Preventing the Catastrophic Diabetes Complications Hiding In Plain Sight:

At-home Foot Temperature Monitoring for Diabetic Foot Ulcers Leads To Positive Clinical & Financial Outcomes

Review of two studies conducted by leading influential healthcare organizations:
Mid-Atlantic Permanente Medical Group & Intermountain Healthcare

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INTRODUCTION

Diabetic foot ulcers (DFUs) have been proven to lead to devastating consequences for a vulnerable subset of the diabetes population, including high risk of lower extremity amputations. Amputations can have a cascading, catastrophic impact on mobility, quality of life, and mortality for members. Early detection of DFUs is key to amputation avoidance, but DFUs are difficult to identify before they present clinically — and once they do become visible, they are extremely challenging to heal due to poor circulation, infection, or neuropathy associated with diabetes. Despite the enormous human and financial cost, DFU prevention is often a blindspot in many comprehensive diabetes programs.

Two assessments were conducted to explore the impact of at-home foot temperature monitoring as part of a comprehensive care program — a long-standing best practice cited in three major diabetic foot clinical guidelines[1,2,3] — in improving both clinical and financial outcomes. The findings of these two assessments, led by Mid-Atlantic Permanente Medical Group and Intermountain Healthcare, showed clear advantages of once-daily, at-home foot temperature monitoring using Podimetrics SmartMat™ technology.

At-home temperature monitoring is an effective way to reduce the negative clinical and financial impact of DFUs, which lead to catastrophic lower extremity amputations. Monitoring for earlier detection — when integrated with patient-centered technology and personalized virtual care support — cost-effectively promotes greater patient engagement, while serving as an extension of support to a health plan's care management team to affect positive outcomes.

TABLE OF CONTENTS

SITUATION

A payors most challenging task: REDEFINING QUALITY

Stakeholders driving leadership decisions within health plans regularly face the challenge of balancing outcomes, cost, and care collaboration — especially when addressing the needs of high-risk, vulnerable member populations. Leaders are increasingly responsible for managing reputational risk associated with clinical outcomes, while driving a "patient-first" culture, and cultivating operational efficiencies.

Reducing cost at the expense of quality is never an option. Yet finding ways to achieve quality measures, like STARS and HEDIS, through affordable means is a needle in a haystack for health plans. Critical to success is also collaboration to identify and drive forth evidence-based programs that continuously demonstrate improvement.

The result? More pressure than ever before to redefine quality care, then deliver it.

According to business strategist Michael Porter in the Harvard Business Review[4], "It's time for a fundamentally new strategy.

At its core is maximizing value for patients: that is, achieving the best outcomes at the lowest cost. We must move away from a supply-driven health care system organized around what physicians do and toward a patient-centered system organized around what patients need. We must shift the focus from the volume and profitability of services provided — physician visits, hospitalizations, procedures, and tests — to the patient outcomes achieved."

Today, few would disagree with that sentiment, yet it's far easier said than done — particularly when it comes to the most complex member cohorts. The diabetes population is uniquely challenging given the co-morbidities that lead to poor clinical outcomes and financial drain. According to a recent study, nearly 98% of American adults with type 2 diabetes have at least one comorbid condition and approximately 90% have two comorbidities, with the burden increasing with age[5].

Researchers in the same study found that the most common comorbid conditions were:

- **hypertension (82.1%)**
- **overweight or obesity (78.2%)**
- **hyperlipidemia (77.2%)**
- **chronic kidney disease (24.1%)**
- **cardiovascular disease (21.6%)**

Most health plan executives and and clinical leaders focus on those conspicuous drivers of poor diabetes-related outcomes because of the large volume of members impacted by these complications, taking advantage of economies of scale.

However, it's also becoming increasingly understood among payers that the sickest 5% of the population consumes 50% of healthcare spending.[6] Despite those very real drivers of poor outcomes resulting from the broader complex diabetes population, it's critical to keep an eye on the hidden sources putting a strain on health for members and cost for payers.

The sickest 5% of the population
consumes 50% of healthcare spending[6]

PROBLEM

THE SLEEPING GIANT
within a vulnerable population

More than 30 million Americans have diabetes, and at-risk health plans and providers are struggling to manage such a complex population. In fact, there exists a diabetes management blindspot that is often hidden, yet very much present in over two hundred procedure and diagnosis codes: lower extremity complications.

The most vulnerable subset of members with diabetes are those at high-risk of diabetic foot complications. They have the greatest magnitude of problems, resulting in the poorest outcomes and highest costs.

On average, 6% of a health plan's diabetes population is at high risk for diabetic foot complications in a calendar year.[7]

Diabetic foot ulcers, or DFUs, occur due to a combination of factors. For example, high blood sugar levels can stiffen and narrow arteries, restricting blood supply. Also, diabetes-induced nerve damage can cause loss of sensation, which can reduce a diabetes patient's ability to notice the signs of a potential ulcer before it starts. Immune system issues, infection, friction, trauma, and foot deformities are also culprits, increasing the risk of DFU formation.

Without the right tools, DFUs are difficult to identify before they present clinically — and once they do become visible, they are extremely challenging to heal due to poor circulation, infection, or neuropathy associated with diabetes. As a result, lower extremity amputation may be required.

But intervention through amputation is not an ideal solution, by any measure.

DID YOU KNOW?

Complications like diabetic foot ulcers (DFUs) are the #1 cause of lower extremity amputations.[8,9]

A single amputation costs as much as $100,000.[10]

34% of diabetes patients have a lifetime risk of developing a DFU.[11]

40% of diabetes patients with a previous DFU will have a DFU recurrence within one year and 50% within two years.[11]

Lower extremity complications and amputations can represent up to one third of total diabetes costs.[12]

Vulnerable populations are in great need of effective amputation reduction programs. It's critical to also consider those high-risk subsets of the population that have an even greater likelihood to receive amputations based on geography, socio-economic status, or race. **Consider, for example, the data revealing that Black Americans lose limbs at four times the rate of others.[13]**

PROBLEM cont.

Devastating complications
HIDING IN PLAIN SIGHT

62% of patients with diabetes who receive a lower extremity amputation die within five years.[14] While this data point is startling on its own, it's also alarming to compare how much higher the mortality rate is for patients with amputations versus the pooled mortality rates for cancer: a 2020 study documented 9.0% for breast cancer and 80.0% for lung cancer, with a pooled 5-year mortality rate for all reported cancer at 31.0%.[12]

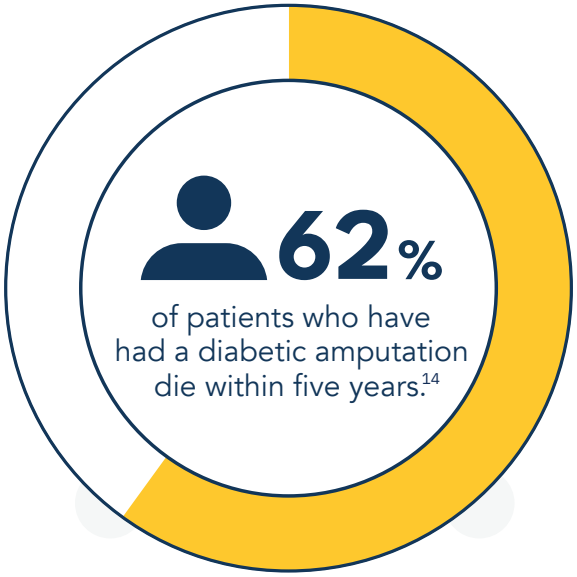
Compounding the overarching prevalence of such a devastating condition is the challenge of preventing DFUs in the first place. More than 95% of diabetes care is done by the patient[15], yet there's a common misconception that members with diabetes often don't take control of their health. This can be true, but only when they aren't empowered through consideration of their environment, lifestyle, motivations, and competing health priorities.

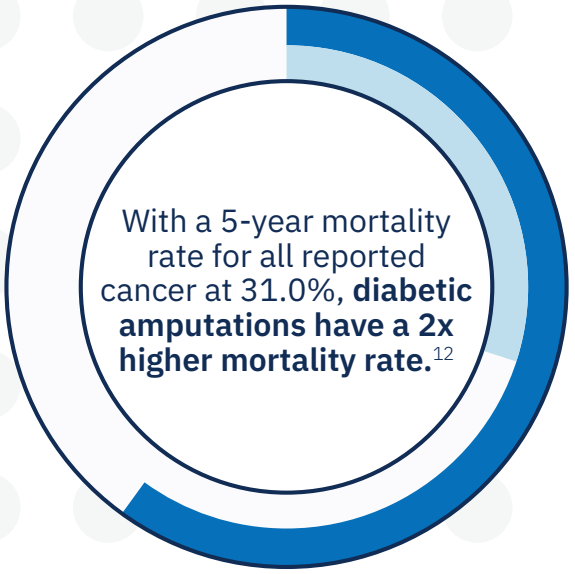
According to modeling conducted by Kaiser Permanente and published in the Harvard Business Review in 2020, the cohort of the sickest 5% driving up to 50% of costs were people with one or more chronic medical conditions that could be improved or kept under control.[16] Vulnerable, complex diabetes members at risk of DFUs certainly fall into this category.

Kaiser Permanente found in their modeling that this particular group could be positively impacted through two effective interventions: the use of technology and low-cost medical staff. Through member empowerment and smarter care mechanisms, this may be a problem that payers have more control over and ability to solve after all.

This concept lead two influential organizations, Mid-Atlantic Permanente Medical Group and Intermountain Health, to pose a critical question which they each set out to answer:

Can detection of the inflammatory precursor to DFUs before they become visible to the clinician — combined with timely virtual care support — prevent amputations, thus improving clinical and financial outcomes?





STUDY DESIGN & ENDPOINTS

TWO ORGANIZATIONS DRIVEN TO REDUCE DFU COMPLICATIONS

Two assessments were conducted to explore the impact of at-home foot temperature monitoring in improving both clinical outcomes for members and financial outcomes for health plans and at-risk provider organizations. The findings of these two assessments, led by Mid-Atlantic Permanente Medical Group and Intermountain Healthcare, showed clear advantages of once-daily, remote foot temperature monitoring using Podimetrics SmartMat™ technology, combined with timely, personalized virtual care support when a "hotspot," or inflammation as a precursor to a visible diabetic foot ulcer (DFU), was detected.

The first study was sponsored by Mid-Atlantic Permanente Medical Group (KP).

They published a retrospective analysis of real-world data[17]. They enrolled 80 participants with a healed diabetic foot ulcer in a year-long foot ulcer recurrence prevention program. Four outpatient centers within this large U.S. integrated healthcare system contributed to enrollment.

The overarching goal of the Mid-Atlantic Permanente Medical Group study was to assess the impact of once-daily, at-home foot temperature monitoring utilizing the Podimetrics SmartMat™ — augmented with virtual care support from their team — on inpatient admissions, emergency department visits, outpatient visits, lower extremity amputations, and rates of diabetic foot ulcer recurrence for patients with previously healed diabetic foot ulcers.

Mid-Atlantic Permanente Medical Group evaluated diabetic foot-related outcomes and associated resource utilization for participants during three periods: the two years before the program, the year during the program, and after the program ended. They first reported unadjusted resource utilization rates during the program and the periods before and after it. They then adjusted rates of outcomes in each phase using an interrupted time series approach, explicitly controlling for overall trends in outcomes during the three periods that may exist due to increasing participant age or disease progression.

ENDPOINTS

In the first study, Mid-Atlantic Permanente Medical Group looked to measure the following endpoints:

- All-cause inpatient hospitalizations
- Emergency department visits
- All-cause outpatient visits
- Rate of diabetic foot ulcer recurrence
- Rate of lower extremity amputations

MID-ATLANTIC PERMANENTE Medical Group

STUDY DESIGN & ENDPOINTS cont.

IN SEARCH OF THE MOST MEANINGFUL OUTCOMES

While both assessments had similar overarching objectives, each assessment took a deeper look at varied outcomes.

Technology combined with an integrated care approach

Both organizations are highly integrated health systems, which value alignment between their health plans and care teams. In other words, "provider alignment" is part of their culture of care, so a critical component of these study designs was ensuring an extension of virtual care support delivered in a timely manner when a potential risk was detected.

The second study was sponsored by Intermountain Healthcare (IHC).

It involved deployment of a 20-patient pilot for six months to patients at risk of diabetic foot ulcers from April 2020 through October 2020.

The primary objective of the assessment was to determine the effectiveness of once-daily, at-home foot temperature monitoring augmented with virtual care support from Podimetrics in the Intermountain Healthcare environment to assess future expansion to a broader set of Intermountain Healthcare patients.

Podimetrics SmartMats™ were delivered to the homes of each patient selected by Intermountain Healthcare. The teams established an integrated care model including data sharing, coordinated clinical escalations to Intermountain Healthcare, and weekly alignment.

*The cost of care calculations for the 20 patients enrolled in the pilot was based on 79 weeks of analyzed claims data. The calculations for the broader eligible set of 428 at-risk Intermountain Healthcare patients was based on 90 weeks of analyzed claims data.

Pilot patients had a high health burden with total medical charges assessed at over $100,000 per member each year. In contrast, the broader eligible Intermountain Healthcare patient set was found to have $68,000 of total medical charges per member per year.*

ENDPOINTS

In the second study, Intermountain Healthcare was focused on assessing these outcomes:

- Scalability and effectiveness of delivering services to patients
- Patient engagement
- Inflammation ("hotspot") detections and DFUs potentially avoided
- Patient and provider satisfaction
- Estimated PMPY cost reduction and Return on Investment (ROI)

Intermountain Health

SOLUTION

Thermometry: A SCIENTIFIC APPROACH AHEAD OF ITS TIME

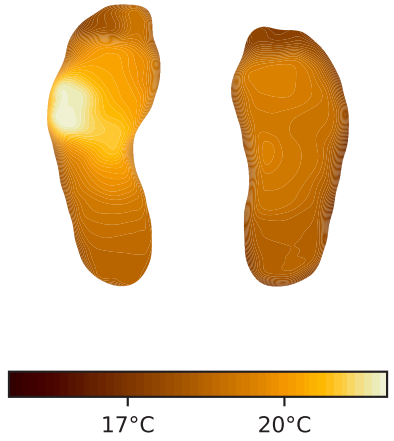
Thermometry, or temperature monitoring, for early detection of diabetic foot ulcers (DFUs), has been a long established scientific method that dates back to the 1950s. Dr. Paul Brand and his colleagues were the earliest to recognize the role of inflammation as a precursor to complications associated with the diabetic foot, such as infections and ulceration.[20]

The pathogenesis is well understood. For example, consider someone with a bunion who takes a long walk in an ill-fitting pair of shoes. The initial biological response to this friction will be localized heat, otherwise known as inflammation or a "hotspot." If the friction persists, it will ultimately result in tissue breakdown. However, if inflammation is detected early, the first course of intervention is commonly off-loading, which reduces stress on the inflamed tissue. It's a low-cost, highly effective preventative strategy for DFUs.

But over the years, despite the proven scientific effectiveness of thermometry, temperature monitoring techniques have historically failed in promoting regular, consistent patient engagement.

This has been attributed to ineffective technology design and implementation. It's often cumbersome or burdensome for patients to engage with.

Because member or patient engagement is critical to success, Podimetrics realized there could be a better way to empower members to take control of their disease management to prevent DFUs — and potential amputations — within the comfort of their own home.



SOLUTION cont.

Podimetrics:
INTERVENE EARLIER, WITH MORE IMPACT

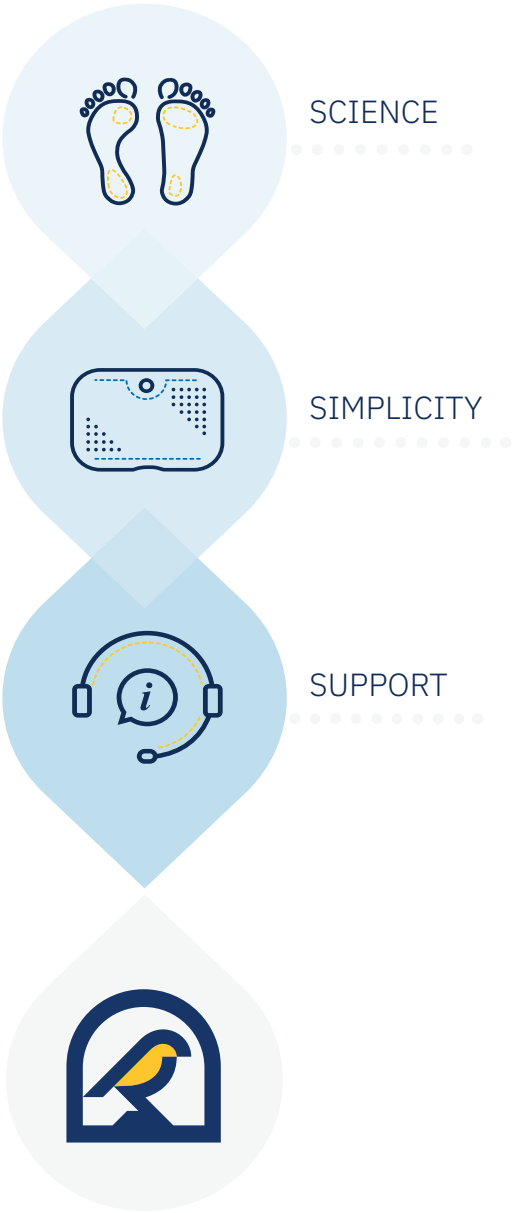
Podimetrics has designed a virtual care support solution to detect early signs of diabetic foot complications before they immobilize members and require drastic and expensive treatments. The solution includes three critical components:

SCIENCE
Thermometry is now an essential component, established in three different clinical guidelines on best-in-class diabetic foot care.[1,2,3]

SIMPLICITY
Podimetrics takes a patient-centered approach to temperature monitoring in the home. Our SmartMat™ is simple to use — members simply step on the mat for 20 seconds a day, and a temperature reading of the feet is sent to Podimetrics via cellular service — no smartphone or Wifi required. Approved by the American Podiatric Medical Association, the SmartMat™ design is proven to promote daily engagement with 75% of members at one year.[18] As a result, it's been shown to detect up to 97% of DFUs on average.[19]

SUPPORT
The member's thermal data is then remotely monitored for early signs of problematic inflammation. Our clinical team provides virtual-based triage, guidance, and support to reduce unnecessary interventions, while escalating issues weeks before a wound would present clinically.[19] This personalized support enables simpler, low-cost interventions to be employed, ultimately promoting a better quality of life for members.

In these two studies, the Podimetrics SmartMat™ was provided to every patient for at-home temperature monitoring. Additionally, both studies incorporated remote virtual care support.



RESULTS

The endpoints for the two studies collectively included clinical outcomes, resource utilization, financial impact, and engagement and experience for patients and providers. Here are the findings.

Positive clinical outcomes with less resource utilization

CLINICAL

- **71%** Diabetic amputation reduction — KP
- **46%** Reduction of all DFUs — KP
- **91%** Reduction of severe DFUs — KP
- **21** Hotspots detected among 14 patients — IHC
- **10** Escalations* — IHC

RESOURCE UTILIZATION

- **52%** Relative risk reduction in all-cause inpatient admissions — KP
- **40%** Relative risk reduction in emergency department visits — KP
- **27%** Relative risk reduction in all-cause outpatient admissions — KP
- **2 FEWER** Podiatry outpatient visits per participant in the year during the treatment phase† — KP

Impactful expected cost savings and ROI

FINANCIAL

- **$9,800 - 14,000** Expected savings Per Member Per Year‡ — IHC
- **3.6x - 5.2x** Expected return on investment‡ — IHC

*Includes two escalations self-reported by patients.
†Net difference was observed despite 1.6 additional podiatry outpatient visits per-participant year resulting from inflammation detected by the study device.
‡Assumptions based on 90 weeks of Intermountain Health claims data for 428 at-risk patients and applying results from our recent peer reviewed study with Kaiser Permanente in the British Journal of Medicine (BMJ).

RESULTS cont.

A scalable program that delivers a positive experience for members and providers

Engagement & Experience

SCALABILITY AND EFFECTIVENESS OF DELIVERING SERVICES

2 WEEKS

Timing for all patients to be enrolled into program

IHC

95%

Patients trained within one month

IHC

PATIENT ENGAGEMENT

82%

Enrolled patients scanning 5.4 times per week (2x per week considered engaged and compliant)

IHC

PATIENT SATISFACTION

75%

Patients who would continue using the mat

IHC

Patient (Member) Satisfaction

"Because people with feet like mine can't always feel their sores, so it is a good way to monitor one's feet."

"It's good to know you were monitoring my feet. It helped me take my mind off it in a trusting way."

"It is easy to use and understand. All one has to do is stand on the mat."

Provider Satisfaction

"When they know they are being monitored and somebody is going to find out whether they are doing something to check their feet, they seem to do it."

"Patients were happy and liked getting calls. Depression is through the roof for this population who suffer with diabetic foot complications."

"Patients came in sooner for care due to the alerts. I do believe it helps catch a lot of potential problems."

CONCLUSION

SHAPING POSITIVE OUTCOMES
for your members

Diabetic foot ulcers (DFUs) have been proven to lead to devastating consequences for a vulnerable subset of the diabetic population, leading to high risk of lower extremity amputations. Yet despite the enormous human and financial cost, DFU prevention is often overlooked and absent from most comprehensive diabetes programs.

The two assessments led by Mid-Atlantic Permanente Medical Group and Intermountain Healthcare were conducted to explore the impact of at-home foot temperature monitoring using Podimetrics SmartMat™ technology as part of a comprehensive care program each revealed positive results in four critical areas:

- Clinical outcomes
- Resource utilization
- Financial impact
- Engagement and experience for patients and providers

Temperature monitoring for earlier detection — when integrated with patient-centered technology and personalized, virtual care support — was found to be an effective way to reduce the negative clinical and financial impact of DFUs, which lead to catastrophic lower extremity amputations.

By employing this type of a program, at-risk health plans and provider groups have a greater ability to shape positive member outcomes.

WITH PODIMETRICS,
discover the diabetic complications hiding in plain sight

Podimetrics is committed to health plans and at-risk health systems improve the lives of members living with the potentially devastating impact of diabetes. Our technology-based program supports early detection of diabetic extremity complications — a clinical and financial burden hiding in plain sight. Improve health outcomes for your complex diabetic population by reducing the rate of expensive, catastrophic amputations — ultimately improving and extending patient lives.

As we expand our programs with health plans and at-risk provider systems across the nation, we would welcome the opportunity to share additional outcomes with like-minded organizations.

To explore the advantages of Podimetrics for your organization, use our simple DFU prevalence calculator to directionally size your DFU population.

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