Testimony before the United States House of Representatives

Committee on Veterans' Affairs Hearing on Harnessing Biomedical Innovation: Modernizing VA Healthcare for the Future

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Statement of Dr. Jon Bloom, Co-Founder and Chief Executive Officer, Podimetrics

Chairman Bost, Ranking Member Takano and distinguished Members of the Committee,

Thank you for offering me the opportunity to testify regarding the lifesaving work we do every day for our Veterans, their families, and caregivers at Podimetrics.

My name is Dr. Jon Bloom, co-founder and Chief Executive Officer of Podimetrics. As a physician and the son of a decorated Vietnam combat Veteran, I am proud to state we have built our company from the bottom up, in partnership with the Department of Veterans Affairs (VA), to improve Veterans' health from needless and costly amputations.

Executive Summary

Diabetic foot ulcers (DFU), a complication of type 2 diabetes, are costly and deadly. Given the diminished sensation and blood flow into the lower limbs of patients affected by type 2 diabetes, a DFU often presents silently, with the Veteran unaware of the severity until the wound is infected, life-threatening, and requires emergent surgical intervention, generally an amputation. For this particular complication, early detection and prevention is key.

DFUs cost VA $3.2 billion every year. The 5-year mortality rate for veterans with diabetic foot ulcers (DFU) exceeds 70%, a rate higher than most cancers To combat the tremendous costs of DFUs, the Veterans Health Administration (VHA) launched a promising practice that incorporates the use of remote temperature monitoring in the prevention of DFUs and amputations.

As part of this program, VHA partnered with Podimetrics to deploy the Podimetrics SmartMat Program to thousands of at-risk Veterans, resulting in major reductions in lower extremity diabetic amputations. By March 2024, VHA estimated the program saved U.S. taxpayers $99.9 million in unnecessary medical care even though fewer than 6% of clinically eligible Veterans had been enrolled in the program for at least one year.

If VHA expanded this program to reach all Veterans who are at greatest risk of amputation, the Department would see cost savings projected at $1.78 billion and would save approximately 5,000 Veteran lives, in the first year alone.

Despite strong clinical outcomes and significant healthcare savings demonstrated by VHA's own data, as well as broad support among both VHA providers and leadership, the Department has encountered persistent challenges in scaling this promising practice to enroll the approximately 110,000 highest-risk Veterans in remote temperature monitoring.

The Unsustainable Toll of Diabetic Foot Ulcers Among Veterans

Diabetic foot complications represent an enormous human and financial burden among our nation's Veterans. A staggering one-in-four Veterans suffer from diabetes, over twice the rate of this disease among non-Veterans in the United States.[1] It is estimated VHA treats approximately 110,000 Veterans at greatest risk of DFU each year and in 2022 this accounted for $3.2 billion in direct medical costs alone.[2] 85% of lower limb amputations are preceded by a DFU,[3] robbing Veterans of their independence and placing them at significant health risks downstream. A single amputation can cost as much as $100,000.[4]

The mortality rate is staggering. Seventy one percent of Veterans with a DFU will die within five years, making it deadlier than most cancers.[5]-

Prevention of DFUs Through Foot Temperature Monitoring

The use of temperature monitoring to identify DFUs prior to their development is not a new practice and was first cited in the 1970s. Between 2004 and 2007, three randomized controlled trials funded by the National Institute of Health were published demonstrating a 71% reduction in annual incidence by employing early offloading (reduced step count) at the first sign of increased, localized foot temperatures.[6-8] *Nearly 3 out of 4 ulcers were prevented!*

As a result, the use of temperature monitoring is now recommended as best practice by the American College of Foot & Ankle Surgeons, the Wound Healing Society, the International Working Group on the Diabetic Foot, and the U.S. Agency for Healthcare Research & Quality (7-10).[9-12] However, despite its recognition as best practice and inclusion in multiple clinical practice guidelines, adoption of temperature monitoring solutions was negligible due to poor patient ease-of-use and the absence of Medicare reimbursement.

Company Founding and Partnership with VHA

Podimetrics was founded in 2011 by a team from the Massachusetts Institute of Technology, Harvard University, and Stanford University, who worked to solve the challenges with existing temperature monitoring devices. As a physician, prior to co-founding the company, I spent far too many days in the operating room participating solely in lower limb amputations due to DFU.

After multiple usability studies, we launched the Podimetrics Remote Temperature Monitoring System, which includes the Podimetrics SmartMat, a home-based medical device that looks for signs of inflammation within the feet, which may signal a developing DFU or foot infection. The device is FDA cleared and is manufactured in the United States. The SmartMat is easy to use –

requiring only 20 seconds of contact (i.e., standing on the SmartMat) per day from the comfort of the Veteran's home – and transmits the data securely for analysis without the need for WiFi or a mobile device.

Our journey as a company would not have happened without the partnership and collaboration with VHA. In 2017, a groundbreaking clinical trial led and published by VHA clinicians found the SmartMat technology/program correctly identified 97% of DFUs on the bottom of either or both feet an average of 37 days prior to clinical presentation, owing to strong patient engagement.[13]

By 2020, based on promising quality improvement data from two VA Medical Centers (VAMC), VHA's Innovation Ecosystem partnered with Podimetrics to pilot this solution and launched The Initiative to End Diabetic Limb Loss, which supplied at-risk Veterans with SmartMats. The program integrated under VHA's telehealth podiatry services nationally under the leadership of Dr. Jeffrey Robbins, VHA's National Chief of Podiatry, and Suzanne Shirley, former Director of Strategic Partnerships within VHA's Office of Healthcare, Innovation & Learning. Thanks to this committee's leadership and funding from the 2020 CARES Act, $7 million was made available to pilot a remote temperature monitoring program.

VA investigators subsequently evaluated the results of the nascent program for 924 Veteran participants from 2019 - 2021.[14] The study showed a remarkable 37% reduction in mortality within 12 months alone, equating to one Veteran's life saved for every 23 Veterans who participated.[15] Though the study was equivocal on amputations and hospitalizations, the mortality reduction was not surprising given the alarmingly high 71.4% five-year mortality rate for Veterans who suffer from a DFU.[5]

The success of The Initiative to End Diabetic Limb Loss led to the development of VHA's current Remote Temperature Monitoring (RTM) Program with the goal of increasing the adoption of this lifesaving preventive care at VA healthcare facilities across the nation. This has allowed for improvements to clinical protocols and standardization of care over time. In a March 2024 briefing to the U.S. Senate Military Construction and VA Appropriations Subcommittee, with fewer than 6% of clinically eligible Veterans enrolled through the prior twelve months, VHA estimated the program saved US taxpayers $99.9 million in unnecessary medical care even though fewer than 6% of clinically eligible Veterans had been enrolled in the program for at least one year.[15]

The Opportunity to Serve More Veterans

The feedback from VHA providers and Veterans has been overwhelmingly positive. In a recent survey of 132 VHA providers who have prescribed the Podimetrics SmartMat program, 100% responded they would recommend the program to other VA healthcare centers and providers, and 99% would recommend the program to new Veteran patients.[16] Similarly, in a recent survey of 1,527 Veterans utilizing the SmartMat, 93% responded as either "satisfied" (22%) or "very satisfied" (71%), with an average satisfaction score of 4.6 out of 5.[16]

While Podimetrics partnership with VHA's RTM Program has made significant progress in lowering amputations among Veterans and saving taxpayers millions of dollars, more work needs to be done to ensure this clinically proven model is accessible to those Veterans who are most vulnerable. A number of challenges have been observed by both VHA leaders and clinical staff.

First, at-risk Veterans do not have equal access to the RTM Program. A recent study by VA investigators demonstrated VHA facilities that participated in the RTM Program were disproportionately urban and served Veterans with better access to care.[17] Furthermore, enrolled Veterans within a given participating VAMC had shorter drive-times to specialty care and were less likely to be low income.[17] This represents a barrier to access of best practice at both the regional and program level that dramatically limits the savings and mortality benefit to our Veterans.

Second, not surprisingly, prescribing clinicians are overwhelmingly VHA Podiatrists (Doctors of Podiatric Medicine) owing to their training, their awareness of the program, and current procurement guidelines. Unfortunately, only half of currently eligible Veterans are receiving their podiatric care within the VA healthcare system, and as a result, never get offered the RTM Program. This acts as a substantial barrier for Veterans at the cost of considerable taxpayer dollars and human life.

Third, siloed budgets challenge VHA's ability to rationally control clinical spending. For example, while SmartMats are covered and managed by the Prosthetics & Sensory Aids Services (PSAS), the primary beneficiary of the clinical savings is Medical Care via reductions in inpatient and outpatient utilization, surgical costs, and more. The program now becomes a source of cost to PSAS – often at the facility level – which serves as a large barrier to savings and outcomes improvement. VHA facilities have cited they do not have the financial resources to support expansion of the preventive program.

Fourth, VHA operates with the same incentive structure as fee-for-service health systems. Facilities with higher caseloads receive greater funding than facilities with lower caseloads, even if the reduction in volume is solely due to increased preventive care. Similarly, clinicians with higher workload credit have greater job safety than clinicians with lower workload credit. *The challenge is that the workload or volume credit for an amputation in the operating room vastly exceeds the credit for the prevention of an amputation (or a hospitalization, etc…).* Until workload credit for proven preventive practices are appropriately incentivized, delivering preventive care is not viable.

Lastly, given the requirement to maintain adequate work volumes, VA facilities often report a self-limited size of their program due to insufficient clinical support resources. In the absence of changes to the incentives for prevention as mentioned above, additional staff may be required at the VISN level to ensure efficient program management for facilities. However, the hyperbolic statement one can make is that the VA Healthcare system already has all the staff it

needs to deliver preventive care; clinicians are just too encumbered providing treatment for complications they could have prevented.

Conclusion

The potential to fully deploy VHA's RTM Program to all eligible Veterans in just one year has the potential to save taxpayers an estimated $1.78 billion.[15] This is in addition to the 5,000 lives saved.[14]

VHA and Podimetrics' collaboration on this program is proof that the agency can deliver considerable cost savings for American taxpayers without sacrificing the integrity of the healthcare services available to our Veterans.

Those who wore the uniform of our nation should not walk into a VA hospital one day and leave the next in a wheelchair – or worse – especially when we possess the technology and capability to change this outcome.

Thank you for the opportunity to testify today. I look forward to answering any questions you may have.

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