



New Developments: Updated Recommendations for Foot Ulcer Prevention

Here's a review of the 2019 International Working Group on the Diabetic Foot Prevention Guidelines.

BY GARY M. ROTHENBERG, DPM, CDE, CWS AND BRIAN J. PETERSEN, MS, MBA

Lower extremity complications associated with diabetes contribute to significant morbidity, mortality, and cost worldwide.¹⁻³ Research details that the lifetime incidence of diabetic foot ulceration (DFU) is 19-34%.⁴ It is also well documented that a DFU is often the precipitating event in the causal pathway that may result in infections and subsequent amputation. A major concern for those high-risk patients who have healed from a DFU is recurrence. Recidivism rates for DFUs are high: 40% of patients have a recurrence within one year, and 65% within three years.⁴ The economic effects of lower extremity complications are tremendous as well, with Chan and colleagues reporting the average one-year cost as \$44,200 for a patient with a DFU.³

Given the sobering statistics associated with DFUs, evidence-based prevention strategies are critical for all patients with diabetes and especially those deemed high risk. In 2016, Bus and colleagues published an article entitled *A Shift in Priority in Diabetic Foot Care*

*and Research: 75% of Foot Ulcers are Preventable.*⁵ They reported that 90% of all spending on diabetic foot complications is allocated to treatment as opposed to prevention. Similarly, 90% of all randomized controlled trials related to the diabetic foot are focused on treatment interventions as opposed to prevention strategies. The authors assert that a shift in priorities is needed. Hicks and colleagues showed that the cost of curative care for diabetic foot ulcers is 5-30 times greater than the cost of preventive care.⁶ Thus, a focus on prevention can help reduce the significant burden associated with diabetic foot complications.

International Working Group on the Diabetic Foot 2019 Prevention Guidelines

Recently, at the International Symposium on the Diabetic Foot in May, 2019 in The Hague, Netherlands, the International Working Group on the Diabetic Foot (IWGDF) updated their evidence-based guidelines for prevention of DFUs.⁷ The guidance document is part of the IWGDF Guidelines on the prevention and management of diabetic foot disease and serves as an update to the 2015 guidelines.

The IWGDF also recommends a risk stratification framework for

DFUs that begins with a comprehensive history and physical examination. Key risk factors to assess include loss of protective sensation (LOPS), peripheral artery disease (PAD), and foot deformity. A history of foot ulceration, Charcot arthropathy, or previous lower extremity amputation will immediately deem a patient high risk. Table 1 shows the IWGDF system for stratifying risk for foot ulceration.

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TABLE 1: IWGDF 2019 Risk Stratification System

The practice guidelines are based on a systematic review of the literature and outline 16 specific recommendations categorized into six areas of focus:

- 1) Identifying the at-risk foot
- 2) Regularly examining and inspecting the at-risk foot
- 3) Educating the family, patient, and healthcare providers
- 4) Ensuring routine wearing of appropriate footwear
- 5) Treating risk factors for ulceration
- 6) Integrated foot care



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Identifying the At-Risk Foot

Recommendation 1: Examine a person with diabetes at very low risk of foot ulceration (IWGDF risk 0) annually for signs or symptoms of loss of protective sensation and peripheral artery disease, to determine if they are at increased risk for foot ulceration. The 10-gram monofilament is the most commonly practiced technique for assessing LOPS.⁸ If a monofilament is unavailable, it is recommended to use the Ipswich Touch Test.^{9,10} Screening for PAD can include taking a cardiovascular history, palpating for foot pulses, listening with hand-held Doppler, and obtaining non-invasive blood flow studies, as indicated.^{11,12}

Unfortunately, a 2015 study by Thompson and colleagues suggests that compliance with annual foot exams in the United States is poor, with only 16% of patients in the study having documented evidence of a comprehensive annual foot exam,¹³ suggesting the need for increased attention and diligence by the care team to ensure that comprehensive foot screening is completed annually.

Regularly Examining and Inspecting the At-Risk Foot

Recommendation 2: Screen a person with diabetes at risk of foot ulceration (IWGDF risk 1-3) for: a history of

foot ulceration or lower-extremity amputation; diagnosis of end-stage renal disease; presence or progression of foot deformity; limited joint mobility; abundant callus; and any pre-ulcerative sign on the foot. Repeat this screening once every 6-12 months for those classified as IWGDF risk 1, once every 3-6 months for IWGDF risk 2, and once every 1-3 months for IWGDF risk 3.

When risk factors for complications are identified in a person with diabetes, more frequent foot care including debridement of pre-ulcerative calluses, assessment of shoes and inserts, and reinforced verbal education is needed. It appears that lower extremity complications associated with diabetes are related to duration of the disease process and glycemic control.¹⁴

One may think of patients on a risk spectrum, and thus a person's risk status may change over time. If findings lead to a change in risk status, visit frequency should be adjusted accordingly. With the possible exception of corrective surgery eliminating significant foot deformity or a revascularization procedure to improve blood flow, a person's risk is generally not going to be downgraded. Providing routine care and employing recommended preventative strategies are likely to reduce financial burden from diabetic foot complications requiring care in higher cost settings such as the emergency department or inpatient.¹⁵⁻¹⁷

Educating the Family, Patient, and Healthcare Providers

Recommendation 3: Instruct a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) to protect their feet by not walking barefoot, in socks without shoes, or in thin-soled slippers, whether indoors or outdoors. There are several mechanisms leading to DFUs, but the most common causal pathway involves neuropathy, deformity, and pressure.¹⁸

Appropriately fitting shoes are thought to provide some protection against trauma and allow for shock absorption during walking. Patients with diabetes should be frequently reminded that appropriate footwear is needed both inside and outside of their homes, as the protective benefit of appropriate footwear is eliminated with poor adherence, which has been challenging.^{19,20} Armstrong and colleagues found that while patients were likely to use appropriate footwear outside the home, only 15% of patients used appropriate footwear in the home.²¹ Thus, patient education related to footwear should emphasize the need to wear it at all times, not just while outdoors.

Recommendation 4: Instruct, and after that encourage and remind, a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3) to: inspect daily the entire surface of both feet and the inside of the shoes that will be worn; wash the feet daily (with careful drying, particularly between the toes); use emollients to lubricate dry skin; cut toenails straight across; and, avoid using chemical agents or plasters or any other technique to remove callus or corns. Traditionally, adherence to annual foot exams has been poor, with one study showing only approximately 30% of patients complete routine self-exams.¹³

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For many patients with diabetes, visual inspection of the feet is not practical due to obesity, limited joint mobility, and visual impairment from concomitant retinopathy or cataract development. For these patients, sometimes a mirror may be helpful, but in many cases they may need to rely on another person physically touching their feet. If a caregiver or spouse is available, this is often the best option for daily foot exams. Use of foot temperature monitoring (Recommendation 6) to augment daily foot self-exams may be beneficial.²²

Recommendation 5: Provide structured education to a person with diabetes who is at risk of foot ulceration

Education should include communication of risk, the value of and empowerment through preventative care, and emotional support.

(IWGDF risk 1-3) about appropriate foot self-care for preventing a foot ulcer. Structured education is generally performed by the clinician, nursing support staff, or certified diabetes educators. Diabetic foot education can take many forms, such as one-on-one sessions, group sessions, videos, and online options such as blogs and social media, which are increasingly popular. DFU prevention education should include recommended self-examination teachings, footwear recommendations, and guidance on when to seek professional help.

Education for the patient at-risk for diabetic foot diseases is complicated by the psychological impact of these diseases on patients, which include depression, anxiety, and feelings of powerlessness.²³ Thus, education should include communication of risk, the value of and empowerment through preventative care, and emotional support.

Recommendation 6: Consider instructing a person with diabetes who is at moderate or high risk of foot ulceration (IWGDF risk 2-3) to self-monitor foot skin temperatures once per day to identify any early signs of foot inflammation and help prevent a first or recurrent plantar foot ulcer. If the temperature difference is above-threshold between similar regions in the two feet on two consecutive days, instruct the patient to reduce ambulatory activity and consult an adequately trained healthcare professional for further diagnosis and treatment.

This recommendation has been updated since 2015 to reflect the research supporting once-daily foot temperature monitoring as opposed to more frequent foot temperature assessments, which are not supported by evidence. The recommendation also better describes appropriate interventions when inflammation is identified

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consistent with the three randomized trials by Lavery and Armstrong in the 2000s.²⁴⁻²⁶

This recommendation is supported by recent data from Frykberg and colleagues, who published on a novel remote foot temperature monitoring system that may address some previously encountered barriers to adoption for daily foot temperature monitoring.²⁷ They studied a smart mat and found it identified 97% of diabetic foot ulcers with an average lead time of 37 days. Adherence was strong, with 86% of participants engaged in routine use of the mat during the study. More recently, Lavery and colleagues presented an approach for unilateral foot temperature monitoring which may be incorporated into future practice guidelines to enable those with a history of high-level amputation to benefit from this evidence-based practice.²⁸

Ensuring Routine Wearing of Appropriate Footwear

Recommendation 7: Instruct a person with diabetes who is at moderate risk for foot ulceration (IWGDF risk 2) or who has healed from a non-plantar foot ulcer (IWGDF risk 3) to wear therapeutic footwear that accommodates the shape of the feet and that fits properly, to reduce plantar pressure and help prevent a foot ulcer. When a foot deformity or a pre-ulcerative sign is present, consider pre-

scribing custom-made footwear, custom-made insoles, or toe orthoses. Enlisting the help of colleagues in the orthotics and prosthetics field can be very helpful to accomplish this important task. Similar to Recommendation 3, adherence can be challenging, requiring ongoing education and reinforcement by the care team.

Recommendation 8: Consider prescribing orthotic interventions, such as toe silicone or semi-rigid orthotic devices, to help reduce abundant callus in a person with diabetes who is at risk for foot ulceration (IWGDF risk 1-3). These protective devices may help avert significant callus build-up along with sub-keratotic hemorrhage and skin breakdown. Understanding the etiology of a potential ulceration can help accommodate, off-load, and avoid excess pressure.

Recommendation 9: In a person with diabetes who has a healed plantar foot ulcer (IWGDF risk 3), prescribe therapeutic footwear that has a demonstrated plantar pressure-relieving effect during walking, to help prevent a recurrent plantar foot ulcer; furthermore, encourage the

Understanding the etiology of a potential ulceration can help accommodate, off-load, and avoid excess pressure.

patient to consistently wear this footwear. The goal of keeping high-risk patients ambulatory while acknowledging pressure points and history of ulceration is important.

Treating Risk Factors for Ulceration

Recommendation 10: Provide appropriate treatment for any pre-ulcerative sign or abundant callus on the foot, for ingrown toenails, and for fungal infections on the foot, to help prevent a foot ulcer in a person with diabetes who is at risk of foot ulceration (IWGDF risk 1-3). While the high-risk patient is in need of frequent assessment, routine care is performed at these visits as well. Patients should be encouraged to contact their team at the first sign of complication or compromise of skin integrity. Providers must be available to address these concerns in a timely manner to avoid more costly and complicated situations.²⁹

Recommendation 11: In a person with diabetes and abundant callus or an ulcer on the apex or distal part of a non-rigid hammertoe that has failed to heal with non-surgical treatment, consider digital flexor tendon tenotomy for preventing a first foot ulcer or recurrent foot ulcer once the active ulcer has healed. Various studies have shown that ulcer healing is superior in patients undergoing flexor tenotomy when compared with non-surgical management. The procedure is often clinic-based and performed under local anesthesia. As a prophylactic procedure, a flexor tenotomy may also reduce the risk of ulcer development in patients with distal toe calluses.³⁰

Recommendation 12: In a person with diabetes and a

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plantar forefoot ulcer that has failed to heal with non-surgical treatment, consider Achilles tendon lengthening, joint arthroplasty, single or pan metatarsal head resection, metatarsophalangeal joint arthroplasty or osteotomy, to help prevent a recurrent plantar forefoot ulcer once the active ulcer has healed. Rigid foot deformity

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is difficult to offload. All attempts at external offloading with shoes and inserts should be attempted, but when the etiology of a foot ulcer is deemed to be rigid deformity, internal offloading should be considered.³¹

Recommendation 13: We suggest not to use a nerve decompression procedure, in preference to accepted standards of good quality care, to help prevent a foot ulcer in a person with diabetes who is at moderate or high risk of foot ulceration (IWGDF risk 2-3) and who is experiencing neuropathic pain. While observational studies on nerve decompression procedures have demonstrated low ulcer incidence rates over follow-up periods in patients with and without a prior DFU experiencing neuropathic-type pain, there is no evidence to support ulcer prevention after nerve decompression surgery.

Recommendation 14: Consider advising a person with diabetes who is at low or moderate risk for foot ulceration (IWGDF risk 1 or 2) to perform foot and mobility-related exercises with the aim of reducing risk factors of ulceration, i.e., decreasing peak pressure and increasing foot and ankle range of motion, and with the aim of improving neuropathy symptoms. This is a new recommendation in the 2019 guidelines. Although there is no direct evidence that mobility exercises reduce DFU incidence or recurrence, they have been shown to mitigate risk factors for DFU.³²

Consultation with physical therapists for personalized exercise programs along with supervised exercises can be useful.

Recommendation 15: Consider communicating to a person with diabetes who is at low or moderate risk for foot ulceration (IWGDF risk 1 or 2) that a moderate increase in the level of walking-related weight-bearing daily activity (i.e., an extra 1,000 steps/day) is likely to be safe. Advise this person to wear appropriate footwear when undertaking weight-bearing activities, and to frequently monitor the skin for pre-ulcerative signs or breakdown.

This recommendation is new to the 2019 guidance. The overall health benefits of exercise should be compared to the potential harms. Issues of balance, especially in those patients with neuropathy, may play a role in

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choice of exercise recommendation. Additionally, some evidence exists that variability in activity levels is an independent risk factor for DFU development.^{33,34} Non-traumatic exercises such as swimming and biking may yield similar health benefits while avoiding repetitive trauma from weight-bearing activities such as treadmill walking.

Integrated Foot Care

Recommendation 16: Provide integrated foot care for a person with diabetes who is at high risk of foot ulceration (IWGDF risk 3) to help prevent a recurrent foot ulcer. This integrated foot care includes professional foot care, adequate footwear, and structured education about self-care. Repeat this foot care or re-evaluate the need for it once every one to three months, as necessary. Integrated foot care will likely involve many team members such as nurses, diabetes educators, physical therapists, and podiatrists. Previous studies have demonstrated a reduction of high-level amputations by up to 80% in centers that function as a multidisciplinary group.³⁵⁻³⁷ The success of these centers of excellence likely revolves around use of mid-level

providers, including nurses, who can provide education, recommending moderate activity, mobility-related exercise, and appropriate footwear.

One of the strongest predictors of diabetic foot ulceration is a previous foot ulcer.⁴ High recurrence rates are due to biologic and behavioral factors. Biologic factors associated with recurrence of foot ulcers include neuropathy, rigid foot deformity, and tissue damage from repeated microtrauma. Behavioral factors such as non-adherence with shoe recommendations and lack of diligence and adherence to

once-daily foot temperature monitoring, which should be considered a foundation for aggressive preventive practice for those in diabetic foot remission. Integrated foot care and accommodative footwear are also recommended to prevent recurrence, and for appropriate patients, surgical interventions may be indicated.

Conclusion

Provision of quality evidence-based preventive care for those at risk for diabetic foot complications has the poten-

DFU prevention should likely be personalized to deliver the right care at the right time for the right patients.

daily foot self-exams also contribute to recurrence of ulceration.

Prevention strategies to minimize foot ulcer recurrence become a shared burden by the provider and the patient. Providers are responsible for screening and educating patients as well as performing routine care such as paring of pre-ulcerative calluses and prescribing appropriate footwear. Patients should perform daily foot

self-exams to reduce incidence and arrest recurrence, thereby minimizing resource utilization, morbidity, and mortality attributable to DFUs. While the IWGDF Prevention Guidelines yield the most evidence-based recommendations, the authors admit that there are still many unanswered questions and future directions for research. Future directions towards ulcer prevention include a strong focus on first ulcer prevention and a second tier for prevention of those who have already demonstrated high risk status with a previous ulceration or amputation. Globally, best practices, including cost-effectiveness, should be shared after interventions and outcomes are studied. DFU prevention should likely be personalized to deliver the right care at the right time for the right patients. **PM**

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el providers and care coordinators, a strong focus on surveillance and education, appropriate and timely consultations, and the expedited management of these complicated patients.

Discussion

For the prevention of a primary foot ulcer, more insight into the effect of interventions and practices already applied globally is needed. Bus and colleagues suggest systematic recording of interventions and outcomes, as well as additional high-quality research with cost-effectiveness outcomes.⁵ Evidence-based and recommended practices for primary preven-

tion include education, recommending moderate activity, mobility-related exercise, and appropriate footwear.

self-exams and be consistently adherent in wearing therapeutic footwear whether indoors or outdoors. Unfortunately, these recommended practices may not suffice to arrest recurrence. A recent study reporting on 18 years of follow-up in 1,640 participants concluded that while conventional preventive care was associated with reduced incidence for those without a history of DFUs, recurrence rates remained unchanged.¹⁶ Thus, a more aggressive preventive regimen is needed for those in remission. One of the only evidence-based and recommended practices found to prevent recurrence of a DFU is

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Dr. Rothenberg is a Board Certified Podiatrist, Certified Diabetes Educator, and Certified Wound Specialist who currently holds a Clinical Assistant Professor Faculty Appointment within the Endocrinology Division at the University of Michigan School of Medicine in Ann Arbor, MI. His previous private practice experience and academic practices within the VA and university settings have focused on conservative and surgical management of the diabetic foot.

Brian Petersen holds a dual Masters of Science in Systems Engineering and Masters of Business Administration from the Massachusetts Institute of Technology. He is co-founder and Chief Scientist of Podometrics, where his research



involves epidemiology and prevention of foot ulceration and other diabetic foot complications.