# Remote Patient Pedal Monitoring for Foot Ulcer Prevention

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# PREFACE

The VA Evidence Synthesis Program (ESP) was established in 2007 to conduct timely, rigorous, and independent systematic reviews to support VA clinicians, program leadership, and policymakers improve the health of Veterans. ESP reviews have been used to develop evidence-informed clinical policies, practice guidelines, and performance measures; to guide implementation of programs and services that improve Veterans' health and well-being; and to set the direction of research to close important evidence gaps. Four ESP Centers are located across the US. Centers are led by recognized experts in evidence synthesis, often with roles as practicing VA clinicians. The Coordinating Center, located in Portland, Oregon, manages program operations, ensures methodological consistency and quality of products, engages with stakeholders, and addresses urgent evidence synthesis needs.

Nominations of review topics are solicited several times each year and submitted via the ESP website. Topics are selected based on the availability of relevant evidence and the likelihood that a review on the topic would be feasible and have broad utility across the VA system. If selected, topics are refined with input from Operational Partners (below), ESP staff, and additional subject matter experts. Draft ESP reviews undergo external peer review to ensure they are methodologically sound, unbiased, and include all important evidence on the topic. Peer reviewers must disclose any relevant financial or non-financial conflicts of interest. In seeking broad expertise and perspectives during review development, conflicting viewpoints are common and often result in productive scientific discourse that improves the relevance and rigor of the review. The ESP works to balance divergent views and to manage or mitigate potential conflicts of interest.

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### *Operational Partners*

Operational partners are system-level stakeholders who help ensure relevance of the review topic to the VA, contribute to the development of and approve final project scope and timeframe for completion, provide feedback on the draft report, and provide consultation on strategies for dissemination of the report to the field and relevant groups.

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### *Technical Expert Panel*

To ensure robust, scientifically relevant work, the technical expert panel (TEP) guides topic refinement; provides input on key questions and eligibility criteria, advising on substantive issues or

possibly overlooked areas of research; assures VA relevance; and provides feedback on work in progress. TEP members included:

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## DISCLOSURES

This report was prepared by the ESP Center located at the **Durham VA Medical Center**, directed by Jennifer M. Gierisch, PhD, MPH, and Karen M. Goldstein, MD, MSPH and funded by the Department of Veterans Affairs, Veterans Health Administration, Health Systems Research.

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# *Executive Summary*

# KEY FINDINGS

- Remote patient pedal monitoring for the prevention of foot ulcers among high-risk individuals was evaluated across 12 comparative studies.
- Among the 6 hand-held thermometry trials, a small rate difference in ulcer incidence was observed equating to a 50% relative reduction in ulceration compared to standard of care (95% CI [70%, 3%]).
- There is little trial-based data on effect of newer temperature-sensing devices with remote transmission of data, though 2 observational studies suggest possible benefit.
- Pressure-based monitoring was only assessed in 1 small, randomized trial with inconclusive results.
- Evidence for amputation, hospitalization, and mortality was limited and mixed.
- Device adherence varied widely across studies and was often low.
- The limited evidence found no consistent effect among those with greater adherence.
- No literature comparing outcomes by device type, monitoring frequency, or feedback method was identified.

Foot ulcers are a significant source of morbidity among individuals with predisposing conditions such as diabetes, peripheral neuropathy, and peripheral arterial disease. Many early signs of ulcer development go unnoticed due to loss of protective sensation. Additionally, the effectiveness of standard self-care like daily visual inspection, prescription footwear, and regular foot examination is limited by poor adherence, inadequate patient education, and co-existing physical limitations. Remote patient pedal monitoring (*eg*, hand-held thermometers, temperature-sensing mats, socks, and pressure-monitoring insoles) with and without data transmission to clinical teams have been proposed as tools to support detection of early physiological changes associated with ulcer formation.

Within the VA, foot ulcer prevention is particularly salient. Nearly 1 in 4 Veterans has type 2 diabetes and more than 3,400 Veterans experience a diabetes-related lower extremity amputation (LEA) each year. The VA's Prevention of Amputation in Veterans Everywhere (PAVE) Program provides risk-stratified preventive foot care, but adherence to recommended screenings and specialist foot evaluations have been inconsistent. Emerging telemedicine approaches have been proposed as a way to supplement self-care, reduce access barriers, and support earlier identification and response to tissue injury. These opportunities to improve Veteran care prompted the request for this systematic review to guide decisions about the use of remote patient pedal monitoring technologies.

With this review, we aimed to evaluate the effectiveness and safety of remote patient pedal monitoring devices designed to detect early physiologic signs of foot ulceration among high-risk adults. In addition, we sought to determine if device benefits vary by device type and by certain patient characteristics.

## CURRENT REVIEW

Across the 12 identified comparative studies (9 randomized controlled trials [RCTs], 3 observational), most evaluated temperature-based monitoring, with only 1 study assessing pressure monitoring. Study populations reflected a spectrum of high-risk comorbidities, including diabetes, peripheral neuropathy, prior ulceration or LEA, peripheral arterial disease, and chronic kidney disease. The monitoring approaches ranged from older hand-held thermometry devices for self-monitoring to newer devices, some of which incorporated remote transmission of data to clinical providers, such as temperature-sensing mats, socks, and continuous pressure sensing insoles. Although the devices varied by design, they all aimed to detect pre-ulcerative physiologic changes through at-home monitoring early enough for patients to take action (*eg,* offloading) and prevent ulceration.

Eight RCTs utilized some type of temperature monitoring ($N$ = 1,260). A subgroup of 6 hand-held thermometry trials without automatic remote data transmission ($N$ = 832) showed a small reduction in ulcer development (rate difference [RD] = -0.09, 95% CI [-0.18, -0.01] or risk ratio = 0.54, 95% CI [0.30, 0.97]). Two RCTs evaluated other methods of temperature monitoring ($N$ = 428*).* One trial compared a temperature-sensing mat with and without receipt of adherence reminders and found a small reduction in ulcers for patients who did not receive reminders. The other trial compared temperature-sensing insoles to standard of care and found no statistically significant benefit. Evidence for pressure-based monitoring was minimal, with only 1 small RCT ($N$ = 58) in which the findings conflicted depending on the analytical method used. Two observational studies provided additional evidence for newer temperature-monitoring devices. One observational study with serious concerns for risk of bias found a 68% relative risk reduction with use of a temperature-monitoring sock. A second observational study found a 46% reduction in relative risk associated with temperature-monitoring smart mats.

Of the 4 studies reporting LEA, only 1 was an RCT, although authors did not report a comparative analysis. The remaining 3 observational studies demonstrated mixed effects of remote patient pedal monitoring on subsequent LEA. Impacts also varied across the 4 studies evaluating the effect of remote patient pedal monitoring on rates of hospitalization and emergency room utilization. Mortality was only reported by 3 studies and effects were similarly varied.

Adherence thresholds ranged from 50% to 91% as reported by 7 studies using a variety of measurement approaches, most of which were self-report. Three studies provided participants with adherence feedback to increase use of the device; however, this had little effect. Safety data were also sparse and did not reveal a signal for frequent or significant device-related harms.

Four studies reporting on the impact of device adherence on ulceration, LEA, and hospitalization found no consistent difference in effect among those with greater adherence compared to those with lower adherence. Otherwise, there was very little data on how effects varied by patient-level characteristics of interest. No studies compared effectiveness by device type, monitoring frequency, or alert protocol.

Collectively, the strength of evidence across ulceration, LEA, hospitalization, and mortality outcomes was generally very low or insufficient due to the limited number of studies, small sample sizes, heterogeneity of effect estimates, device and population differences, and inconsistent definitions. We note that there are 4 ongoing studies which may fill some evidence gaps. Future research should address existing evidence limitations by using consistent definitions of ulcer outcomes, standardized eligibility criteria for identifying high-risk populations, and objective adherence measures. Studies

should also evaluate newer devices with automated feedback or continuous monitoring features that may improve usability and sustained engagement. Research conducted within the VA is needed to assess how remote patient pedal monitoring integrates with existing preventive care workflows, particularly the PAVE Program, and to obtain a better understanding of patient preferences, staff workload implications, and long-term clinical outcomes. Additional work is also needed to evaluate potential cost savings, system-level benefits, and strategies for sustaining device use over time.

## CONCLUSIONS

Definitive evidence is lacking for the benefit of newer remote monitoring devices on the prevention of foot ulcers among at-risk individuals, although older hand-held thermometry models without remote data transmission showed a clinically meaningful reduction in ulcer incidence. The current evidence also does not demonstrate clear reductions in LEA, hospitalization, or mortality. Ongoing trials may provide needed guidance on the clinical value of newer remote monitoring technology to improve outcomes for Veterans.