

PROTOCOL TITLE: Implementation of Telemedicine for patients with wounds and ulcers.

1) Protocol Title

Title: Implementation of Telemedicine for patients with wounds and ulcers.

Protocol Version Date: March 11th, 2021

2) Objectives:

The objective of this quality improvement project is to assess if telemedicine can improve the quality of specialty care offered for new patients with wounds and ulcers due to peripheral artery disease (PAD) and diabetes mellitus (DM) at RHCs. The specific aims of this project are:

- a) Implement telemedicine consultations at rural health clinics.
- b) Evaluate the effect of telemedicine consultation to improve time to specialist evaluation and time to definitive treatment for patients with wounds and ulcers in rural clinics.
- c) To determine if patients with lower levels of activation need more resources to help get care when offered telemedicine

Hypothesis: *Telemedicine consultation can decrease mean time to specialist consultation and time to definitive vascular treatment by 50%. Use of telemedicine will be able to overcome low levels of patient activation by allowing patients to get care in their home area.*

3) Background

Each year, more than 185,000 patients with PAD, DM, or combined PAD/DM undergo leg amputation. Costs to treat wounds and ulcers currently approach \$25 billion annually and are expected to double in the next decade.^{1,2} When ulcer treatment is not effective, amputation is the outcome and currently, 1.4 million people live with an amputation in the United States.^{3,4} Predictors of higher amputation rates include worse ankle-brachial index,⁵ African-American race⁶, lower socio-economic status, dialysis dependence, and older age.⁷⁻¹⁰ Patients living in rural areas are 51% more likely to undergo amputation than those in urban areas.^{11,12}

Patients residing in rural areas face numerous barriers to care. Their concerns are poorly understood, however, these patients are typically of lower socioeconomic status and have limited knowledge of chronic diseases which results in lower patient activation. The distance and burden of coordinating travel, time off work, and need to attend multiple clinic visits can be impossible for patients and families. The hardships patients endure in an effort to attend remote appointments results in unrealistic patient expectations, physician dissatisfaction, non-compliance with treatment, increased hospitalizations, and lower patient activation in disease management.

In February 2016 focused guidelines for assessment of ulcers were published as a joint effort by the Society for Vascular Surgery, American Podiatric Medical Society, and Society of Vascular Medicine. Implementation of these guidelines

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has been poor, especially in rural areas. Telemedicine improves access to expert specialty consultation and patient-centered care in the ambulatory settings. Implementation of telemedicine combines involved faculty with a team-building mentality, concise web-based tools for incorporation into daily practice, and specialty consultation. Telemedicine has been effective in psychiatry, pediatrics, dermatology, and cardiovascular diseases. In telemedicine wound programs for the treatment of ulcers in other countries, physicians found images at remote consultation showed a high concordance compared to in-person evaluation and providers were successful at making wound care recommendations based on images.

The NHLBI strategic vision prioritized community-based effectiveness and implementation research strategies to address health inequalities. Multiple countries have implemented telemedicine wound care programs to improve cost effectiveness of treatment. These programs decreased costs for transportation to provide wound care by 46%. Extrapolation to US wound care costs could indicate a potential savings of nearly \$15 billion annually by implementing a national telemedicine treatment program for ulcer management.

The Vascular Clinic at UC Davis currently conducts telehealth medical visits as a part of the general referral program at UC Davis Health. Within this referral program the clinic works with several Rural Health Centers (RHC) in California and utilizes telehealth medicine as a part of the referral process. This research study proposes to examine the information that is collected during these visits the primary endpoint for this study is time to specialty consultation

4) Inclusion and Exclusion Criteria

Patients will be identified by the clinic when they come in for their regular visit.

Inclusion Criteria

1. 18 years or older
2. Have a wound or ulcer for more than two weeks.
3. Have a diagnosis of Diabetes Mellitus (DM), Peripheral Artery Disease (PAD), vascular disease, or combined PAD/DM
4. Willing to see a provider by telemedicine
5. Able to complete the Patient Activation Measurement (PAM) survey
6. Willing to be contacted by research team

Exclusion Criteria

1. Patients who do not want to participate in the telemedicine visit
2. Adults unable to read and write English. The PAM study is only in English at this time
3. Patients that do not have a home phone or home internet. This is needed to do follow up and any follow up telemedicine visits
4. Patients that do not have a smart phone or computer that can connect to the internet

PROTOCOL TITLE: Implementation of Telemedicine for patients with wounds and ulcers.

We do not plan to include:

- Pregnant women- low incidence of wounds in these patients due to PAD and DM
- Prisoners- Cannot accurately determine care and outcomes

Number of Subjects:

Rural Health Clinic A	25
Rural Health Clinic B	25
Rural Health Clinic C	25
Rural Health Clinic D	25
Rural Health Clinic E	25
Total Number of Patients	125

We plan to include 25 subjects at each of the 5 out of network clinics that are referred to the UC Davis Vascular Clinic for telehealth services for a total enrollment of 125 patients.

5) Study Timelines

The Screening and follow up of data of all patients will start approximately from 5/01/2020 – and end 12/31/2021

Review and Analysis should will be completed by approximately 06/30/2022

6) Study Endpoints

The primary endpoint for this study is time to specialty consultation.

Secondary endpoints are time to revascularization, time to other specialty consultation, time to wound healing, number of telemedicine visits, major amputation, number of hospitalizations, number of emergency room visits, and number of in person visits.

PROTOCOL TITLE: Implementation of Telemedicine for patients with wounds and ulcers.

7) Procedures Involved

Screening: Patients referred from rural clinics will be screened when they are referred to the UC Davis Vascular Clinic for telehealth services to determine if they meet the inclusion/exclusion criteria.

Enrollment/Procedures at Baseline Telehealth Visit: Patients receiving telehealth services will follow the standard operating procedures for those visits. Which includes asking new patients to complete the UCD Privacy statement for new patients and a patient activation questionnaire on the day of their telemedicine visit.

Follow-Up Post Telehealth Visit: All patients will be contacted every 4 weeks to determine if they have had a procedure for their leg wound (revascularization) and if the wound has healed. Patients will be followed until they reach a secondary study end-point which is wound healing, amputation, or for a maximum of 12 months.

8) Withdrawal of Subjects

Patients who choose not to participate in completing a patient activation questionnaire will not be included in this QI project. Patient care is not directed in this project and is clinical driven per standard of care and standard operating procedures for the Vascular Clinic.

9) Risks to Subjects

This is a minimal risk study and the only risk foreseen is a potential breach of confidentiality which will be minimized by securing the data as outlined in the protocol.

10) Potential Benefits to Subjects

No direct benefits to the patient will occur during the data collection and review of the QI project. Future patients may receive a benefit from increased access to telehealth visits or proven to shorten time to care for patients referred from rural clinics.

PROTOCOL TITLE: Implementation of Telemedicine for patients with wounds and ulcers.

Statistical Analysis Plan: Changed as a result of COVID and removal of the comparison arm of the study

The data will be analyzed by Kaplan-Meier analysis comparing time to specialty visit for patients who underwent telemedicine visits to those who did not. Secondary outcome analysis will include chi-squared analysis of the proportion of patients that had wound healing in the telemedicine group compared to those that did not have a telemedicine visit, and Kaplan-Meier analysis of time to definitive revascularization and wound healing for patients that underwent telemedicine and were treated at UCD.

Assuming a historical median time to a specialist consultation of 9 weeks, we will utilize a one-sample log-rank test. We want a sample large enough to detect a hazard ratio (HR) of 3.0 or higher. An HR of 3.0 indicates that at any time, three times as many specialists will consult many patients with telemedicine consultations compared to in-person consultations. A two-sided, one-sample log-rank test calculated from a sample of 24 individuals achieves 89.2% power at a 0.05 significance level to detect a hazard ratio of 3.0 when the median time to consultation of the historical control group is 9 weeks. The probability that a patient experienced a specialist consultation during the study is 0.44. The expected number of events during the study is 11. The time to specialist consultation is likely distributed by the Weibull distribution (shape parameter 1) by both groups (telemedicine and historical controls).