

Screening and Risk Stratification for the Prevention of Diabetic Foot Ulcers: A Summary of Evidence-Based Guidelines

Diabetic foot ulcers are the most common complication of diabetes, affecting 4% to 10% of patients. Diabetic foot ulcers tend to be chronic and can develop into serious complications, including wound infection, osteomyelitis (infection in bone), or cellulitis (infection of the skin), and may lead to amputation (surgical removal of infected foot or toe).

Early detection can prevent foot ulceration and related complications. Early treatment can improve the healing of diabetic foot ulcers and reduce the risk for amputation.

Primary care screening programs for diabetic foot ulcers in patients with diabetes may include assessment of risk (risk stratification), patient education, and referral to more specialized care. Risk stratification considers factors such as whether a patient has neuropathy (damage to peripheral nerves, often causing weakness, numbness, and pain, usually in hands and feet) or peripheral vascular disease (a circulatory problem in which narrowed arteries reduce blood flow to the limbs) to help determine their risk for developing a diabetic foot ulcer. Depending on a patient's level of risk, suitable preventive measures can be undertaken.

CADTH has reviewed available evidence-based guidelines (from Canada and from other countries) as part of a review of the evidence on screening and assessing risk for diabetic foot ulcers in adults with diabetes.¹

The recommendations from nine evidence-based guidelines are summarized in Table 1.

Table 1: Summary of Evidence-Based Recommendations on Screening and Risk Stratification for Diabetic Foot Ulcers

| CDA ¹ | RNAO ² | SVS ^{3,a} | ADA ⁴ | NWPS ⁵ | SIGN ⁶ | OSTEBA ⁷ | NHMRC ⁸ | UofA ⁹ |
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| Target Users | | | | | | | | |
| Health care professionals | Nurses, other health care professionals, and administrators | Health care professionals | Not described | National Health Service podiatrists, managers, and commissioners | Health care professionals involved in the care of patients with diabetes Patients with diabetes and their caregivers | <ul style="list-style-type: none"> Health care professionals Specialist care professionals Patients with diabetes Family and caregivers | Health care professionals and health care workers in urban and rural or remote primary care and specialist centres | Not described |
| Recommendation for Screening | | | | | | | | |
| "In people with diabetes, foot examinations by health care providers should be an integral component of diabetes management to identify persons at risk for ulceration and lower-extremity amputation." | "Physical examination of the feet to assess risk factors for foot ulceration/ amputation should be performed by a health care professional." | "[It is recommended] that patients with diabetes undergo annual interval foot inspections by physicians ... or advanced practice providers with training in foot care." | "For all patients with diabetes ... an annual comprehensive foot examination to identify risk factors predictive of ulcers and amputations [should be performed]." | "As part of an annual review, trained personnel should examine patients' feet to detect risk factors for ulceration." | "All patients with diabetes should be screened to assess their risk developing a foot ulcer." | "It is recommended that patients with diabetes mellitus type 1 are included in structured programs of screening, risk stratification, and prevention and treatment of the foot at risk." | All people with diabetes should be assessed by a suitably trained health care professional and their risk for developing complications should be stratified. | For patients visiting a general diabetes clinic: "The evidence suggests that a two-stage foot screening program, followed by a protection program for those patients identified with a high risk foot... may reduce the incidence of major amputation." |
| Recommended Components of Screening and Risk Assessment | | | | | | | | |
| "Assessment ... of skin changes, structural abnormalities (e.g., range of motion of ankles and toe joints, callus patterns, bony deformities), skin temperature, evaluation for neuropathy and [peripheral artery disease], ulcerations and evidence of infection [is recommended]." | In patients with diabetes, risk assessment includes: <ul style="list-style-type: none"> History of previous foot ulcers; Sensation; Structural and biomedical abnormalities; Circulation; and Self-care behaviour and knowledge." | "A history of prior foot ulceration or amputation and a history of poor visual acuity should be evaluated." It is recommended that the foot examination include: <ul style="list-style-type: none"> Testing for peripheral neuropathy using the Semmes-Weinstein test Testing for palpation of pedal pulses Testing for foot deformity. | "Clinicians should ask about history of previous foot ulceration or amputation, neuropathic or peripheral vascular symptoms, impaired vision, tobacco use, and foot care practices." It is recommended that the foot examination include: <ul style="list-style-type: none"> Inspection Assessment of foot pulses Testing for loss of protective sensation (LOPS) (10 g monofilament plus testing any one of the following: vibration using 128 Hz tuning fork, pinprick sensation, ankle reflexes, or vibration perception threshold)." | "Visual inspection of a patient's feet, assessment of foot sensation and palpation of foot pulses by trained personnel is important for the detection of risk factors for ulceration." | "Tests such as the use of 10 g monofilament, palpation of pulses, neuropathy disability score, presence of significant structural abnormality and previous ulceration, when routinely used during screening are effective at predicting ulceration." | "Diabetic foot screening should include: <ul style="list-style-type: none"> A thorough annual examination of the feet to identify risk factors, predict ulcers and amputations [Inspection of] the foot and soft tissues [Assessment of] footwear Musculoskeletal exploration [Assessment of] peripheral arterial disease symptoms by evaluation of foot pulses, supplemented by the determination of ankle-arm index, in some cases, and loss of sensitivity tests assessed using monofilament or alternatively tuning fork." | Risk should be assessed by: <ul style="list-style-type: none"> Inquiring about previous foot ulceration and amputation Visually inspecting the feet for structural abnormalities and ulceration Assessing for neuropathy using either the Neuropathy Disability Score or a 10 g monofilament and palpating foot pulses." | "Risk assessment using a combination of patient history, foot pulses, neuropathy, and foot deformity is a strong predictor of foot ulcer in the general diabetes population." |
| Recommended Frequency of Screening and Risk Assessment | | | | | | | | |
| "At least annually and at more frequent intervals in those at high risk." | "At least annually in all people with diabetes over the age of 15 and at more frequent intervals in those at higher risk." | Annual interval foot inspections for patients with diabetes "[Patients] determined to be at increased risk (presence of neuropathy, ischemia, anatomic deformity) should have more frequent foot evaluations by foot specialists and increased reinforcement of direct patient education." (See below for recommended frequency according to specific risk profiles) | Annual comprehensive foot examination for all patients with diabetes | "Regular (at least annual)." | "There is no evidence to support the frequency of screening; however, the guideline group considers that at least annual screening from the diagnosis of diabetes is appropriate." | Annual inspection is recommended for low-risk patients Inspection every 3 to 6 months (monitoring visits) is recommended for patients at increased risk Inspection every 1 to 3 months is recommended for patients at high risk. | "In people stratified as having low-risk feet (where no risk factors or previous foot complications have been identified), foot examination should occur annually." "In people stratified as having intermediate-risk or high-risk feet (without current foot ulceration), foot examination should occur at least every 3 to 6 months." | Not described |
| Criteria for Risk | | | | | | | | |
| The University of Texas Diabetic Wound Classification System is cited (see guideline for classification) | "Based on assessment of risk factors, [patients] should be classified as 'lower' or 'higher' risk for foot ulceration/ amputation." (See guideline for classification) | Category 0: Normal Risk Profile (annual evaluation) Category 1: Peripheral Neuropathy (semi-annual evaluation) Category 2: Neuropathy With Deformity and/or Peripheral Arterial Disease (quarterly evaluation) Category 3: Previous Ulcer or Amputation (monthly or quarterly evaluation) | "The risk of ulcers or amputations is increased in people who have the following risk factors: <ul style="list-style-type: none"> Previous amputation Past foot ulcer history Peripheral neuropathy Foot deformity Peripheral vascular disease Visual impairment Diabetic nephropathy (especially patients on dialysis) Poor glycemic control Cigarette smoking." | Low Risk: "Normal sensation, palpable pulses" Increased/High Risk: "Neuropathy and/or absent pulses +/- intermittent claudication +/- deformity or skin changes or previous ulcers" Emergency Foot; Ulceration/Charcot: "New ulceration, cellulitis, new or sudden discoloration/pain/swelling" | Low Risk: "No risk factors present" Moderate Risk: "One risk factor present; e.g., loss of sensation or signs of peripheral vascular disease without callus or deformity" High Risk: "Previous ulceration or amputation or more than one risk factor present" Active Diabetic Foot: "Presence of active ulceration, spreading infection, critical ischemia, gangrene or unexplained hot, red, swollen foot with or without the presence of pain" | Low Risk: "Preserved sensitivity, palpable pulses" Increased Risk: "Neuropathy, absence of pulses and other risk factors" High Risk: "Neuropathy or absent pulses together with deformity or skin changes or previous ulcer" Ulcerated Foot | Low risk: "People with no risk factors and no previous history of foot ulcer/ amputation" Intermediate risk: "People with one risk factor (neuropathy, peripheral arterial disease or foot deformity) and no previous history of foot ulcer/ amputation" High risk: "People with two or more risk factors (neuropathy, peripheral arterial disease or foot deformity) and/ or a previous history of foot ulcer/ amputation" | Same risk criteria as National Health and Medical Research Council |
| Recommended Interventions for High-Risk Patients | | | | | | | | |
| "People at high risk of foot ulceration and amputation should receive foot care education (including counselling to avoid foot trauma), professionally fitted footwear, and early referrals to a health care professional trained in foot care management if foot complications occur." | "Individuals assessed as being at 'higher risk' for foot ulcer/amputation should be advised of their risk status and referred to their primary care provider for additional assessment or to specialized diabetes or foot care treatment and education teams as appropriate." | "Patients identified as having significant neuropathy should be considered for increased interval examinations as well as for customized orthotic footwear." | "A multidisciplinary approach is recommended for individuals with foot ulcers and high-risk feet, especially those with a history of prior ulcer or amputation." "Patients who smoke, have loss of protective sensation (LOPS) and structural abnormalities, or have history of prior lower-extremity complications [should be referred] to foot care specialists for ongoing preventive care and lifelong surveillance." | "Patients with risk factors for ulceration should be referred to a foot protection team." | For people at high diabetic foot risk, an annual assessment and a tailored management plan by a specialist podiatrist is recommended. Referral for specialist intervention, if needed, is also recommended. | Individualized treatment and possible referral for patients with ulcerated foot is recommended. | "People assessed as having 'intermediate-risk' or 'high-risk' feet should be offered a foot protection program that includes foot care education, podiatry review, and appropriate footwear." | "Patients at high risk of lower-extremity amputation [should be] followed by a protection program to prevent amputation." |

ADA = American Diabetes Association; CDA = Canadian Diabetes Association; NHMRC = National Health and Medical Research Council; NWPS = North West Podiatry Services; OSTEBA = Basque Office for Health Technology Assessment; RNAO = Registered Nurses' Association of Ontario; SIGN = Scottish Intercollegiate Guidelines Network; SVS = Society for Vascular Surgery; UofA = University of Adelaide.

^a In collaboration with the American Podiatric Medical Association and the Society for Vascular Medicine.

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