, conducting interviews, and transcribing interviews.
2. Data analysis, both quantitative and qualitative, will be performed on de-identified datasets and transcripts only.
3. The key linking de-identified study data to identifiable study participants will be kept by the research assistants generating this data on the HIPAA-compliant HIP server and Dr. Meghan Brennan's UW Restricted ResearchDrive.
4. Audio recordings of interviews will be destroyed after they have been transcribed and the transcripts were verified to be accurate by the person who conducted the interview. This limits accidental disclosure of identifiable information.
5. Original paper data abstraction forms will be kept in a locked filing cabinet in a locked office at the UW Medical Foundation Centennial Building. Using paper data abstraction forms limits cyber security issues.
6. Laptops will not be used for data collection, storage, or access.
7. Identifiable data will not be shared outside of UW.
8. Electronic data will be stored on the HIPAA-complaint HIP server, which has the following levels of security, and UW Restricted ResearchDrive:
    a. Physical Security: the server is located in a secure data center under control of UW School of Medicine and Public Health (SMPH) IT, which is a dedicated computer machine room fitted with passkey access, video surveillance, emergency back-up power, an un-interruptible power supply, and an automatic fire detection and suppression system. SMPH IT does not have access to the server.
    b. Firewall: the server is located behind the SMPH firewall.
    c. Access Control: Data directory access is limited to HIP Faculty Director-approved individuals.
    d. Domain Access Restrictions: access to HIP computing resources is restricted to individuals with a logon ID for the HIP Domain. Logon IDs are issued only upon approval of the HIP Director.
    e. Authentication: Password protection is used at the network level for all transactions that allow entry and editing of data, provide access to electronic PHI data, or administrative activities.

12.4.6 Procedures to Release Data or Biospecimens

Authorized representatives of the following groups may need to review this research as part of their responsibilities to protect research subjects: authorized representatives of the sponsor, representatives of the IRB, DSMB/DMC, regulatory agencies, and federal oversight agencies. The clinical study site will permit access to such records following written request. The PI will also grant access to de-identified datasets upon reasonable request to independent researchers wishing to confirm our findings.

12.4.7 Process for Returning Results

N/A.

12.4.8 Process for Tracking Subject Consent and Authorization

Participants may withdraw consent by informing the PI in writing and specifying at that time whether they would like the study team to omit previously collected data pertaining to them from datasets and analysis. If this is not explicitly stated, the study team will use data collected about that study participant

from the time consent was originally signed up until the date the participant withdrew from the study. The research coordinator working with the clinic associated with the study participant who withdrew consent will be informed of their decision by the PI and asked to modify data sets and transcripts accordingly. It is the expectation that datasets will be amended due to participant withdrawal within one week of receiving written notice.

12.5 Protocol Deviations

A protocol deviation is any noncompliance with the clinical trial protocol or investigational plan requirements. The noncompliance may be either on the part of the participant, the investigator, or another member of the study team. As a result of deviations, corrective actions are to be developed by the study team and implemented promptly.

It is the responsibility of the Principal Investigator and all study team members to use continuous vigilance to identify and report deviations. The Principal Investigator is responsible for assessing whether the deviation constitutes noncompliance as defined by the reviewing IRB and if so, reporting it within the required time frames. The site investigator is responsible for knowing and adhering to the reviewing IRB requirements.

12.6 Publication and Data Sharing Policies

This study will be conducted in accordance with the following publication and data sharing policies and regulations:

National Institutes of Health (NIH) Public Access Policy, which ensures that the public has access to the published results of NIH-funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central (https://www.ncbi.nlm.nih.gov/pmc/) upon acceptance for publication.

This study will comply with the NIH Data Sharing Policy and Policy on the Dissemination of NIH-Funded Clinical Trial Information and the Clinical Trials Registration and Results Information Submission rule. As such, this trial will be registered at ClinicalTrials.gov, and resulting information from this trial will be submitted to ClinicalTrials.gov. In addition, every attempt will be made to publish results in peer-reviewed journals. Data from this study may be requested from other researchers up to seven years after the completion of the primary endpoint by contacting the PI in writing.

13.0 STUDY ANALYSIS

13.1 Statistical Hypotheses

- **Primary Efficacy Endpoint(s):**
  - Completion of 5 vascular and 4 infectious disease care processes, modeled as percent indicated and dichotomously (all relevant completed vs. missing ≥1). *Hypothesis*: A larger proportion of patients in the integrated care model arm, compared to historical controls, will complete the 5 vascular and 4 infectious disease care processes.

- **Secondary Efficacy Endpoint(s):**
  - Amputation, defined as either major or minor. *Hypothesis*: A smaller proportion of patients in the integrated care arm, compared to historical controls, will undergo either major or minor amputation within 3 months of diabetic foot ulcer diagnosis.

13.2 Sample Size and Statistical Analysis

We have now finished enrolling active patients into the intervention. Our final number of active patients is 27. This is lower than our target enrollment of 45. Therefore, we re-calcuated the number of historical controls needed to achieve adequate power for care processes. First we assume the probability of exposure among sampled control subjects is 0.6 and the correlation coefficient for exposure between matched cases and control subjects in 0.3. To detect an odds ratio of 0.26 versus the alternative of equal odds with 27 active patients and a matching sample of 5 historical controls per active patient (totaling 162 active and historical patients combined), and with a Type I error rate of 0.05, the power is 0.80706 (computed using PASS 2024, version 24.0.1.

When analyzing pilot data, descriptive statistics will be run on variables other than our primary and secondary outcomes. When analyzing our primary and secondary outcomes, we will stratify by clinic because they serve communities of differing socioeconomic status. Care processes will be modeled both dichotomously (all relevant completed vs. missing at least one) and continuously (as a percent of indicated care processes that occurred). In analyzing our primary outcome dichotomously, we will use a factorial experimental approach where the guideline-concordant and -discordant measures will be calculated. Additionally, due to the categorical nature of both our primary (dichotomously modeled care processes) and secondary (major and minor amputation) outcomes, we will build a multivariable Poisson regression model. When modeling guideline concordance care processes continuously, we use linear regression. In the primary analysis, we will require patients referred to a vascular or infectious disease specialist to be seen by that specialty, either in-person or via telemedicine, within 2 weeks per our algorithm. We will also conduct an intention-to-treat analysis where we include consults placed but not completed or delayed. Pre/post differences in completed referral rates, coupled with data on why a referral did not take place, will allow us to determine whether referral gaps would be best addressed by focusing on primary or specialty clinic processes.

13.3 Planned Interim Analysis

Not applicable.

13.4 Handling of Missing Data

Guidelines promulgated in the National Research Council report on handling of missing data will be followed.[1,2]

14.0 RISK/BENEFIT ASSESSMENT

14.1 Known Potential Benefits to the Subjects

The potential benefits to patient participants associated with this study includes possible improvement of care for their diabetic foot ulcers. These improvements may extend to a reduction in the risk of major or minor amputation due to ulcers. Healthcare workers are not expected to benefit directly, though participation in the integrated care model may provide improved understanding of guideline concordant care of diabetic foot ulcers.

14.2 Known Potential Risks

There are no direct physical risks associated with the integrated care model. Patient participants' care will continue to be overseen by their primary care provider, who will retain final clinical decision making and will be allowed to deviate from the integrated care model should it be in the patient's best interest. To ensure there are no unforeseen negative consequences, the study team will track adverse events. The following is a list of adverse events that will be tracked by the study team:

- Hypoglycemia requiring hospitalization or an emergency room visit
- Adverse reaction to a smoking cessation product
- Muscle aches after starting or changing a statin
- Complication of a revascularization procedure
- Adverse reaction to a wound care product or dressing
- Adverse reaction to an antibiotic prescribed for an infection complicating the diabetic foot ulcer
- Hospitalization for a diabetic foot ulcer (occurs in 30% of patients with diabetic foot ulcers)
- Major (above-ankle) amputation (risk increases with ulcer severity but is 5% in the overall national cohort of patients with diabetic foot ulcers)
- Death
- Patient reported adverse events that the patient attributes to study participation

All serious, unanticipated adverse events, deaths (whether anticipated or not), and major amputations (whether anticipated or not) will be reported to the ICTR DMC within 14 days of the study team becoming aware of these events as well as the IRB. The baseline rate of major amputations among patients with diabetic foot ulcers is ~5% using national cohort data, although risk varies by ulcer severity.[8] If the baseline rate in our pilot exceeds 15%, the study will be stopped and reviewed by the DMC and IRB for any necessary changes to the protocol. Particular attention will be paid to whether or not the major amputation caused by the integrated care model.

The primary risk to patient and healthcare worker participants is presented by a potential breach of confidentiality. These risks will be minimized by performing research activities in private spaces to the degree possible and complying with confidentiality procedures outlined above. Rural providers who participate may also face a risk to reputation. Again, this risk is minimized by protecting confidentiality.

14.3 Risk/Benefit Analysis

This project directly addresses the escalating national rate of major (above-ankle) amputations due to diabetic foot ulcers; it focuses on rural patients, who face 37% higher odds of major amputation compared to their urban counterparts. The project pilots the first integrated care model adapted to rural settings, an approach that has reduced major amputations in urban settings by approximately 40%. Pilot data will be used to improve recruitment and retention strategies and provide preliminary evidence of efficacy needed to conduct a robust, statewide efficacy trial.

15.0 DATA AND SAFETY MONITORING

15.1 Unanticipated Problems

An unanticipated problem (UP), as defined by the DHHS Office for Human Research Protection (OHRP), is any incident, experience, or outcome that meets all of the following criteria:

- The incidence, experience, or outcome is unexpected given the research procedures described in protocol-related documents (e.g., the study protocol and informed consent documents) and the characteristics of the population being studied. An event may be considered unexpected if it exceeds the nature, severity, or frequency described in the study-related documents.
- The incidence, experience, or outcome is related or probably related to participation in the research study. “Probably related” means the incidence, experience, or outcome is more likely than not to be caused by the research study procedures.
- The occurrence of the incidence, experience, or outcome suggests that the research places subjects or others at a greater risk of harm (physical, psychological, economic, or social) than was previously known or recognized.

The investigator will report UPs to the reviewing IRB and ICTR DMC. The UP report will include the following information:

- Protocol identifying information: protocol title and number, PI's name, and the IRB project number;
- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol, informed consent documents, or other corrective actions that have been taken or are proposed in response to the UP.

For this study, UPs will include all major amputations and deaths, even though these are anticipated to some degree in this study population. Please see section 14.2 (Known Potential Risks) for further details. Study Stopping Rule will be a major amputation rate of 10% or more. Report UPs within the timeframe specified by the IRB of record and DMC.

15.2 Safety Oversight

Safety oversight will be under the direction of a Data and Safety Monitoring Board (DSMB) composed of individuals with the appropriate expertise, including rural providers and specialists. Members of the DSMB should be independent from the study conduct and free of conflict of interest, or measures should be in place to minimize perceived conflict of interest. The DSMB will meet at least semiannually to assess safety and efficacy data on each arm of the study. The DMSB will operate under the rules of an approved charter that will be written and reviewed at the organizational meeting of the DSMB. At this time, each data element that the DSMB needs to assess will be clearly defined. The DSMB will provide its input to the PI and funder (NIDDK).

The ICTR DMC will provide an independent biostatistician to create reports of overall data analysis preparation for review by the DMC for bi-annual meetings.

16.0 STUDY FEASIBILITY

16.1 Economic Burden to Subjects

Patient participants will be responsible for any costs related to the care they receive as part of the integrated care model, such as clinic visits, including costs associated with referrals to specialty clinics, and treatment costs, including all out-of-pocket costs.

16.2 Facilities and Locations

The first clinic will be UW Health Belleville Family Medicine. The second and third clinics will be SPH Diabetes and Wound Care clinics. Data will be collated, stored, and analyzed at the Health Innovation Program (HIP) and/or the UW Medical Foundation Centennial Building. A co-design session with the Cooperative will be conducted at their headquarters in Sauk City.

The PI has ample experience working with UW Health Belleville Family Medicine, having enlisted the help of their providers in qualitative studies leading up to this intervention. She has over 5 years of experience working with the Cooperative on this issue as well. She is a HIP investigator.

16.3 Feasibility of Recruiting the Required Number of Subjects

The Cooperative clinics that will be approached for participation in this study each serve between 1513-1791 patients with diabetes. Using a 2% annual incidence, we estimate 30-35 patients will be diagnosed with a diabetic foot ulcer at each clinic annually. Taking into consideration rolling activation of clinics over a two year period, and using a conservative estimate of 30 patients with diabetic foot ulcer, we would expect

a pool of 135 eligible patient participants during the course of the study. Given planned recruitment and retention efforts, we reasonably expect to be able to enroll 45 patient participants throughout the course of the study. However, patient recruitment has been slower than initially expected. To offset this, we are 1) activating clinic 3 simultaneously with clinic 2 to provider a longer timeframe over which to recruit patients, and 2) increasing our active: historical control ratio from 1:1 to 1:5o ensure we are adequately powered.

Regarding the feasibility of recruiting healthcare workers, our prior engagement of these individuals in the research leading up to this interventions leads us to believe recruiting individual healthcare workers will be feasible at each clinic. Full healthcare worker participation at clinic 1 offers further data to suggest we will be able to make our healthcare worker recruitment goals.

16.4 Principal Investigator Considerations

16.4.1 Time Devoted to Conducting the Research

The Principle Investigator, Meghan Brennan, has ensured that a sufficient amount of time will be devoted to conducting and completing this research, budgeting 30% of her effort on the NIDDK grant funding this project.

16.4.2 Process for Informing Study Teams

In the month leading up to a clinic's activation and through the end of data collection at that site, the PI will meet weekly with research coordinators engaging active clinics. Meetings will include reviewing the study protocol, any changes, and research coordinator duties. The greater study team will meet to review preliminary findings just prior to presenting them to on-boarding clinics and after the co-design session, to debrief and finalize changes to the recruitment and retention strategies. Additional meetings will also be held as needed and at the conclusion of the study.

16.5 Availability of Medical or Psychological Resources

Not applicable.

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18.0 APPENDICES

18.1 Appendix 1: Recruitment Table Top Flyer for Belleville

UWHealth

Do you have a diabetic foot ulcer?

Are you interested in helping your community by participating in research?

If so, please tell your healthcare provider. You may be able to enroll in a research study with the UW Health Belleville clinic and University of Wisconsin–Madison.

Participants will be paid to complete a 3-month study.

WISCONSIN
UNIVERSITY OF WISCONSIN-MADISON

18.2 Appendix 2: Recruitment Bi-fold Pamphlet for Belleville

Study Goal

- To improve care for rural patients with diabetic foot ulcers by helping their clinicians provide coordinated care

What Does It Involve?

- Meeting with a University of Wisconsin study team member to review the study and make sure you consent to participate
- Allowing your providers to use a flow chart that helps coordinate care across different clinics
- A 3-month phone call

Who Can Participate

- UW Health Belleville patients with a new diabetic foot ulcer

Next Steps

- Talk to the UW Health primary care provider, who can put you in touch with the study coordinator

OR

- Contact the study coordinator directly at: (608) 262-2390 or dmcclain4@wisc.edu

Compensation

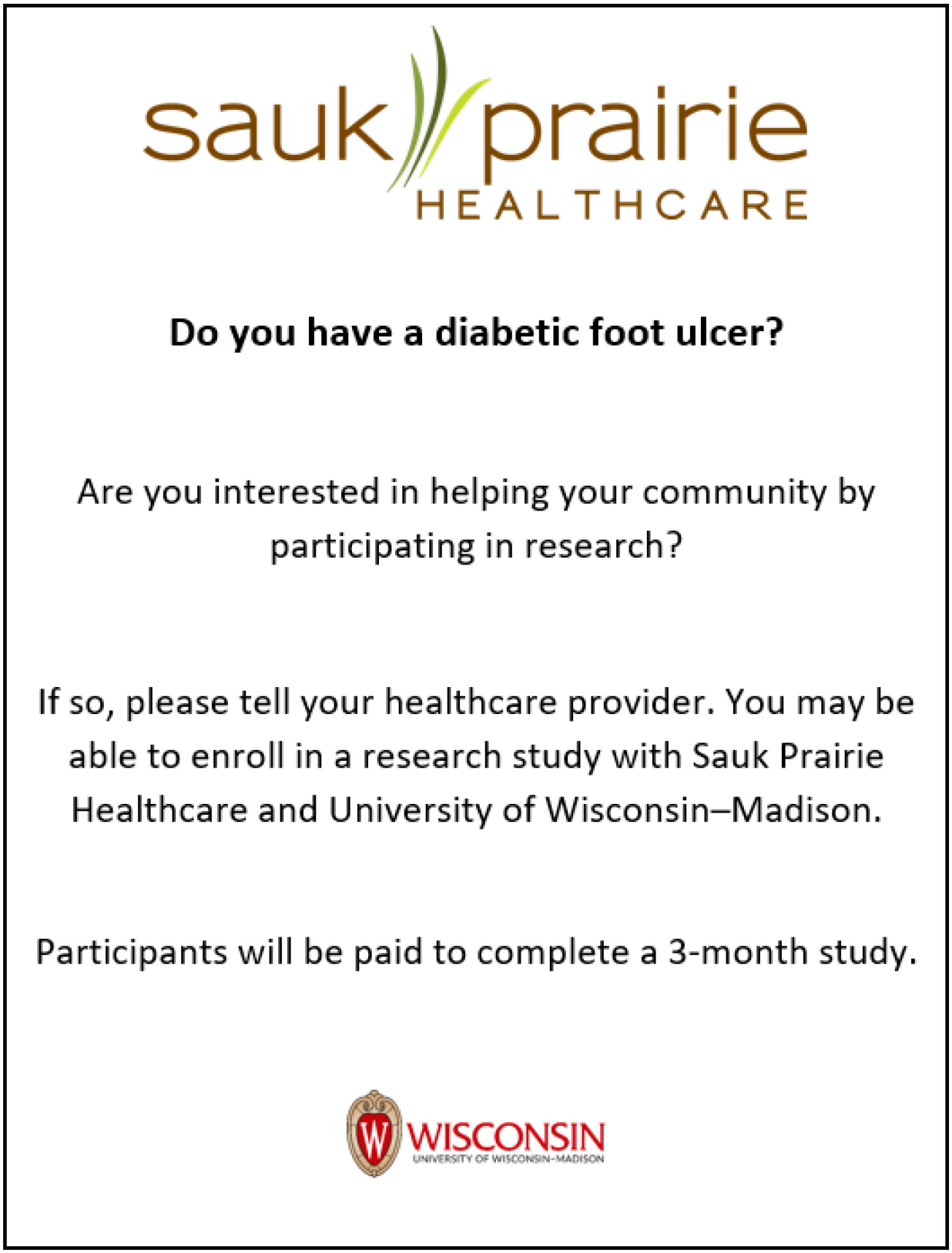
- $100 upon enrollment
- $100 upon completing the 3-month phone call

Crossing the Divide

A Diabetic Foot Ulcer Study

WISCONSIN
UNIVERSITY OF WISCONSIN-MADISON

18.3 Appendix 3: Recruitment Table Top Flyer for Sauk Prairie Healthcare



18.4 Appendix 4: Recruitment Bi-fold Pamphlet for Sauk Prairie Healthcare

Study Goal

- To improve care for rural patients with diabetic foot ulcers by helping their clinicians provide coordinated care

What Does It Involve?

- Meeting with a University of Wisconsin study team member to review the study and make sure you consent to participate
- Allowing your providers to use a flow chart that helps coordinate care across different clinics
- A 3-month phone call

Who Can Participate

- Sauk Prairie Healthcare patients with a new diabetic foot ulcer

Next Steps

- Talk to the Sauk Prairie Healthcare Diabetes or Wound Care Team, who can put you in touch with the study team

OR

- Contact the study coordinator directly at: (608) 262-2390 or dmcclain4@wisc.edu

Compensation

- $100 upon enrollment
- $100 upon completing the 3-month phone call

Crossing the Divide

A Diabetic Foot Ulcer Study

sauk prairie HEALTHCARE & WISCONSIN UNIVERSITY OF WISCONSIN-MADISON

18.5 Appendix 5: Recruitment Telephone Screening Script for Patient Participants for the Integrated Care Model

Recruitment Telephone Screening Script for Patient Participants for the Integrated Care Model

If no answer… Hello, this message is for _____. My name is _____ from Dr. Meghan Brennan's research team at the University of Wisconsin. Please give me a call back at your convenience at [phone number].

If someone else answers… Hello, may I speak with _____? My name is _____ from Dr. Meghan Brennan's research team at the University of Wisconsin. *(If not available):* Will you please ask them to give me a call back at their earliest convenience at [phone number]?

Hello _____. My name is _____ and I'm calling about the Crossing the Divide research study. Hopefully you received a letter from our study team about our pilot, and perhaps [name of participating provider] told you a bit about it. Is now a good time to chat?

We received your contact information because [name of participating provider] is participating in our pilot study and you recently developed a diabetic foot ulcer. As an overview, the Crossing the Divide study was developed to improve treatment of diabetic foot ulcers for patients who live and receive healthcare in rural areas. This is a pilot study of an intervention to help clinicians provide care based on national standards. It was developed by clinicians and healthcare workers who practice in rural settings, with help from our research team. This current study will help us prepare for a larger study across rural Wisconsin, at which point we hope to find out how good the intervention is at getting people back on their feet.

To participate in the study, I will need to do a screening now over the phone to see if you qualify. If you do qualify and are interested in participating, you would come in 30 minutes prior to your next clinic visit to review and sign informed consent. At that time, you would receive $100 for enrolling in the study. After that, participation includes just coming in for your regular visits with your doctor. We would also track your progress through your medical chart over the next 3 months. After that 3-month period, we would stop checking your medical record and give you a quick phone call to see whether your ulcer has healed. Once that phone call is done, you will have completed the study and receive another $100 for your participation. In total, you would receive $200 for enrolling in and completing the study.

Do you have any questions about the study at this time?

Would you be interested in completing the phone screening to see if you qualify for the study?

If no… Thank you for your time. Goodbye.

If yes, proceed.

As mentioned, if you choose to enroll and participate in the study, we would need to meet with you for 30 minutes prior to your next clinic visit. Before I can schedule that, I need to ask you a few questions while on the phone. The purpose of the questions are to determine eligibility for the study. This phone screening is voluntary, and you can stop the phone screening at any time. If you are not eligible for this study, we will record the reason as to why you are not eligible. The purpose of keeping this information is to allow us to track the number of people who have decided to enroll or not enroll in the study. Only our study personnel will have access to this information.

1. **Call Attempt #1**
   a. **Telephone Screener:** ☐
   b. **DATE (mm/dd/yyyy):** ☐☐ / ☐☐ / ☐☐☐☐
   c. **Check One:**
      ☐ Answered → Proceed to #4
      ☐ Left message → END CALL (complete Call Attempt #2 at a later date)
      ☐ No message → END CALL (complete Call Attempt #2 at a later date)

2. **Call Attempt #2**
   a. **Telephone Screener:** ☐
   b. **DATE (mm/dd/yyyy):** ☐☐ / ☐☐ / ☐☐☐☐
   c. **Check One:**
      ☐ Answered → Proceed to #4
      ☐ Left message → END CALL (complete Call Attempt #3 at a later date)
      ☐ No message → END CALL (complete Call Attempt #3 in at a later date)

3. **Call Attempt #3**
   a. **Telephone Screener:** ☐

b. **DATE (mm/dd/yyyy):** ☐☐ / ☐☐ / ☐☐☐☐

c. **Check One:**

☐ Answered → Proceed to next question

☐ No answer / No message → *End Call* → **EXCLUDED**

4. **Are you interested in proceeding to the next step in recruitment for the study by answering the following questions?**

☐ If **Yes** → *Proceed with questions*

☐ If **No** → **Thank you for your time.** *End call* → **EXCLUDED**

5. **Do you feel comfortable reading and communicating in English?**

☐ If **NO** → EXCLUDED; end call; no additional contact

I am sorry we do not have translators at this time for this research study. We look forward to including translators for multiple languages in the future. *End call* → **EXCLUDED**

☐ If **YES** → proceed to next question

6. **Do you have an ulcer or sore on your foot?**

☐ If **NO** → EXCLUDED; end call; no additional contact

I am glad you don't. The study is for patients with foot ulcers or sores, so you don't qualify at this time. Thanks for your time today. *End call* → **EXCLUDED**

☐ If **YES** → proceed to next question

7. **Do you have health insurance?**

☐ **If NO insurance coverage →** EXCLUDED; end call; no additional contact

Okay. Unfortunately, you don't qualify at this time because we don't want you to get stuck with additional bills from specialty care that participating in this study might cause. Thanks so much for your time. *End call* → **EXCLUDED**

☐

If **YES** → proceed to next question

8. What health insurance do you currently have?

Record name of health insurance:

9. Does the insurance match the information provided by the clinic?

☐ If **NO** → ***NOTE!*** **If insurance <u>does NOT</u> match information provided by clinic:**

Okay. I'm going to have to get back with you to see if you qualify to participate. We want to make sure your insurance would cover specialty care at UW Health should it be necessary, and we don't want you to get stuck with the bill if it doesn't. Is it okay if I give you a call back at this number? Are any dates and times better for you? *End call* →

Record potential dates/times to try back:

☐ If **YES** → *Proceed.*

Based on your answers, you do qualify for the study. Are you willing to come in to the clinic 30 minutes before your next scheduled visit? It is on _____ at _____, so that would require you to come in at _____ am/pm. This time would be for reviewing and signing consent to enroll and participate in the study.

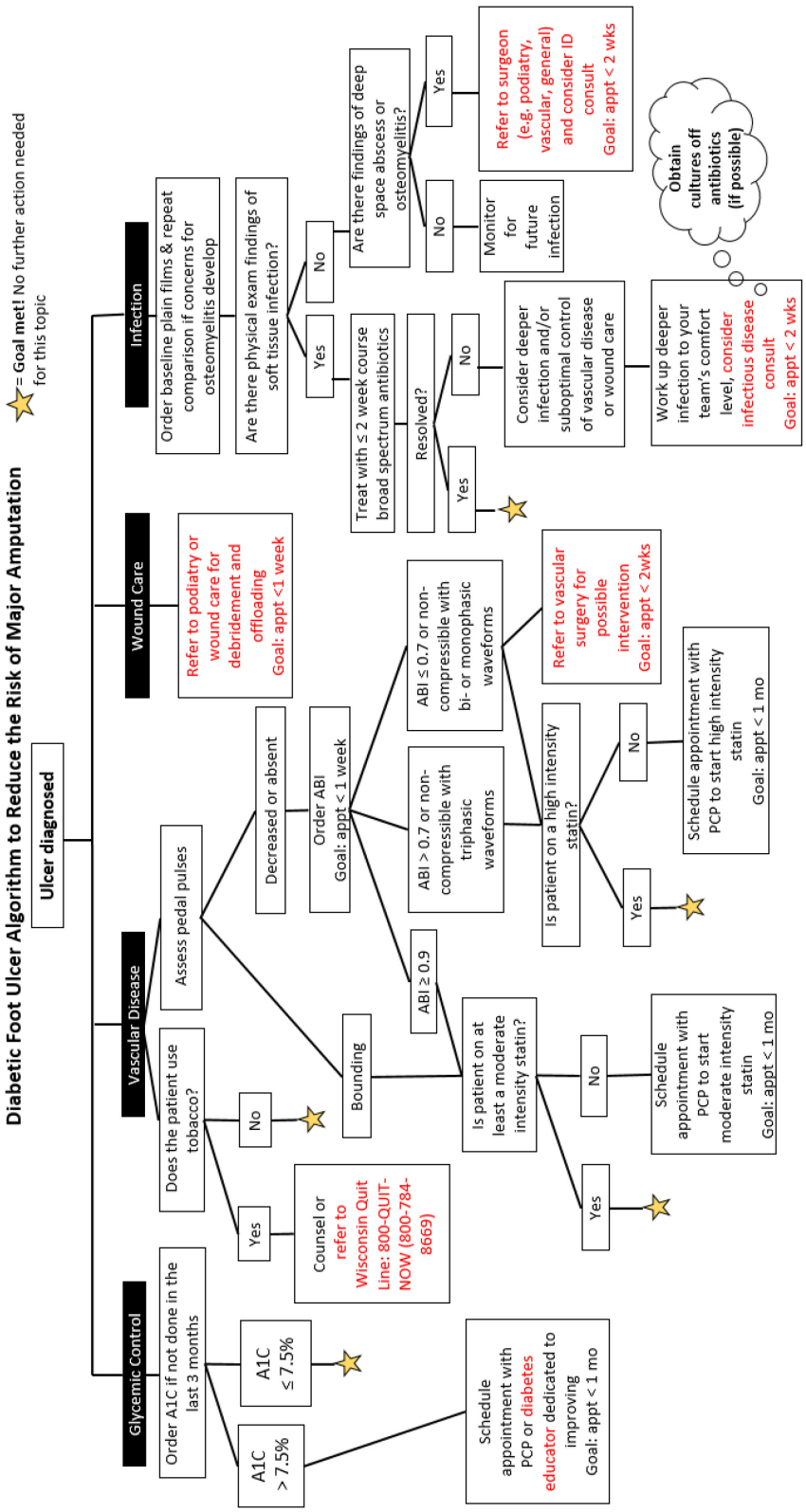
We will contact you with a reminder the business day prior to your visit. Would you prefer the reminder be a phone call or email?

☐ **Phone call** ☐ **Email**

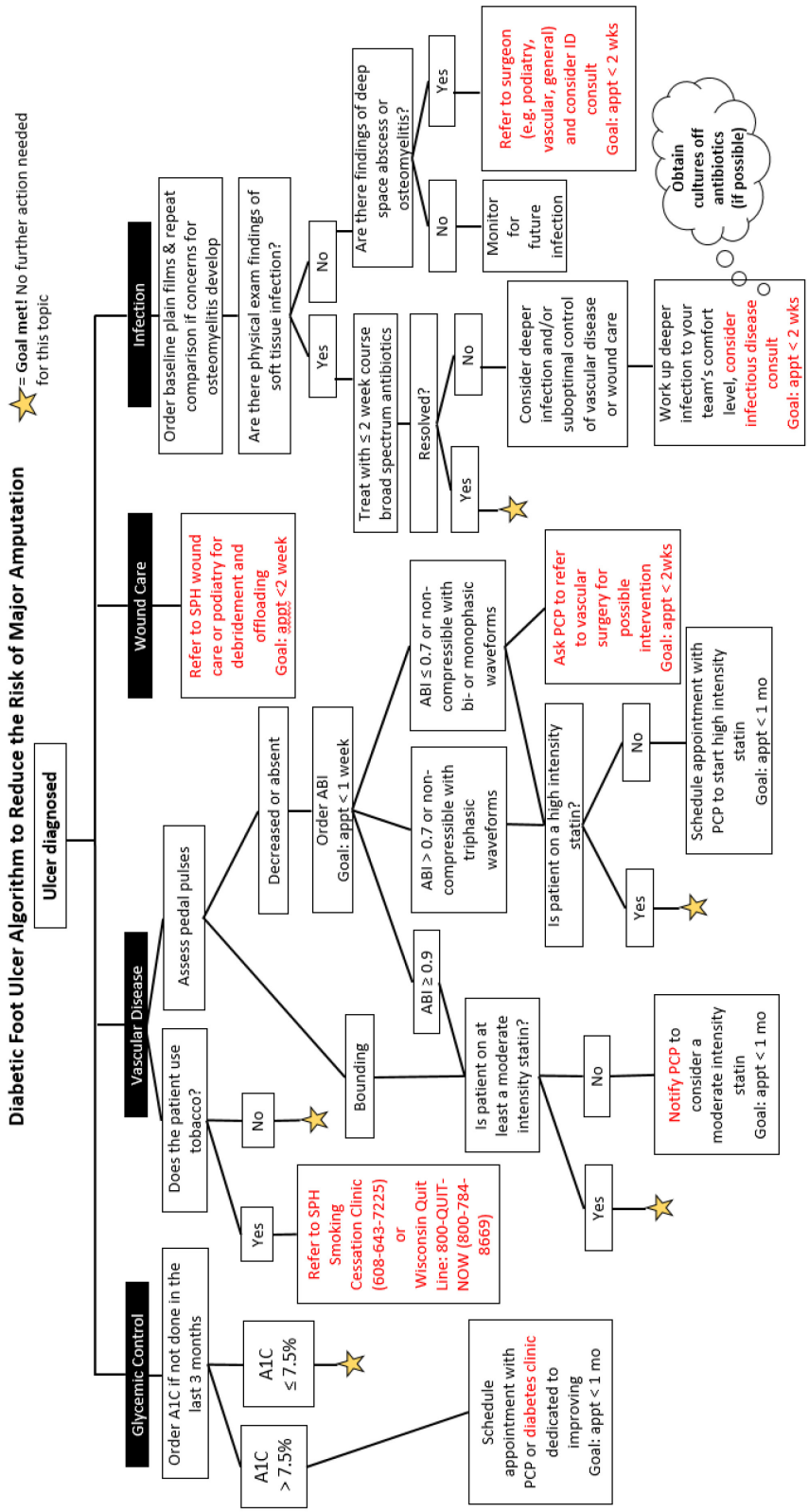
Record email address or phone number here:

Great! We look forward to seeing you on [DATE] at [TIME] before your next clinic visit. Thank you.

18.6 Appendix 6: Integrated Care Algorithm for Rural Providers at Belleville



18.7 Appendix 7: Integrated Care Algorithm for Rural Providers at Sauk Prairie Healthcare



18.8 Appendix 8: Referral Form for Patients with Diabetic Foot Ulcers at Belleville

Referral Form for Patients with Diabetic Foot Ulcers

Patient Name:_____DOB_____
mm/dd/yyyy

Primary Care Provider (PCP):_____

PCP Clinic Phone:(___)____-_____PCP Clinic Fax:(___)____-_____

TO THE SPECIALIST'S OFFICE: Please contact the PCP clinic with
1) the scheduled appointment date
2) an office phone number and contact name for this referral
3) your provider's visit/procedure notes.

Reason for consultation: Assistance managing diabetic foot ulcer

This patient is being referred to (check appropriate box):
- ☐ Podiatry/wound care (goal appointment <1 week)
- ☐ Vascular surgery (goal appointment in <2 weeks)
- ☐ Infectious disease (goal appointment in < 2 weeks)
- ☐ Other:_____(goal appointment in_____weeks)

This referral packet includes the following:

Clinic Notes from Referring Facility:
- ☐ Initial note describing the ulcer
- ☐ Most recent note describing the ulcer
- ☐ Procedure notes (*these might be outside PCP system)*
- ☐ Current medication list
- ☐ Consult notes (e.g. podiatry, wound care, vascular, infectious disease)

Labs from Referring Facility:
- ☐ Most recent A1C (*this might be outside PCP system)*
- ☐ Wound/bone cultures with susceptibilities (*this might be outside PCP system)*
- ☐ Pathology reports related to the ulcer

Imaging from Referring Facility:
- ☐ Plain film reports of the foot
- ☐ MRI reports of the foot
- ☐ Ankle-brachial index (ABI) testing (include the full report with waveforms); Venus reflux study; Transcutaneous tissue pressure oxygenation study (*these might be outside PCP system*)
- ☐ CT angiogram of the lower extremities report

18.9 Appendix 9: Referral Form for Patients with Diabetic Foot Ulcers at Sauk Prairie Healthcare

Referral Form for Patients with Diabetic Foot Ulcers

Patient Name:_____DOB_____
mm/dd/yyyy

Sauk Prairie Healthcare Referring Provider:_____

Sauk Prairie Healthcare Clinic Phone: (___) ____-_____

Sauk Prairie Healthcare Clinic Fax: (___) ____-_____
UW Health Infectious Disease Clinic Fax number: 608-265-8885
UW Health Vascular Surgery Clinic Fax number: 608-265-5755

TO THE SPECIALIST'S OFFICE: Please contact the PCP clinic with
1) the scheduled appointment date
2) an office phone number and contact name for this referral
3) your provider's visit/procedure notes.

Reason for consultation: Assistance managing diabetic foot ulcer

This patient is being referred to (check appropriate box):
- ☐ Podiatry/wound care (goal appointment <2 weeks)
- ☐ Vascular surgery (goal appointment in <2 weeks)
- ☐ Infectious disease (goal appointment in < 2 weeks)
- ☐ Other:_____(goal appointment in_____weeks)

This referral packet includes the following:

Clinic Notes from Referring Facility:
- ☐ Initial note describing the ulcer
- ☐ Most recent note describing the ulcer
- ☐ Procedure notes (*these might be outside PCP system)*
- ☐ Current medication list
- ☐ Consult notes (e.g. podiatry, wound care, vascular, infectious disease)

Labs from Referring Facility:
- ☐ Most recent A1C (*this might be outside PCP system)*
- ☐ Wound/bone cultures with susceptibilities (*this might be outside PCP system)*
- ☐ Pathology reports related to the ulcer

Imaging from Referring Facility:
- ☐ Plain film reports of the foot
- ☐ MRI reports of the foot
- ☐ Ankle-brachial index (ABI) testing (include the full report with waveforms); Venus reflux study; Transcutaneous tissue pressure oxygenation study (*these might be outside PCP system*)
- ☐ CT angiogram of the lower extremities report

Other
- ☐
- ☐
- ☐

18.10 Appendix 10: Integrated Care Model Chart Review Variables

Patient characteristics	Sociodemographics	Age, sex, race, marital status, area deprivation index, insurance, clinic 1-3, primary care provider, all assessed at baseline
	Comorbidities	Charlson comorbidity index, hypertension, hyperlipidemia, coronary artery disease, stroke/TIA, peripheral vascular disease, end-stage renal disease, peripheral neuropathy, Charcot arthropathy, body mass index, smoking status, all assessed at baseline
	Medications	Use of anticoagulant, angiotensin reductase inhibitor, angiotensin II receptor blocker, all assessed at baseline and 3-month follow-up
	Lab values	Hemoglobin A1C, serum creatinine, both assessed at baseline and 3-month follow-up
	Ulcer characteristics	Date of diagnosis, Wagner severity[104] grade at baseline and 3-month follow-up
Care processes	5 Vascular disease care processes	**1)** Baseline exam documents pedal pulse assessment
		2) Baseline visit documents smoking status and cessation counseling within 3-months if indicated
		3) Baseline visit documents statin use, and started within 3-months if indicated
		4) ABI completed in 1 week for patients with decreased/absent pulses
		5) Patients with ABIs ≤0.7 seen by vascular surgery within 2 weeks
	4 Infectious disease care processes	**1)** Baseline plain films for serial assessment of osteomyelitis
		2) All exams document the presence/absence of findings suggestive of infection
		3) Initial soft tissue infections treated with 2 weeks of broad spectrum antibiotics
		4) Patients with concerns of, deep space abscess or osteomyelitis referred to a surgeon and/or infectious disease consultation in 2 weeks
	Other care processes	ABI results, referral to additional consultants (e.g., podiatry), whether vascular surgery and infectiousdisease consults were in-person or via telehealth, whether vascular surgery or infectious disease consults were never scheduled, canceled, or no-shows, all assessed at 3-month follow-up
	Ulcer status	Healed, ulcerated, major or minor amputation at 3 months, assessed by chart review for all patients & by patient report for those receiving integrated care
	Death	Patient died within the 3-month follow-up

18.11 Appendix 11: Phone Script for Recruitment of Participants for Qualitative Recruitment Interviews

Recruitment Telephone Script for Qualitative Recruitment Interviews

**If enrolled/consented in the care algorithm pilot, check demographics form for preferred contact method to determine whether to call or email and check appropriate box for contact method*

☐ Telephone call preferred ☐ Email preferred

First call/email attempt (date & time): _____

Second call/email attempt, *if needed* (date & time): _____

Final call/email attempt, *if needed* (date & time): _____

If no answer… Hello, this message is for _____. My name is _____ from Dr. Meghan Brennan's research team at the University of Wisconsin–Madison. Please give me a call back at your convenience at [phone number].

If someone else answers… Hello, may I speak with _____? My name is _____ from Dr. Meghan Brennan's research team at the University of Wisconsin–Madison. *(If not available):* Will you please ask them to give me a call back at their earliest convenience at [phone number]?

Hello, this is _____ from the University of Wisconsin–Madison. I am calling to see if you might be interested in participating in an interview regarding the recruitment process for the Crossing the Divide research study that you [did or did not] choose to enroll in. We want to obtain feedback regarding the recruitment process in order to improve it. We'd like to get your opinion about what you think works well and what you would change. The interview will take about 30 minutes. You will be asked a number of open-ended questions, such as:

> [For healthcare workers]: 'What do you think about your clinic participating in research?' or 'How would you improve the recruitment process for healthcare workers at your clinic?'
>
> [For patient participants]: 'What do you think motivates people in your community to participate in clinical research?' or 'What makes you hesitate to participate in research like this?'

The interview would take place in your preferred format, either in person at your primary care clinic, via video conference, or by phone. It will be audio recorded and transcribed with the exception that personal identifying information like your name will be removed. After the interview, you will receive $50 as a thank you for your participation.

Are you willing to participate in an interview? Yes _____ No _____

What date and time would work well for you?

Date and time: _____

How would you like to do the interview: in person, by phone or via video call?

a) **in person** at [clinic name and location]. [*Provide information specific to the clinic, such as where to park, where to enter building, what to do once inside the building, etc. – will need to be determined with clinic staff*]

b) **by phone**. Is this the number that is best to reach you at? *If not, record preferred number:* _____

c) **via video conference**.

[*If enrolled – based on Demographics form*]: I have your email address as [email address]. Is this the address that I should use to send you a reminder email with meeting link? *If not, record preferred email address:* _____

[*If NOT enrolled*]: Can I please get the email address that you'd prefer I use to send you a reminder email with meeting link? *Record email address:* _____

If "a" (in person) or "b" (by phone) above:

[*If enrolled*]: I have your preferred contact method as phone. Is that still correct, and can I make a reminder call to this number the business day prior to your interview?

If preferred contact method, email, or phone has changed, record that info here:

_____

[*If enrollment was previously declined*]: We will contact you with a reminder the business day prior to your visit. Would you prefer a phone call or email?

Record phone or email here: _____

Thank you for your time, and I look forward to speaking with you on [interview date & time].

18.12 Appendix 12: Email Template for Recruitment of Participants for Qualitative Recruitment Interviews

Recruitment Email Template for Qualitative Recruitment Interviews

**If enrolled/consented in the care algorithm pilot, check demographics form for preferred contact method to determine whether to call or email*

Subject: Interested in providing feedback on Crossing the Divide research study?

Dear [name],

My name is _____ with the Crossing the Divide research study team. I am reaching out to see if you might be interested in participating in an interview regarding the recruitment process for the Crossing the Divide research study about diabetic foot ulcers that you [did or did not] choose to enroll in at your clinic. We want to obtain feedback regarding the recruitment process for our study. We'd like to get your opinion about what you think works well and what you would change. The interview will take about 30 minutes, and would take place in your preferred format, either in person at your primary care clinic, via video conference, or by phone.

Might you be interested in participating in an interview? Please let me know if you are interested or not, by either replying to this email or calling me at _____.

Thank you for your time,
_____ from the Crossing the Divide research study team

Email is generally not a secure way to communicate sensitive or health related information as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately or would prefer not to receive study communication by email, please contact Jamie LaMantia, one of the study coordinators, at (608) 262-8316.

18.13 Appendix 8: Phone Script for Recruitment of Participants for Qualitative Retention Interviews

Recruitment Telephone Script for Qualitative Retention Interviews

**Check demographics form for preferred contact method to determine whether to call or email and check appropriate box for contact method*

☐ Telephone call preferred ☐ Email preferred

First call/email attempt (date & time): _____

Second call/email attempt, *if needed* (date & time): _____

Final call/email attempt, *if needed* (date & time): _____

If no answer… Hello, this message is for _____. My name is _____ from Dr. Meghan Brennan's research team at the University of Wisconsin–Madison. Please give me a call back at your convenience at [phone number].

If someone else answers… Hello, may I speak with _____? My name is _____ from Dr. Meghan Brennan's research team at the University of Wisconsin–Madison. *(If not available):* Will you please ask them to give me a call back at their earliest convenience at [phone number]?

Hello, this is _____ from the University of Wisconsin–Madison. I am calling you to see if you might be interested in participating in an interview regarding the Crossing the Divide research study that you are enrolled in. We want to obtain feedback regarding how the study is doing in terms of keeping you enrolled and participating. We'd like to get your opinion about what you think works well and what you would change. The interview will take about 30 minutes. You will be asked a number of open-ended questions, such as:

'What types of changes have you experienced in terms of your attitude towards, or willingness to participate in, research?'

The interview would take place in your preferred format, either in person at your primary care clinic, via video conference, or by phone. It will be audio recorded and transcribed with the exception that personal identifying information like your name will be removed. After the interview, you will receive $50 as a thank you for your participation.

Are you willing to participate in an interview? Yes _____ No _____

Do you have a date and time that would work well for you?

Date and time: _____

How would you liked to be interviewed: in person, by phone, or via a video call?

a) **in person** at [clinic name and location]. [*Provide information specific to the clinic, such as where to park, where to enter building, what to do once inside the building, etc. – will need to be determined with clinic staff*]

   Can I verify the email address that you'd prefer I use to send you a reminder? *Record email address:* _____

b) **by phone**. Is this the number that is best to reach you at? *If not, record preferred number:* _____

   Can I verify the email address that you'd prefer I use to send you a reminder? *Record email address:* _____

c) **via video conference**. Can I verify the email address that you'd prefer I use to send you a reminder email with meeting link? *Record email address:*

   _____

If "a" (in person) or "b" (by phone) above:

I have your preferred contact method as phone. Is that still correct, and can I make a reminder call to this number the business day prior to your interview?

If preferred contact method, email, or phone has changed, record that info here:

_____

Thank you for your time, and I look forward to speaking with you on [interview date & time].

18.14 Appendix 14: Email Template for Recruitment of Participants for Qualitative Retention Interviews

Recruitment Email Template for Qualitative Retention Interviews

**Check demographics form for preferred contact method to determine whether to call or email*

Subject: Interested in providing feedback on Crossing the Divide research study?

Dear [name],

My name is _____ with the Crossing the Divide research study team. I am reaching out to see if you might be interested in participating in an interview regarding participant retention for the Crossing the Divide research study about diabetic foot ulcers. We want to obtain feedback on how to improve retention for our study. We'd like to get your opinion about what you think works well and what you would change. The interview will take about 30 minutes, and would take place in your preferred format, either in person at your primary care clinic, via video conference, or by phone.

Might you be interested in participating in an interview? Please let me know if you are interested or not, by either replying to this email or calling me at _____.

Thank you for your time,
_____ from the Crossing the Divide research study team

Email is generally not a secure way to communicate sensitive or health related information as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately or would prefer not to receive study communication by email, please contact Jamie LaMantia, one of the study coordinators, at (608) 262-8316.

18.15 Appendix 15: Script for Verbal Consent for Participants of Qualitative Interviews

Verbal Consent Script for Qualitative Recruitment and Retention Interviews

My name is _____. I am part of a research team from the University of Wisconsin–Madison, and we are interested in getting your feedback regarding the [recruitment process -or- participant retention] for the Crossing the Divide study. The interview should take about 30 minutes. We hope that the results of this study will improve recruitment and retention rates for not only this study, but future studies focused on rural health as well.

A potential risk to participating in the interview is loss of confidentiality. We will do everything we can to minimize this risk. The interview will be audio-recorded, but the transcripts will be de-identified before analysis and the audio recordings will be kept in a secure location. At the end of the study, all identifiable information will be destroyed. Any presentation of the results will NOT include your personal information, your healthcare system's information, or patient information. The questions that we ask are not particularly sensitive, however, you can stop the interview or skip a question at any time.

Do you have any questions?

Do you agree to participate?

18.16 Appendix 16: Qualitative Interview Guides

Interview Guides (~30 minutes each)

Healthcare Worker Recruitment Interview

You recently attended an informational session about a diabetic foot ulcer study called *Crossing the Divide*. What did you think of it?

Probes: How was the study explained to you? Did it make sense to you why it was being done, and what we were asking of you? What do you think would be the best way to present information about research studies to healthcare workers at your clinic – group meeting, individual meetings, or an entirely different mode?

What do you think about your clinic participating in research?

Probes: What types of research, if any, have you participated in before? How about other people who work at your clinic? Do you think the clinic is set up for research like this – why or why not?

What types of things did you factor or weigh in when making your decision to participate or not?

Probes: Do you think you have enough patients with diabetic foot ulcers to make participating worth it? Are you interested in diabetic foot ulcers, or diabetes in general?

How would you improve the recruitment process for healthcare workers at this clinic?

Probes: What did you think about the email invitation (if applicable)? What did you think about the length of the meeting? Was there too much detail or not enough? What information were you missing to make the best decision for you?

What else would you like to share?

Additional Questions if healthcare worker attended the informational session/consent virtually:

Was the presentation appropriate for virtual format?

How did the process of signing the consent form go?

How could we do either the virtual aspect of the presentation or the signing of the consent form for participants that attended virtually better?

Additional Questions if healthcare worker was involved in the recruitment process of the clinic:

We are also interested in the recruitment process of a clinic leading up to the informational session.

1. Can you describe the process from your end?
2. How did that work for you?
3. What could have gone better?

4. Who do you think needs to be involved in those initial conversations?
5. What is the key info we need to present to get us through the door?

**Before ending call, complete demographics form for individuals who did not enroll in the care algorithm pilot part of the study.

Patient Recruitment Interview

You recently spoke with a research coordinator to discuss participating in a study for patients with diabetic foot ulcers called *Crossing the Divide*. How did that [insert "initial" for those that proceeded to meet with the research coordinator for consent] phone conversation go from your standpoint?

Probes: What information was important to you when making your decision whether or not to meet and discuss the study further? What might have been clearer? What should we make sure we do the same? Did your provider let you know anything about the study?

Was the timing of the phone call okay? (in terms of day of week, time)

SPH Only: We put some brochures at the checkout desk. Did you notice them? Was this a good spot? What did you think of the brochures?

[Only for those patients who participated in an informed consent discussion]: *Most recently, you met with a member of the research team at your clinic to discuss participation in Crossing the Divide and go through informed consent. How was that process from your standpoint?*

Probes: What parts of the form could have been clearer? What kinds of questions did you have? What did you think about meeting in clinic before your appointment to do this? Was there enough time?

What types of things did you factor or weigh in when making your decision to participate or not?

Probes: Did your provider talk to you about the study beforehand? If so, how did that conversation go? What seemed like the biggest risk for you? What seemed like the biggest benefit?

Have you participated in research before? Why or why not?

In general, what do you think about your clinic and community participating in research?

Probes: Do you think it's a good fit? Why or why not?

What else would improve the recruitment process for patients?

Probes: Would an information letter have been preferred? Would an onsite coordinator be more helpful?

**Before ending call, complete demographics form for individuals who did not enroll in the care algorithm pilot part of the study.

Healthcare Worker Retention Interviews

Thanks so much for participating in *Crossing the Divide*. We wanted to check in to see how we are doing in terms of retaining healthcare workers in our study. From your standpoint, how have things been going?

Probes: How has communication with the research team been? What should we continue to do? What should we stop? What should we be doing differently? What should we start doing?

FOR BELLEVILLE ONLY:

Dr. Brennan came out in December (2023) and May (2024). Did her presentations contain information you were interested in? Was anything missing that you would like to know?

What might be a better way to give updates? Email/letter?

What about the frequency of contact with the study team?

BOTH BELLEVILLE & SPH:

What are your expectations about getting information/study updates moving forward?

Do you want to see a final analysis? Do you want an opportunity to give input on preliminary analysis? Would you like us to distribute publications at the end of the study?

What about the frequency and modality of updates and information shared? What would you prefer?

FOR SPH ONLY:

What, if anything, have you heard from other healthcare workers or patients about your clinic participating in research?

BOTH BELLEVILLE & SPH:

What do you think are the top 3 things we need to do to keep clinics like yours willing to participate in research?

[Clinicians only]:

How could we improve the workflow for identifying patients so that it is easy on you?

How could we improve implementation of the care algorithm or referral checklist so that it is easier for you?

When people like you are signing up to participate in the study, what sorts of things do you think they need to know in terms of roles and responsibilities?

Probe: Did anything catch you off guard that you didn't expect?

Is there anything I'm missing that you think would improve retention in the study for the healthcare team?

Patient Retention Interviews

Thanks so much for participating in the *Crossing the Divide* study. We wanted to check in to see how things went from your standpoint.

We recently added a letter that we sent out to patients about a month after they enrolled. Do you remember getting it? What did you think about it?

Probes: We wanted to send a letter to remind people why we were doing the study and what they could expect. How clear was the information? Did we leave anything out? Was it helpful, or did it seem redundant? Should we keep doing this? Why or why not?

What did you think about the 3-month follow-up phone call?

Probes: How was the timing? Would you have liked any advanced notice that it was coming?

How did the reimbursement process go for you?

Probes: How could we improve it? Moving forward, the university is going to require studies to reimburse participants with a VISA card, check, or direct deposit. How do you think that might affect your decision to participate? Which of the new payment options appeals to you and why?

What type of updates about the study would you like to receive? What information would you most like to know?

Probes: Would you prefer graphics vs. words? The published manuscript? Just the abstract of the manuscript? A bulleted list of our key findings?

How would you prefer to receive updates about the study?

Probes: A flyer in the clinic? A letter sent via USPS? An email?

When patients are signing up for the study, what types of information should they know about participating? Is there anything that we can make clearer up front, or anything that caught you off guard as you moved through the study?

What did your family and friends think about you participating? How is the fit of this type of research for your community?

What did you think about participating in research in general before agreeing to this study, and how has your opinion changed over the course of the study?

Probes: Do you think you would be willing to sign up for something similar again? Why or why not?

Is there anything else you'd like to share about your experience participating in this study, research in general, or anything else?

18.17 Appendix 17: Patient Information Letter

University of Wisconsin
SCHOOL OF MEDICINE AND PUBLIC HEALTH
Department of Medicine

Dear [NAME],

Thank you for enrolling in our research study, Crossing the Divide. It's been about a month since you agreed to participate, and we wanted to send a brief letter to remind you a bit about the study.

The goal of our research is to improve treatment for rural patients with diabetic foot ulcers and prevent amputations. Right now, we are studying two things: 1) how to design a study based in rural clinics so that it runs effectively, and 2) whether a care algorithm that follows national recommendations and helps get people in to see specialists sooner might improve care. A few reminders about this study:

- No extra research visits are required—keep attending your normally scheduled appointments.
- Your clinician will use the care algorithm. You do not need to do anything special beyond following their medical advice.
- We are following your progress through your medical record.
- You will receive a brief (~10 minute) phone call from a member of our research team between [DATES] to complete the study.

Thank you again for participating. If you have any questions, please do not hesitate to reach out to the research coordinator, Devan McClain (608-262-2390; *dmcclain@medicine.wisc.edu*), or myself with questions.

Sincerely,

[SIGNATURE]

Principal Investigator, Crossing the Divide
mbbrennan@medicine.wisc.edu
+1 (608) 263-1545