CLINICAL MANAGEMENT extra

Validation of the Healthy Foot Screen: A Novel Assessment Tool for Common Clinical Abnormalities

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GENERAL PURPOSE:

The purpose of this learning activity is to provide information about the Healthy Foot Screen, a new tool for assessment of common foot abnormalities.

TARGET AUDIENCE:

This continuing education activity is intended for physicians, physician assistants, nurse practitioners, and nurses with an interest in skin and wound care.

LEARNING OBJECTIVES/OUTCOMES:

After completing this continuing education activity, you should be able to:

1. Recognize prevalence, causes, risk factors, signs, and types of common foot problems.

2. Identify the results of this study about the new foot screening tool and its implications in primary care.

ABSTRACT

BACKGROUND: Foot health is a key component of general health and well-being. Nevertheless, feet are often overlooked by healthcare providers and patients. Common foot problems include infections or inflammatory conditions, abnormal nail disorders (eg, onychomycosis), structural bony abnormalities, circulation disorders, and other conditions. The development of an easy-to-use, rapid, clinical tool to assess foot health can facilitate primary care provider recognition and treatment of common foot problems. This study ascertained interrater item reliability and validity from the preliminary version of one such tool called the Healthy Foot Screen.

METHODS: A total of 18 patients from a community dermatology clinic were individually screened by 11 interprofessional healthcare assessors using the preliminary tool. The assessors included a dermatologist/internist, family physicians, nurses, and podiatrists. The initial draft of the Healthy Foot Screen was created through an extensive literature review, complemented by the clinical judgment of the study team. Cronbach α was calculated for each item to determine interrater reliability. A minimum value of 0.6 was set for an item to be included in the final tool. Where applicable, scores for each item on the screen were calculated for right and left lower limbs and then averaged. Assessors were asked to complete a short survey.

RESULTS: Interrater reliability scores for items on the screen were as follows: diabetes and smoking, 1.0; neuropathy, 0.988; palpable foot pulse, 0.916; abnormal fourth to fifth toe web space, 0.905; previous ulcer/amputation, 0.869; pitting edema, 0.872; bony abnormality, 0.804; dry bottom of foot, 0.799; toenail infection, 0.793; other spots/lesions,0.688; and red areas/blisters/pustules, 0.659. Generally, assessors found the tool easy to use, although some areas for improvement were noted.

CONCLUSIONS: The Healthy Foot Screen can facilitate primary care provider diagnosis and treatment of common foot problems.

KEYWORDS: arterial disease, foot assessment tool, foot deformity, foot fungus, foot health, leg edema, onychomycosis, screening, validation

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INTRODUCTION

Foot health is a key component of general health and well-being. Currently, its importance is often taken for granted. This lack of awareness among providers and patients may result in underdiagnosis and delayed treatment.[1–3] Foot health problems have been linked to obesity, diabetes, vascular insufficiency, autoimmune disorders, musculoskeletal pathologies, and trauma.[4] These problems also can impair ambulation, decreasing physical activity. Foot changes can also be a source of pain, may be associated with negative body image, and can decrease quality of life.[5–10] A comprehensive assessment that documents risk factors for potential limb-threatening events is critical. These risk factors include history of diabetes, neuropathies, smoking, previous or current foot ulceration, or lower-limb amputation. If a patient has diabetes, healthcare providers should complete the Simplified 60-Second Screen (a validated tool to identify persons at high risk of a diabetic foot ulcer and potential amputation).[11–15]

Robust evidence supports foot screening for patients with diabetes.[11,16–18] However, for the general population, only a few foot screens are described in the literature.[19,20] A systematic review by Riskowski et al[21] concluded that there was insufficient evidence of validation and clinical replication of these tools, emphasizing the need for validated tools for common foot problems in the general population. Common foot problems include fungal infection of the skin (tinea pedis) and toenails (onychomycosis), signs of neuropathy (dry plantar skin), secondary bacterial infection (fourth to fifth toe web space maceration), bony abnormalities (hallux valgus/bunion, claw toe), compromised vascular supply (arterial or venous), and edema of the lower limbs/feet.

Onychomycosis is a very common nail disorder, comprising approximately 50% of all nail pathologies.[22] The age- and sex-adjusted prevalence of onychomycosis in a large Canadian study was 6.4%.[23] The clinical signs and symptoms of onychomycosis and tinea pedis can be confusing. Currently, there is no simple clinical tool to guide primary care provider management of these conditions. As a result, these conditions are often missed or diagnosed only after advanced nail plate involvement. This can cause unnecessary discomfort, difficulty with ambulation, nail loss, and a predisposition to secondary bacterial infection.

Peripheral neuropathy is another common foot problem. Approximately 30% to 50% of people with diabetes are affected.[24,25] In the general population, neuropathy is also relatively common and linked to a number of causes including vitamin B_{12} deficiency, trauma, kidney disease, autoimmune disorders, alcohol abuse, infection, and environmental toxins (eg, mercury, lead).[26] Peripheral neuropathy results in the loss

of protective sensation, dry plantar skin, and fat pad herniation distally. This can cause abnormal pressure points on the plantar aspect of the foot, especially over the metatarsal heads. Increased foot pressure, in turn, leads to callus formation that can predispose patients to ulceration.[12] Bony deformities also constitute an important risk factor for foot ulceration because of increased foot pressures, local trauma, and the friction and shear forces they create.[13]

Lower-limb edema and peripheral arterial disease are other common foot health issues. Timely diagnosis and control of lower-limb edema related to chronic venous insufficiency may prevent leg ulcers. Absent foot pulses may be a sign of peripheral arterial disease and should trigger the measurement of vascular supply and ankle brachial pressure index. As with other foot problems, early diagnosis can lead to improved control of vascular risk factors, which in turn may prevent arterial insufficiency ulcers, critical limb ischemia, and amputations.[27]

An easy-to-use, rapid, validated, and clinical tool for assessing foot health would help primary care providers identify common foot problems. For this reason, the authors have developed the Healthy Foot Screen. The Healthy Foot Screen may also facilitate appropriate and timely interventions to prevent further complications, including amputations.[16,17] The aims of this study were to ascertain the interrater reliability and validity of the newly created Healthy Foot Screen (Figure 1) and assess its value as a routine screening tool.

METHODS

Ethics and Consent

This study received ethics approval (#Pro00022415) from Institutional Review Board Services (Aurora, Ontario). This study also adhered to the Tri-Council Policy Statement for Ethical Conduct for Research Involving Humans, the Ontario Personal Health Information Protection Act, and the Declaration of Helsinki.[28,29] Informed consent forms that outlined the study purpose and the need for screening and photographic documentation were signed by participants. There were no refusals. No treatment was applied as a result of this study.

Development of Screening Tool

The methodology for this study was broadly similar to that of Woodbury et al.[17] An overview of the study design is shown in Figure 2. Cochrane Library, PubMed, the Centre for Reviews and Dissemination, and Google Scholar databases were searched by the authors. A search strategy was devised to determine the most important risk factors to include in the risk assessment tool for foot health applicable to the general population. Results were limited to English language articles.

The authors' clinical experiences were also pivotal in selecting the risk factors to develop the screen. Therapeutic and other management actions were attached to each risk factor as a guide for primary care physicians' plans of care. This screen used in the validation process comprised items in the following categories:

1. history: diabetes, smoking, neuropathy, previous ulcer or amputation
2. infection: signs of toenail fungal infection, abnormal toe web space (especially fourth to fifth), dry plantar foot skin
3. structural changes: bony abnormalities
4. circulation: palpable pedal pulses
5. others: pitting edema and other lesions

An accompanying 'enabler' document was created that features extensive definitions, conceptual frameworks, suggested actions, and pictures of these abnormalities and their management. This document was designed to improve the assessor's diagnostic acumen and knowledge base when using the tool. See http://woundpedia.com for more information.

Recruitment of Patients and Clinical Assessors

Eighteen patients who were known to have common foot abnormalities (fungal nail infections, foot deformities, absent pedal pulses, pedal edema, etc) were selected from a community dermatology clinic to participate in the study by the principal investigator. Patients younger than 18 years or with bilateral foot amputations were excluded.

An interprofessional group of 11 healthcare assessors invited by the study group participated in a daylong validation process. The group comprised 1 dermatologist/internist, 3 family physicians, 2 podiatrists, and 5 registered nurses, all with foot examination and wound care expertise. Each assessor examined every patient independently and had no knowledge of the other assessments. Patients were instructed not to divulge results of previous screens to other assessors. The assessors completed a postscreen questionnaire (on a paper handout) about the screening exercise.

Data Collection

Demographics, medical history, and items of the screening tool were recorded by each assessor as part of the screening process. Photographs of the lower limb and foot were taken for clinical verification. Care was taken to maintain patient privacy, such as avoiding photographic capture of the face. Samples were taken from 3 different sites of 1 foot of each participant by the primary investigator for fungal cultures from the distal toenails, plantar surface scale, and scale from the fourth to fifth toe web space. Bacterial swabs were also taken if secondary bacterial colonization

Figure 1.
HEALTHY FOOT SCREEN 2017

Name: _____

DOB (dd/mm/yy): ___/___/___ **Gender: M □ F □**

ID#: _____ **Phone #:** _____

Completed by: _____ **Date of Exam (dd/mm/yy):** ___/___/___

Check both feet and circle responses where applicable

HISTORY	**1. Is the patient known to have diabetes mellitus type 1 or type 2?** *(If yes, perform the 60 Second Diabetic Foot Screen)*	Yes		No	
	2. Is the patient currently a smoker? *(If yes, counsel on smoking cessation)*	Yes		No	
	3. Does the patient have neuropathy? Ask about burning, stinging, shooting or stabbing in either foot. *(For any patient with neuropathy, perform the 60 Second Diabetic Foot Screen)*	**RIGHT** Yes	No	**LEFT** Yes	No
	4. Has the patient had a previous foot ulcer (U) or amputation (A) on either foot? *(If yes, perform the 60 Second Diabetic Foot Screen)*	Yes U | A	No	Yes U | A	No
INFECTION	**5. Are there signs of toenail fungal infection/inflammatory changes, eg. trauma, psoriasis?** *(If yes, treat)*	**RIGHT** Yes	No	**LEFT** Yes	No
	6. Are toe webs abnormal, especially 4th/5th toe web? *(If yes, treat)*	Yes	No	Yes	No
	7. Is the bottom of the foot dry? *(If yes, diagnose cause and treat)*	Yes	No	Yes	No
STRUCTURAL CHANGES ***List specific changes in the comments section below***	**8. Is there a significant bony abnormality or associated change?** *(Any significant bony change should trigger a foot specialist referral)*	**RIGHT** Yes	No	**LEFT** Yes	No
CIRCULATION	**9. Can you feel a foot pulse?** *(Absent dorsalis pedis & posterior tibial pulse = vascular laboratory assessment/referral)*	Yes	No	Yes	No
	10. Any pitting edema of the feet/ankle? *(If yes, diagnose cause and treat)*	Yes	No	Yes	No

Refer to enabler for more information. Local referral patterns may vary depending on available resources.

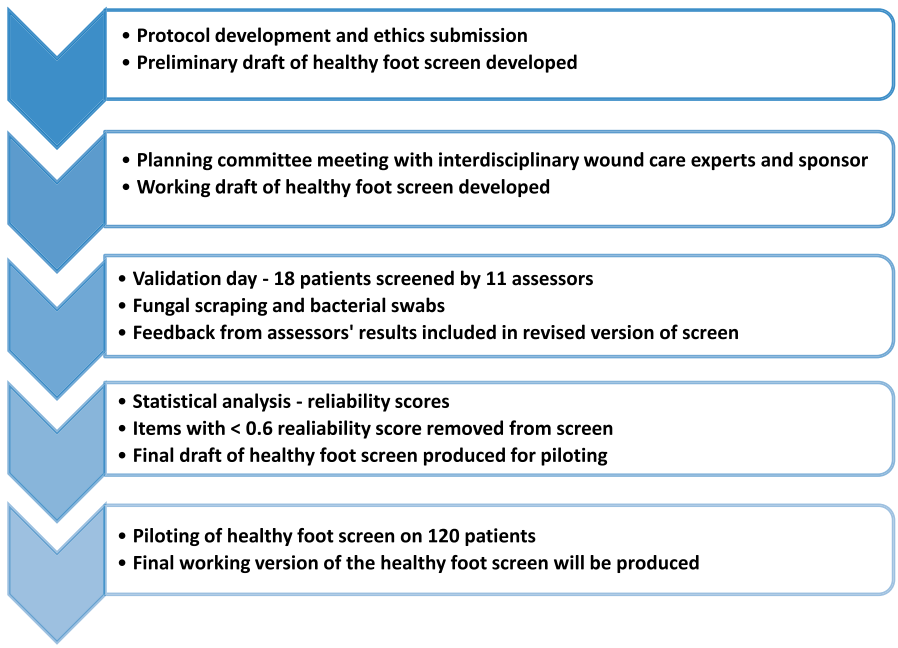
Other Comments/Abnormalities

_____
_____
_____
_____
_____

Recommendations/Treatment

_____
_____
_____
_____
_____

Figure 2.
STUDY DESIGN, DEVELOPMENT, AND VALIDATION OF THE HEALTHY FOOT SCREEN



or infection was suspected, including maceration between the fourth and fifth toe web spaces.

Statistical Analysis

Data from the screen were transferred from paper forms into an SPSS version 22 (IBM, Armonk, New York) data set by a trained researcher. As multiple assessors were utilized, the interrater reliability was assessed by calculating Cronbach α.[30–32] The validation procedure matched the criteria based on Donner and Eliasziw[33]:

- 6 or more assessors
- minimum acceptable reliability value of 0.60
- α-level of .05
- β-level of .20
- expected reliability value for the population of 0.80

Results from the postscreen questionnaire completed by the assessors were transferred from paper to an online survey and were exported to Microsoft Excel.

RESULTS

Patient Demographics and History

The patients who participated in the screening process were all nonsmokers, primarily female (n = 13 [72.2%]), with a mean age of 61.4 years (range, 23–88 years). The recorded mean body mass index was 30.3 kg/m^2 and ranged from 19.5 to 48.4 kg/m^2. The majority (n = 14 [77.7%]) had 1 or more comorbidities. The most common comorbidities reported were hypertension (n = 8 [44.4%]), type 2 diabetes (n = 4 [22.2%]), peripheral vascular disease (n = 2 [11.1%]), and other cardiovascular disease (n = 2 [11.1%]).

Finalizing the Screening Tool

As a result of the literature review, 66 articles were analyzed by the study team prior to the initial tool development. The data from these 66 articles were used as the basis for the original tool in combination with clinical experience.

The original version of the tool tested in the validation process comprised 12 major groups of items under the following categories: history, infection, structural change, circulation, inflammatory lesions, bacterial/viral infections, infestations, and all other lesions.

After the validation process was completed, the results were analyzed, and items with an interrater reliability less than 0.60 were dropped from the tool. The order of some items also changed depending on observations and feedback from the assessors.

Interrater Reliability Scores

The results from the calculation of Cronbach α determined that the majority of items were reliable (>0.60; Table 1). The subsets of

Table 1.
CRONBACH α RELIABILITY SCORES

Item on Screen	Cronbach α	Items on Screen	Cronbach α
Diabetes	1.000	R bottom of foot dry	.830
Smoking	1.000	L bottom of foot dry	.451
Neuropathy (R+L)	.988	Dry skin extends to bottom of foot	.659
R neuropathy	.986	Bony abnormality (R+L)	.804
L neuropathy	.981	R bony abnormality	.646
Previous ulcer/ amputation (R+L)	.869	L bony abnormality	.655
R previous ulcer/amp	.883	Foot pulse palpable (R+L)	.916
L previous ulcer/amp	.715	R foot pulse palpable	.862
Toenail infection (R+L)	.793	L foot pulse palpable	.806
R toenail infection	**.565**	Pitting edema (R+L)	.872
L toenail infection	.614	R pitting edema	.872
Distal streaks	**.380**	L pitting edema	.698
Discoloration	**.503**	Varicosities	.754
Subungal debris	**.420**	Pigment	.870
4th–5th toe web abnormal (R+L)	.905	Hard/firm skin dorsum, feet	.859
R 4th–5th toe web abnormal	.782	Red areas/blisters/ pustules (R+L)	.659
L 4th–5th toe web abnormal	.851	**R red areas/blisters/ pustules**	**.471**
Dry (fungus)	.654	**L red areas/blisters/ pustules**	**.276**
Wet	**.233**	Other spots/lesions (R+L)	.688
Other web spaces	**.385**	**R other spots/lesions**	**.371**
Bottom of foot dry (R+L)	.799	**L other spots/lesions**	**.364**

Abbreviations: L, left; R, right.
Note: Bolded text indicates those items that did not meet the accepted reliability score (those that were <.06).

toenail infection all had low reliability (distal streaks, 0.380; discoloration, 0.503; and subungual debris, 0.420). Subsets of abnormal toe webs also had low reliability (wet, 0.233; other web spaces involved, 0.385). As a result, the subsets for these items were removed from the screen for consistency. The last 2 items on the preliminary screen (red areas/blisters/pustules and other spots/lesions) also had low reliability scores when calculated and analyzed on right and left extremities individually. These items were removed from the screen, even though their combined value was greater than 0.60.

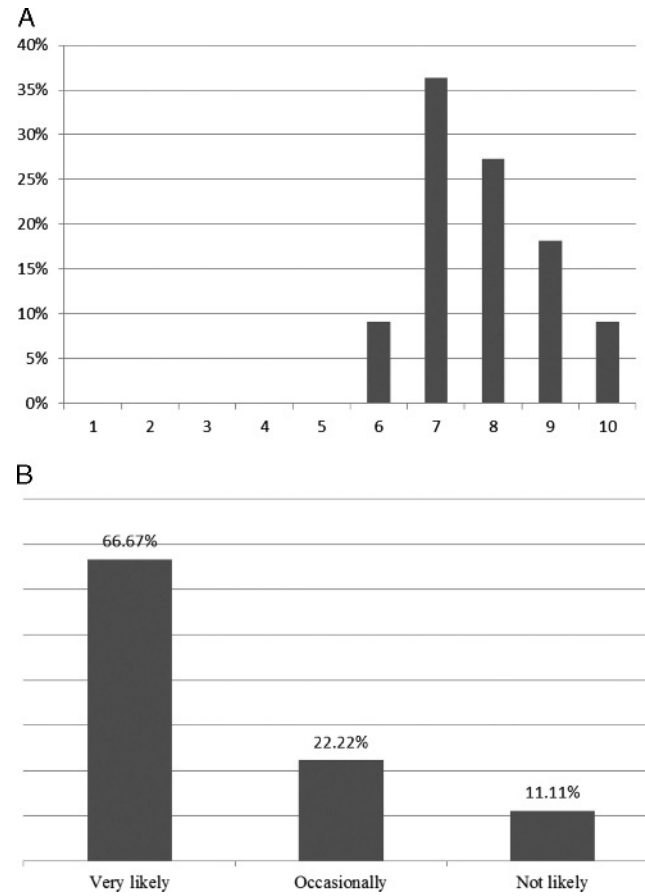
The majority of the assessors commented that the screen was relatively easy to perform, rating ease of use at 7 to 9 on a Likert scale of 1 to 10, with 10 being extremely simple. When asked how likely they are to use an approved version of the screen in their practice, 6 (67%) said "very likely," 2 (22%) said "occasionally," and 1 (11%) said "never" (Figure 3).

The strengths, weaknesses, and areas for improvement of the screen, based on the assessors' feedback from the questionnaire, are summarized in Table 2.

DISCUSSION

The Healthy Foot Screen tool covers common foot abnormalities prevalent in the general population. The patients involved in the screening were also representative of literature findings

Figure 3.
ASSESSOR RESPONSES



A, Assessor responses to "On a Likert scale of 1 to 10, with 10 being extremely simple, how easy was it to perform the screen?" No respondents skipped this question. B, Assessor responses to "If approved, how likely are you to use this screen in your practice?" Two respondents skipped this question.

Table 2.
SUMMARY OF ASSESSORS' FEEDBACK POSTSCREEN EXERCISE

Strengths	Weaknesses	Areas for Improvement
"Having a screen starts the conversation on foot health." "It forces you to look very carefully at the foot without much writing as my normal assessment. Nice check boxes." "Looks at major areas and helps guide assessment for those who do not regularly examine feet (provides structure)." "Serves to identify commonly missed conditions and red flags for appropriate treatment." "Can identify foot disorders, illnesses, early that may lead to complications and increase mortality."	"Needs to be less 'wordy' format—too busy; needs to be cleaner, concise." "Felt like some of the questions (eg, #7 about dry feet) were a bit subjective." "Harder to use with patients who have known abnormalities such as treated fungal infections, edema." "What about current wounds that are existing on foot?" "Toenail infection difficult to diagnose by subungual debris, discoloration; many other disorders have similar signs." "Results can vary if patient sits or stands as foot structure changes." "For #1: It is patient's 'perception' that they have diabetes? Or is it clearly by lab results? (if so, this will cannot be done during screening time frame)."	"[Needed] clearer instructions or more time prior to understand what we were really identifying." "I wanted to provide education and health teaching today vs evaluating the tool." "Nonpalpable pulses not always [equal] to peripheral vascular disease. vascular lab assessment might be necessary to include? Suggest include [sic] other signs of peripheral vascular disease." "Description of items of the screen with associated pictures need to be easily identified." "Drawing of feet on form to pictorially identify where abnormalities are found."

of patients who are more prone to foot abnormalities.[34–36] They were older adults with elevated body mass indices (obese)[37] who had associated comorbidities such as hypertension, diabetes, and peripheral vascular disease. This validation process was the basis for modifying the tool so that it contains only items with acceptable reliability scores. The subset items for toenail fungal infection, distal streaks, discoloration, and subungual debris all had low Cronbach α scores. The low scores demonstrate that it is problematic to accurately identify these specific signs (also reflected in assessors' comments in Table 2).

Although onychomycosis is the most prevalent nail disease, accounting for approximately 50% of nail disorders, identifying specific signs on the nail is difficult.[22,38] Other conditions can mimic the signs of onychomycosis, including psoriasis, lichen planus, chronic paronychia, and even trauma (eg, physical activity, pedicures).[39–41] These related subsigns were removed as items from the screen, and the more general item, signs of toenail infection, was left as the validated, standalone item on the screen. This may serve as a red flag for further investigation of local nail disorders or nail changes related to systemic disease.

Items on identifying the presence of maceration also had a low Cronbach α. This may be because, as in the case of onychomycosis, other conditions resemble toe web maceration. These conditions include erythrasma, interdigital psoriasis, and even skin cancer.[42,43] Identifying "red areas" and "other skin lesions" also had a low Cronbach α. This may be because of the open-ended nature of these items, along with vague written descriptions provided. A consensus among the authors and assessors was reached to remove these items of the screen for ease of use and speed of application of the screen. An open text box was included in the revised version for comments on other possible abnormalities not included in the screen.

The Cronbach α scores aligned with responses on the postassessment questionnaire that assessors completed after the validation process (Table 2). These recommendations were used to develop a revised version of the screen. The interrater reliability testing of the tool resulted in conclusive and credible validation. A further strength of this validation process was that it was performed on a group of subjects with conditions representative of the items on the tool. The process and tool were also enhanced by the interprofessional group of healthcare assessors with foot health expertise.

Limitations

All assessors had at least some expertise in foot health. This may have attributed to some degree of proficiency in using the screen that may not be generalizable to all settings. It may be that healthcare providers with no prior expertise in foot health may have a somewhat different interpretation of the items of the screen.

The patient sample size and the location of the validation (a single clinic in a high-income country) may be a limitation to the universal generalizability of the screen. Further, the literature search, although thorough, was limited to the English language, and relevant information in other languages may have been missed.

Next Steps

In the future, healthcare providers will pilot the tool in primary care, outpatient, and hospital wound clinics. Lessons learned

will inform the final version of the tool, including the optimal ordering of items, layout, and graphic design.

CONCLUSIONS

The Healthy Foot Screen is a validated, quick, and easy-to-use tool that can assist clinicians, especially primary care providers, to identify common foot problems, including tinea pedis and toenail onychomycosis, inflammatory lesions, bony abnormalities, vascular insufficiency, and leg/foot edema. Ultimately, the Healthy Foot Screen may promote early management of foot conditions to improve patient outcomes with appropriate referrals and optimal use of resources. In combination with HbA_{1c}, the Healthy Foot Screen may help identify people with undiagnosed or undertreated diabetes by screening for common nail and foot abnormalities.

PRACTICE PEARLS

1. Foot health is a key component of general health and well-being. There is general lack of foot care awareness among healthcare providers and patients, resulting in delayed diagnosis and treatment.
2. Common foot problems include:
   - fungal infection of the skin (tinea pedis) and toenails (onychomycosis), and of toe webs (especially fourth to fifth),
   - signs of neuropathy (dry plantar skin),
   - secondary bacterial infection (fourth to fifth toe web space maceration),
   - bony abnormalities (hallux valgus/bunion, claw toe),
   - compromised vascular supply (arterial or venous), and edema of the lower limbs/feet.
3. Onychomycosis is the most prevalent nail disease, accounting for approximately 50% of nail disorders, but identification of specific signs on the nail is difficult. In persons with diabetes, the presence of onychomycosis now indicates a high-risk foot for ulceration.
4. The Healthy Foot Screen may promote the early management of foot conditions to improve patient outcomes with appropriate referrals and optimal use of resources.
5. In combination with HbA_{1c}, the Healthy Foot Screen may help identify people with diabetes by screening for common nail and foot abnormalities.

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