THE BIG DIABETES COMPLICATION **THAT'S FLYING UNDER THE RADAR**

Measuring the Impact of Diabetic Foot Ulcers and Amputations

The Snowball Effect of Diabetic Foot Complications

We're all familiar with the snowball effect. Something begins as just a small problem, maybe not even noticeable at all. As it rolls downhill, it picks up speed and size. Soon you have a huge problem — and it's heading right at you.

This is a common analogy that demonstrates how something that seems insignificant can quickly hurl out of control. Using the snowball analogy shows us that if we could just know about something before it rolls downhill, it wouldn't become such a huge issue. Hindsight is 20/20, isn't it? The snowball effect also hinges on the idea that ***we can do something***.

We can intervene. We can stop it.
We just need to know what to look for.

When it comes to diabetic complications, foot ulcers are snowballs. These seemingly small complications can go unnoticed until they become big, big problems: diabetic amputations. And once they cause amputations, they wreak havoc on the lives of patients and the nation's health care system.

Why are diabetic foot ulcers so hard to catch early?

Diabetic foot ulcers are snowballs because they're especially hard to see at the beginning. Patients may struggle to notice signs of developing ulcers due to diabetic retinopathy and neuropathy, which inhibits their ability to see or feel these wounds forming. And if they aren't regularly seeing their doctor, it's hard for anyone to notice.

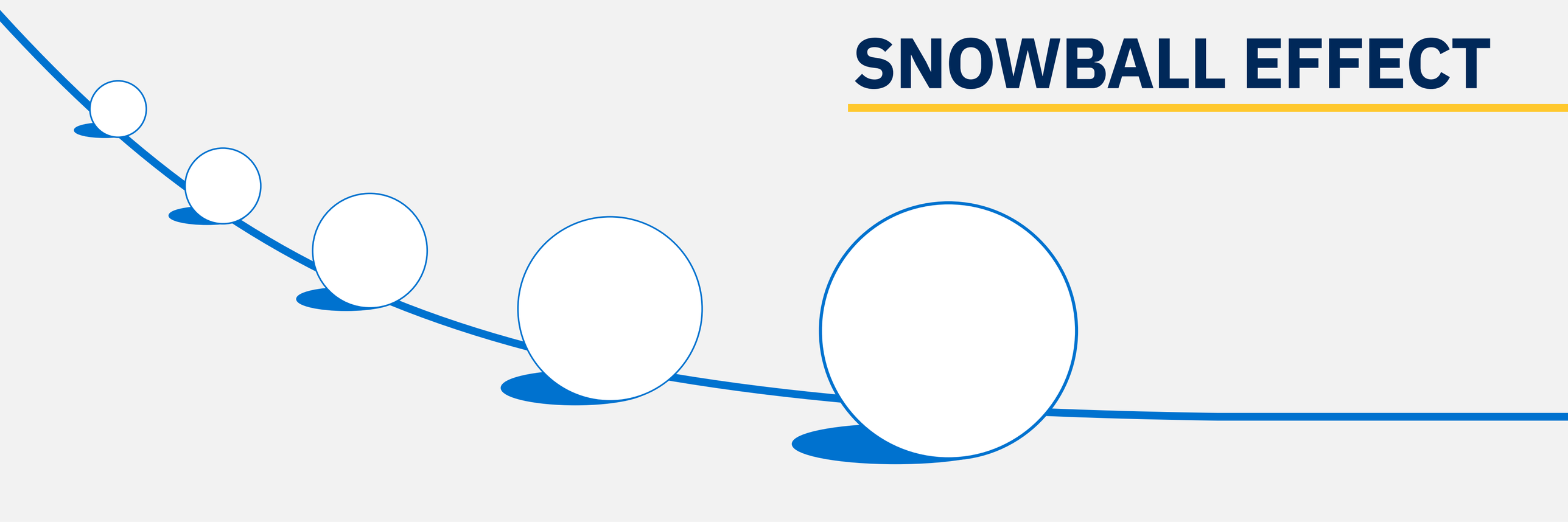
Patients may not be seeing doctors through no fault of their own: transportation may be unreliable, hospitals may be too far away, health care may cost too much, or patients could be dealing with many comorbidities — simply exhausted by the toll of taking care of themselves in a complicated, expensive health care system.

In a larger sense, diabetic foot complications are also competing against other top complications of diabetes, including heart disease, kidney disease, vascular disorders, and eye problems. While foot problems are quite common and can lead to devastating consequences, it’s hard to prioritize when patients are facing so much.

And let’s remember that this is a small, distinct population.

There is a lot of high-quality diabetes care aimed at the prevention of the disease altogether, often through diet and exercise. This approach targets a broader group, including those at risk or with pre-diabetes. For the subset of patients with foot complications, the snowball has already become packed with ice. And it’s picking up speed. There’s nothing they can do but hope for the best — and brace for impact.

To understand the severity of these complications on patients, providers, payers, and the overall health care system, it’s critical to look at it from a holistic perspective. That’s what we’re going to do.



Explore the problem and understand the magnitude of diabetic foot complications

In this eBook, you’ll find everything you need to know about the problem we’re facing with diabetic foot complications. It’s organized into four sections that outline the true nature of this problem, which is flying under the radar and impacting 11.6 million Americans every year.[1] You’ll learn how it begins, why it’s so important, and what you can do about it.

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Section One: Diabetic Foot Complications and the Body

To begin, let's define the term "diabetic foot complication." In this eBook, we'll use it when referring to both foot ulcers and lower extremity amputations. When required, we'll break them apart to discuss specific issues associated with either ulcers or amputations — as we have data on both.

Quick Glossary

Diabetic foot complication:
Either a foot ulcer, an amputation of the lower extremity, or both

Diabetic foot ulcer:
An open wound on the foot of a patient with diabetes

Diabetic amputation:
A lower extremity amputation caused by a diabetic foot ulcer

To understand the impact, let's think about the chain of events in the body that precede the devastating result: a diabetic amputation.

Diabetic amputations begin as diabetic foot ulcers.
A diabetic foot ulcer is an open wound that forms on the foot.

A patient with diabetes can get foot ulcers from a variety of causes. They could stub a toe and break open the skin. They could step on something and not notice. They could get a blister from ill-fitting shoes. All of these can begin quite innocently, but they quickly advance into troublesome ulcers. For patients without diabetes, these wounds usually heal on their own. For patients who do have diabetes, it can become quite a different story.

It can be hard for patients with diabetes to notice a foot ulcer forming Why? In many cases, diabetes complications occurring in other parts of the body can hinder awareness of a foot ulcer.

For example, diabetes can often lead to retinopathy and neuropathy. Diabetic retinopathy causes vision problems. Diabetic neuropathy causes numbness and loss of feeling, often in the extremities. This means patients have a hard time seeing an open wound, feeling pain caused by it, or both.

What makes a diabetic foot ulcer hard to notice?

Diabetic retinopathy:
Causes vision problems and makes foot ulcers hard to see

Diabetic neuropathy:
Causes numbness and makes foot ulcers hard to feel

The best way for a patient to catch a foot wound early is by performing daily foot exams. Of course, that's much easier if they don't have retinopathy or neuropathy. And many patients rely on caretakers to help conduct daily foot exams. For those without caretakers, the task can be quite difficult.

It's critical to catch foot wounds early.

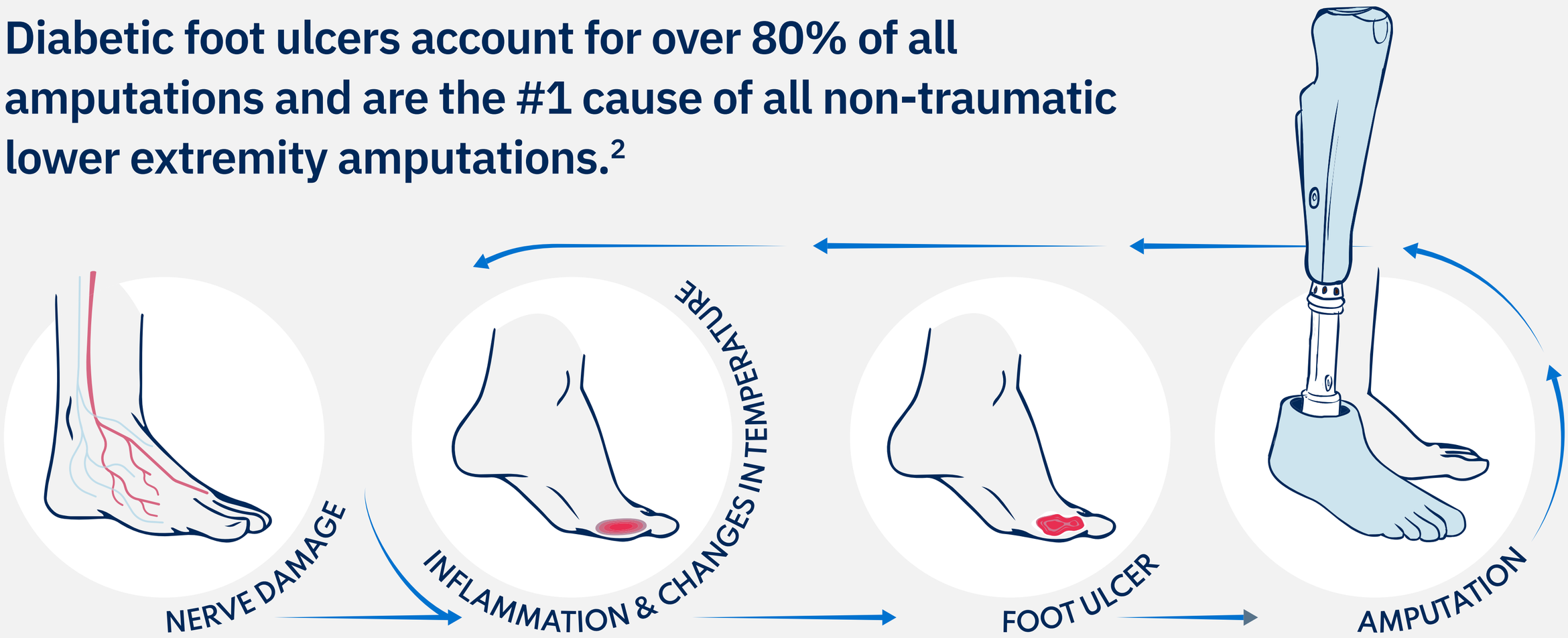
Once a wound forms on the foot of a patient with diabetes, it can be harder to heal than if the patient didn't have diabetes. This is for several reasons. Increased blood sugar can lead to slower healing. Also, comorbidities are very common with diabetes. Many comorbidities also impact healing rates with some having a direct correlation, like vascular disease.

And once you have one diabetic foot ulcer — you're likely to have another. Forty percent of patients with diabetes with a previous diabetic foot ulcer will have another within one year.[1] This begins a deeply traumatic cycle, where the likelihood of recurrence increases once you've already had one.

As these wounds struggle to heal, they can grow in both size and severity. When this happens, a small foot wound can suddenly become a huge problem. If the tissue has broken down beyond repair, doctors may

decide that full or partial amputation is the only option. In particularly severe cases, tissue can break down layer after layer, reaching the bone and causing gangrene.

Diabetic foot ulcers account for over 80% of all amputations and are the #1 cause of all non-traumatic lower extremity amputations.[2]



Because diabetic foot ulcers are the leading cause of amputations, it's critical that we understand they're tied together in many ways.

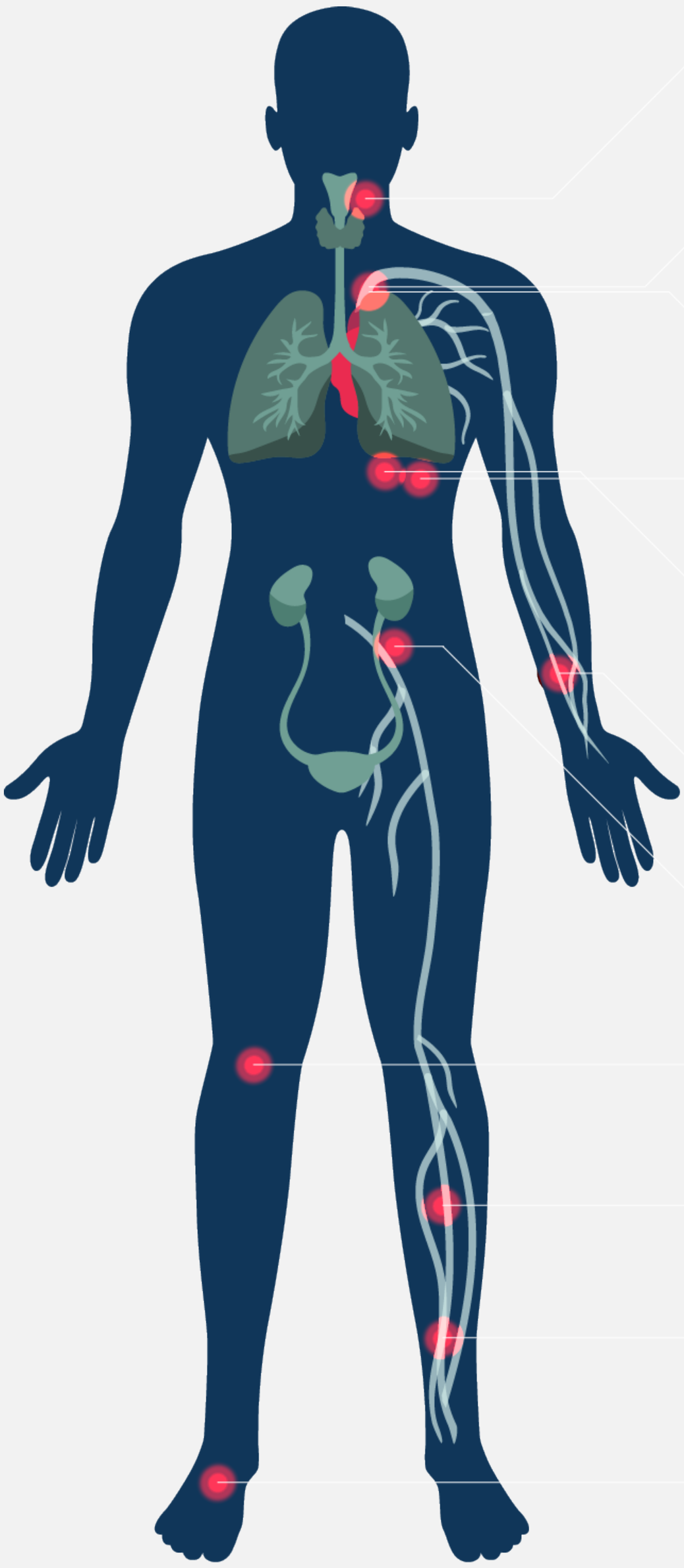
The diabetic foot ulcer is a warning signal.

Over eighty-five percent of high-level diabetes-related amputations are preceded by foot ulceration.[3] It indicates that an amputation could be coming down the road (in fact, lower extremity amputations are 30 times more likely when someone has a diabetic foot ulcer) and can be considered a marker of other significant health events.[4]

Research shows that when patients are experiencing diabetic foot ulcers, what we've defined as a "diabetic foot ulcer episode-of-care," they're three times more likely to be admitted to the hospital during this same time period for any reason at all. The mortality rate also jumps to fifty percent more likely to occur. Additionally, there is a wide range of serious health conditions that cause hospitalization at the same time when someone is experiencing a diabetic foot ulcer.[4]

Diabetic foot ulcers are not innocent bystanders — they're accomplices.

Complex health issues are more likely during a diabetic foot ulcer episode-of-care, with large relative increases found in the rates of many diagnosis codes.



7X more likely to be hospitalized for diseases or disorders of the endocrine system

2X more likely to be hospitalized for a heart attack

2X more likely to be hospitalized for congestive heart failure (CHF)

2X more likely to be hospitalized for pulmonary edema

2X more likely to be hospitalized for chronic obstructive pulmonary disease (COPD)

3X more likely to be hospitalized for a circulatory disease or disorder

2X more likely to be hospitalized for renal failure

2X more likely to be hospitalized for sepsis

10X more likely to be hospitalized for vascular procedures

8X more likely to be hospitalized for peripheral vascular disorders

30X more likely to have a lower limb amputation

As you can see, diabetic foot complications are not simple. And they shouldn't be overlooked. It's a problem that can quickly impact the entire body. A ripple effect. A waterfall. Definitely a snowball. The one thing we know for sure is that these complications are not limited to just the foot, and that's part of why they're so destructive.

Section Two: The True Cost of Diabetic Foot Complications

Diabetic foot complications are underestimated, especially in terms of cost. While it's true that they occur in a small population, it's this population that drives the highest overall health care spending and, more importantly, tends to struggle the hardest. It's also not at all an insignificant metric: **Patients with diabetes have a thirty-four percent lifetime risk of developing a diabetic foot ulcer, equal to 11.6 million people.**[1]

Patients with diabetes normally cost around $17,000 each year. For those with diabetic foot ulcers, the number increases to $58,000.[5]

Diabetic foot ulcers are so costly, they're more expensive than the five most costly forms of cancer.[6]

Diabetic foot ulcers represent one-third of the $327 billion spent every single year on diabetes in America.[8] The cost of lower extremity complications totals over $100 billion.[7] Every three minutes in America, a limb is amputated due to diabetes.[9] Each amputation costs as much as $100,000.[10]

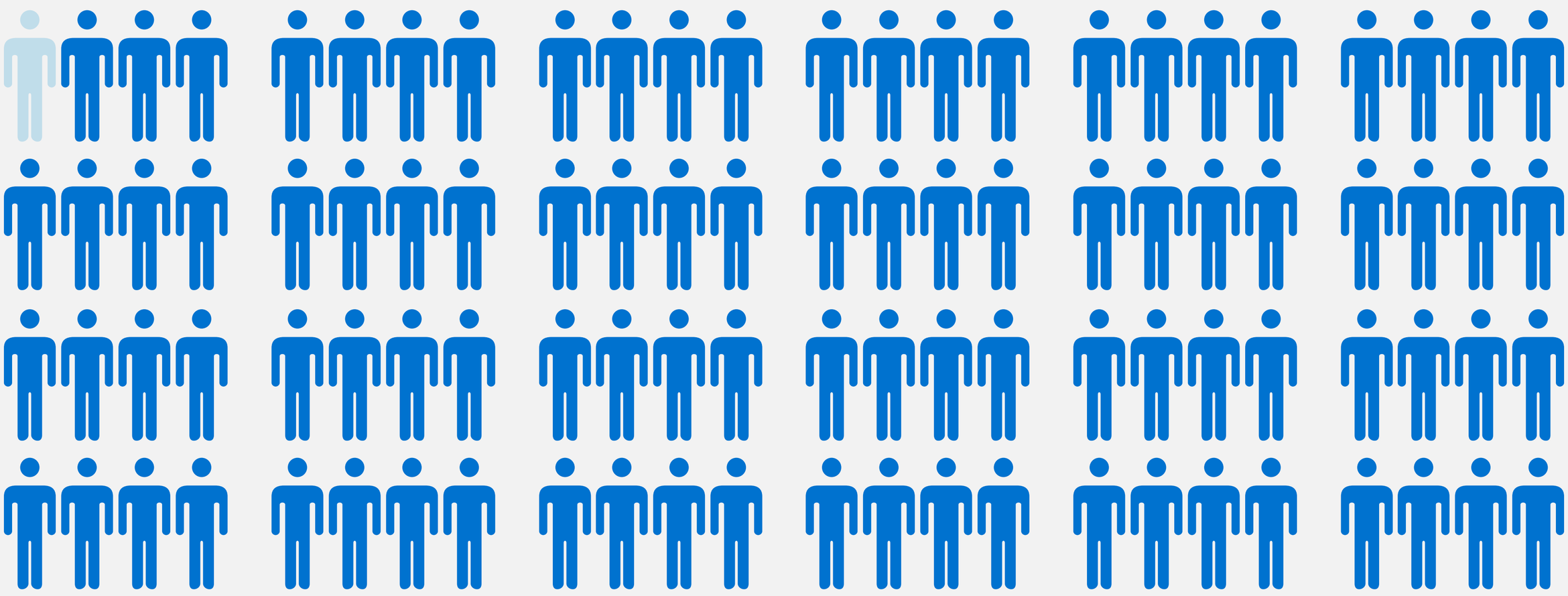
Amputations are also cyclical, much like diabetic foot ulcers. Nineteen percent of patients with diabetes will suffer another amputation within one year after their first surgery, while nearly thirty-seven percent will do so within five years.[11] This only compounds the toll on patients, and their out-of-pocket costs for each procedure.

As these costs accumulate, the burden grows and grows.

It can be hard to focus on a single group of patients when there are so many that need help. But this group is particularly important to every health care system that prioritizes value-based care. These high-risk patients are vulnerable to many serious health conditions, including seemingly unrelated ones like congestive heart failure (CHF) or COVID-19 complications. Nearly ninety-eight percent of American adults with type 2

diabetes have at least one comorbid condition, and approximately ninety percent have two comorbidities.[12]

Because this group tends to have multiple conditions on top of diabetic foot ulcers, they can drive significant medical costs. The majority of all health care spending is associated with this very small population. Just one percent of the total population accounts for nearly a quarter of all out-of-pocket spending. Even widening to five percent associates the group with nearly half of all out-of-pocket spending.[13]



1% of the population accounts for **24%** of all out-of-pocket spending for health services[13]

Unfortunately, this small group suffers a lot. And that means everything costs more for them. As each correlated condition is treated, another cost is tacked on. It's a devastating cycle and a huge reason why this group deserves more attention.

When considering medical codes, lower extremity complications are present in over 200 DRG and ICD-10 codes. It can be shocking to see how big the impact is. For many, diabetic foot complications seem like a small problem. They're not. And that's why we need to take action to prevent diabetic foot ulcers from forming and causing lower extremity amputation.

But cost can't be measured simply in dollars alone.

To understand the true cost of diabetic foot complications, we must understand that it takes a huge toll on the mental health and well-being of the patient. Most patients fear amputation more than death.[14] Diagnosed depression is associated with a thirty-three percent higher risk of incident major lower limb amputation in Veterans with diabetes.[15] Learning more about this patient is key to understanding how to help when it comes to diabetic foot complications.

Section Three:
The Underserved Patient Population with Diabetic Foot Complications

The patient with diabetic foot complications is struggling. If they aren't calling out for help, it's only because everything has become so exhausting that their voice gets drowned out. And as we dig deeper into some of the reasons why, it will be apparent exactly how important it is for us to help them navigate their diabetic foot complications.

We know the patient prone to forming diabetic foot complications also tends to have multiple comorbidities. We also know this patient drives the highest out-of-pocket spending because of these comorbidities — and because of the high cost of diabetic foot complications alone.

Everything is harder for the patient with diabetic foot complications.

For these patients, everything's an uphill battle. Diabetes makes it more likely for them to suffer from diabetic foot complications. And diabetic foot complications make it more likely for them to suffer from many other serious health conditions.[16]

This group is associated with the highest out-of-pocket spending in the health care system.[13] And health care is becoming increasingly hard to afford. These expenses keep adding up, and these patients are often lost in a shuffle along with ballooning medical debt, hard-to-find preventive care, and health inequity.

As we look to social determinants of health, we know that health trends in populations can be associated with the way someone lives, works, and plays due to what's available in their environment.

These aren't issues of individual responsibility. There are distinct, proven connections between conditions in their environment and health outcomes.

Five domains exist that comprise our understanding of social determinants of health:[17]

ECONOMIC STABILITY

EDUCATION ACCESS & QUALITY

HEALTHCARE ACCESS & QUALITY

NEIGHBORHOOD AND BUILT ENVIRONMENT

SOCIAL & COMMUNITY CONTEXT

Every single one of these domains has a direct impact on someone's health outcomes. None of us exist in a vacuum. Everything around us bears weight.

A common example is the concept of a "food desert." As the push for better nutrition began to reach national levels, researchers found that it's significantly harder to eat a recommended diet when you're living far away from grocery stores, or you're living near or below the poverty line, or both.

For so long, diet had been prescribed as a cure for nearly every ailment. And people blamed others who couldn't "eat right." As we now know, "eating right" is a lot harder than it sounds. A lot of success depends on the environment around you. Many live far away from grocery stores with fresh produce or organic options. And even if they did live close, they simply can't afford the skyrocketing prices.

Diabetic amputation is the greatest marker of health inequity.

It's now more understood that these factors play largely into many health outcomes. And they greatly impact the patient who suffers from diabetic foot complications. Diabetic patients living in the nation's poorest communities are thirty-nine percent more likely to have a high-level amputation.[18] Black Americans are three times more likely to require a diabetic amputation than others.[19]

In fact, it's such an issue that The American Diabetes Association recently listed "The Right to Avoid Preventable Amputations" in their Health Equity Bill of Rights.[9] News outlets have started to bring this injustice to attention, with the L.A. Times[20] and ProPublica[21] both covering the staggering impact of diabetic amputations on certain populations in south Los Angeles and the Mississippi Delta, respectively.

What both outlets elucidated is that diabetic amputation rates can serve as an indicator or flag of health disparities. As reported in ProPublica, "They [a disproportionately high number of Black Americans with diabetes] were at a disadvantage, put at risk by an array of factors, from unequal health care access to racial biases to cuts in public health funding. These elements have long driven disparities, particularly across the South. One of the clearest ways to see them is by tracking who suffers diabetic amputations, which are, by one measure[22], the most preventable surgery in the country."[21]

The article highlights the work of Dr. Foluso Fakorede, the only cardiologist in Bolivar County, Mississippi, and a member of the Podimetrics advisory board. What Dr. Fakorede has seen is astonishing, and a calling to save limbs has dedicated him to the Mississippi Delta region. He references two maps in the article, one of the country's vascular disease-related amputations, another of the enslaved population pre-Civil War. They mirror each other with near perfection.

Diabetic amputation weighs heavy on its patient.

And remember, we talked briefly about the toll on mental health and well-being for a patient who undergoes an amputation. Now that we know this isn't happening in a vacuum, consider all the uphill battles that might come up daily.

1. Low income and underinsured populations struggle to afford any health care treatment and may also find transportation expenses unreasonable to accommodate ongoing care.
2. Rural populations living far from hospitals, clinics, and other treatment centers find it challenging to get to appointments.

They might also find it hard to access food suggested by a nutritionist and realistically complete other recommendations.

3. Socioeconomic status and race play a part in access to health care, health outcomes, and mental well-being. For patients facing unequal treatment across the board, it's not going to be easy to feel optimistic and the loop of ulcers-to-amputations will be very overwhelming.

4. The loop of ulcers-to-amputations makes everything harder each time it comes around. The first time a patient has an ulcer, it's difficult. If it advances to an amputation, it's traumatizing and life-altering. If this repeats, it's devastating — and mobility will decrease each time, additionally complicating health outcomes.

It's time to make a difference.

Even though diabetes has become an area of focus for the health care industry, the rate of amputations actually grew by 50% from 2009 to 2015.[23] Of the 130,000 diabetic amputations that occur each year, it's mostly happening in low-income, underinsured areas.

> ***"It is the cardinal sin of the American health system in a single surgery: save on preventive care, pay big on the backend, and let the chronically sick and underprivileged feel the extreme consequences."***[21]

The population that suffers most from diabetic amputations is the same population that suffers most from nearly every failure of the American health care and social system. It's also precisely why we must act.
To prevent an amputation is to give someone their independence back.
Because amputations are so preventable, why not do exactly this?

Section Four:
The Power of Prevention: Catching Diabetic Foot Complications Earlier

Now that it's clear why we must address this diabetic complication, the question is how. The patients most at risk of an amputation are facing an enormous amount of pressure (and not only from the health care system).

Designing a solution that works requires careful consideration of the population that it serves.

Some considerations include the following:

- **Will everyone have insurance?**
- **Will they have Wi-Fi?**
- **Do they have smartphones?**
- **Is it easy to get to a treatment center if intervention is needed?**

Based on what we just learned in the previous chapter, it's likely that patients are not going to find it easy to prevent diabetic foot ulcers if there is a high cost involved, lots of appointments, or it's locked behind a technological wall.

Additionally, there are doctors like Dr. Fakorede to consider. How simple will it be for a medical team to assist these patients? What kinds of challenges do they face? Many in the health care system are overworked, exhausted, and burnt out from the pandemic. Adding another cumbersome thing to their plate is just not realistic. It must be easy.

What's a proven prevention method for diabetic amputation?

As we know, diabetic amputation starts as a foot ulcer. So let's prevent the foot ulcer.

How? ***Thermometry.***

What is thermometry?

Thermometry is the measurement of temperature, and it's been used successfully for the prevention of diabetic foot ulcers since the 1970s.[24] Its success has also been measured and evaluated in peer-reviewed studies. In 1975, Dr. Paul Brand and his colleagues first recognized that inflammation of the foot was a precursor to foot complications in high-risk patients with diabetes mellitus. Inflammation would lead to ulceration or infection. Ulceration and infection would often lead to an amputation.

Dr. Brand's original research was focused on leprosy patients; however, the findings would impact diabetic foot care for years to come.[25] By associating inflammation as a precursor to additional foot complications, temperature rises could be extracted as a signal of inflammation. When the foot is inflamed, the temperature in that spot will be higher.

Because temperature could so accurately predict and point out areas of inflammation, the practice of thermometry was initiated to detect hot spots with the hopes of staving off further complications like ulceration and infection.

How effective is thermometry at detecting inflammation?

Outside of the initial study during the 1970s, more recent studies have confirmed thermometry's effectiveness in the detection and prevention of diabetic foot complications. In 2017, The Agency for Healthcare Research and Quality (AHRQ) found that home monitoring of foot skin temperature was proven to be effective for preventing the incidence and/or recurrence of foot ulcers.[26]

Thermometry has been studied in three randomized clinical trials (RCTs) with positive results: one in 2004,[27] another by the same group in 2007,[28] and additionally by another cohort in 2007.[29] All three of these trials are considered evidence of thermometry's effectiveness. To drill down even further into metrics that prove success, the three RCTs reported a 70% mean relative diabetic foot ulcer reduction which was reflected in the clinical practice guidelines.

Thermometry's temperature guided avoidance therapy is now recommended in clinical practice guidelines for high-risk patients with diabetes from the following authorities: The International Workgroup on the Diabetic Foot,[30] The Wound Healing Society,[31] and The American College of Foot and Ankle Surgeons.[32]

How do thermometry-based solutions work?

While Dr. Brand's original method included a self-held thermometer, it's recognized that this method can be difficult for patients struggling with many diabetic comorbidities, including retinopathy and neuropathy.

Today, several solutions deploy thermometry as a preventive measure. If you can measure the foot's temperature regularly, signs of inflammation can be detected and both patients and doctors can be notified (when applicable).

As technology continues to advance, thermometry applications for diabetic foot complications have become significantly easier to use for patients. A variety of options are available on the market, including socks, insoles, and SmartMats™.[33]

To determine which technology is the best for a patient, it's important to look for clinical research,[34] ease-of-use and engagement data,[35] case studies,[36] and metrics on resource utilization.[37] Successful programs will integrate technology and care. They'll be easy for patients, helpful to doctors, and be able to support any claims of improving health outcomes either from a financial or medical standpoint. In some cases, these solutions can detect signs of inflammation up to five weeks before they would clinically present[38] — allowing for patients to offload, visit their doctors and specialty teams, and get the help they need.

By stepping in early, we can help prevent diabetic foot ulcers from forming.

For these and the many other reasons we've covered in this eBook, it's clear that diabetic foot complications warrant a strong response. Diabetic amputations are a silent killer, and they're impacting vulnerable

populations that deserve better medical treatment.

Learning is just the beginning. From here, it's critical to spread awareness and share ideas for the prevention of diabetic foot ulcers. We must get ahead of diabetic foot amputations through early detection — saving limbs and lives. This can make a world of difference for a patient with diabetes who is at high risk of developing a foot ulcer. It can mean that we secure someone's independence from the ongoing loop of diabetic foot complications, giving them back the freedom to live without the burden of an amputation.

CONTACT US

to learn more about foot health and thermometry-based solutions at **learnmore@podimetrics.com**.

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