A Prospective, Descriptive Study to Assess the Reliability and Usability of a Rapid Foot Screen for Patients with Diabetes Mellitus in a Complex Continuing Care Setting

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Abstract
Inlow’s 60-second Diabetic Foot Screen is a paper-pencil tool developed to guide professionals in the completion of a quick foot assessment of persons with diabetes mellitus to determine recommended frequency of assessments. The tool has been used in various healthcare settings and its reliability and validity previously tested in acute and long-term care settings. The purpose of this study was to assess content, time to complete assessment, ease of use, and reliability of the tool in a complex continuing care setting. The tool includes questions about 10 variables; skin, nails, deformities, footwear, temperature, range of motion, sensation, pulses, dependent rubor, and erythema. Answers convert to a score ranging from 0 (low risk, yearly screenings) to 23 (high risk, weekly screenings). Using the tool, the study questionnaire, and a watch, three nurse assessors experienced in assessing the feet of persons with diabetes completed 70 assessments on 35 patients during a period of 30 days. Content areas assessed included significance of comorbidities and interval screening times. Mean time to complete the assessment was 7 minutes (range 2 to 21 minutes); 39% of assessments took 6 to 7 minutes. Times to perform assessment varied widely due to the functional and cognitive well-being of the patient. Inter-rater reliability was low (ICC 0.608 [95% confidence interval 0.349–0.781]), perhaps due to varying interpretations of assessment parameters related to the complexity of the study patient population. Comments suggest that some tool revisions may increase ease of use as well as tool validity and reliability, especially for complex care patients with multiple comorbidities.

Keywords: clinical study, diabetes complications, risk assessment, foot, reliability


Potential Conflicts of Interest: none disclosed

Literature Review
Diabetes affects people worldwide and spans all age groups; the International Diabetes Federation estimates that current global prevalence is 6% or 250 million people worldwide. In 2010, Statistics Canada estimated that 1.8 million Canadians live with diabetes. Diabetes has been shown to reduce quality of life due to the various short- and long-term complications affecting organs, most commonly the heart, eyes, kidneys, and skin. Some of these complications, when left untreated, can be fatal; others are preventable. One of the major complications persons with diabetes (PWD) develop is a foot ulcer. According to global research, the lifetime risk of PWD developing a foot ulcer has been estimated to be as high as 25%. Reviews of clinical epidemiologic studies from the United States (US) suggest foot ulcers precede 85% of lower limb amputations in PWD. Nonhealing foot ulcerations are the leading cause of nontraumatic amputation in the US. The risk factors associated with the development of a foot ulcer include neuropathy, deformities, and trauma.
Identifying patients at risk by means of a thorough and regularly scheduled screening foot exam is a key factor in preventing foot ulceration. Several clinical practice guidelines recommend annual foot examinations for PWD as critical to identifying feet at higher risk of developing ulcers. The Canadian Diabetes Association recommends performing annual foot examinations at minimum for all PWD and at more frequent intervals for persons at high risk in order to decrease the likelihood of foot ulcers and amputation through early detection and intervention.

Although they are the most serious and costly complications of diabetes, most foot ulcers are preventable. Boulton’s literature review comparing the incidence of amputations in PWD across the world concluded a foot screening program in PWD with risk factors could prevent foot ulcers. Essential components of the program should include prevention, the interprofessional treatment of foot ulcers, diligent monitoring, and education directed at both PWD and healthcare professionals.

PWD and concomitant renal disease have been identified as risk factors for lower extremity amputation. A retrospective study by Eggers utilizing US hospital invoicedata from 1991 to 1994 investigated the rate of lower limb amputation among 232,193 persons with end-stage renal disease (ESRD). PWD accounted for 67,460 (29%) of the sample; within this group, 25% required amputation. The study strongly recommended use of programs to screen high-risk persons while providing regular foot care and referrals to specialists involved in the care of PWD as needed.

Various diabetic foot risk classification systems are available that predict ulceration and amputation. The International Working Group on the Diabetic Foot (IWGDF) developed a 4-point international risk classification system that recommends the use of inexpensive and easily accessible tools to assess the feet of PWD. Despite the classification system’s ability to predict risk of diabetic foot complications such as the development of foot ulcers, some researchers have indicated the IWGDF framework may underestimate peripheral arterial occlusive disease and amputation history. In a prospective study to determine the role of peripheral arterial occlusive disease, foot ulcers, and amputation as variables to predict lower leg complications, Lavery modified the IWGDF classification system from a four-group (0 = patients without risk factors; 1 = patients with peripheral neuropathy (PN); 2 = patients with PN, a deformity, and vascular disease; 3 = patients with a history of ulcer or amputation) into a six-tiered risk classification system. The former group 2 was subdivided: 2A = patients with PN and foot deformity and 2B = patients with peripheral arterial occlusive disease (PAOD). Group 3 also was subdivided: 3A = history of ulceration and 3B = history of amputation. Thus, classifications were based on peripheral neuropathy, peripheral arterial occlusive disease, deformity, ulcer history, amputation history, and absence of PN and PAOD. Based on the results of the study, Lavery suggested a five-tiered system identified as the Texas Foot Risk Classification System. This was developed by combining patients with PN and PAOD and excluding deformities as a category assignment. However, the Texas Classification System can be time-intensive and requires specialized training in diabetic foot complications, thereby making it difficult to implement in a hospital setting where training limitations may exist. A need for a more basic, easy-to-use, quick bedside foot assessment tool that front-line staff could use to screen PWD risk for foot complications, with or without ulcers, was identified.

Inlow’s 60-second Diabetic Foot Screen is a practice-ready, bedside tool that can guide professionals to complete a quick diabetic foot assessment; it has been applied across varied healthcare settings. Initial work by Inlow, a clinical expert in the field of diabetic foot ulcers, provided the framework for the new screening tool, which complied with the recommendations from the IWGDF and took into consideration the need for a quick, easy-to-use tool, used at regular intervals, that included both observational and palpation criteria in the screening process. An expert consensus panel consisting of clinicians involved in the care of PWD reviewed and provided content feedback, which resulted in modifications to the tool before it was tested for validity and reliability within the clinical settings.

The purpose of this study was to further assess the content of the tool using expert nursing opinion and to evaluate its ease of use, time to completion, and inter-rater reliability within a 30-day period in a complex continuing care (CCC) facility.

**Methods**

**Setting.** Following approval from the institution’s research ethics board, the project was initiated across Saint...
Vincent Hospital (SVH), a French/English 348-bed CCC facility in Ottawa, Ontario, part of the Bruyère Continuing Care organization. Patients requiring >3 hours of nursing care per day across the site’s four major care streams (complex care, restorative care, supportive care, and transitional care) are admitted to SVH. It is important to note that patients admitted in any of the four streams are considered complex because most (statistics not captured by the authors’ organization; approximately 95%) are afflicted with one or more chronic illnesses. Examples of primary diagnosis of patients at SVH include diabetes, stroke, multiple sclerosis, amyotrophic lateral sclerosis, advanced Parkinson’s disease, and spinal cord injury. More than 80% of the population is nonambulatory, with an average of 715 total days in the facility. At the time of the study, 125 patients (36%) were diagnosed with diabetes; 13 (10%) also had renal disease, primarily attributed to complications from diabetes.

Participants. French and English PWD (type 1 and type 2) across all clinical units participated in the study from August through September 2010. Participants were recruited based on location and their need to be seen by a nurse for a foot assessment. Participants already being followed by the research team’s Advanced Practice Nurses (APN) and who required foot assessments were included in the sample. Nondiabetic patients and patients with bilateral lower limb amputation with or without ulcers were excluded.

Instrument: Inlow’s 60-second Diabetic Foot Screen. Administration of the tool requires that each foot be observed, assessed, palpated, and scored based on distinct parameters: skin, nails, deformities, footwear, temperature, range of motion, sensation, pulses, dependent rubor, and erythema. Each parameter has several criteria linked to a score that must be selected based on foot assessment findings. The scores of each criteria are combined, resulting in an overall composite score ranging from 0 to 23 for each foot; the higher the score, the more frequent the screening recommended. The screening is intended to provide a guide for assessment frequency, not recommended treatment. The highest score from either foot determines the recommended reassessment intervals: yearly screening (score 0–5); biannual screening (score 6–12); monthly screening (score 12–17); and weekly screening (score 18–23), along with the recommendation of a specialist referral. Although currently only available in English, the tool’s four interview questions pertaining to the sensation parameter — burning, tingling, numbness, and crawling sensations — were translated into French by the research group and cross-translated back to English for validation. Due to resource restrictions, no further language validation process occurred. At the time of writing this manuscript, a newer version of the tool was released and translation of the tool into French had begun.

Procedure. Current practice at SVH requires foot assessment for all patients at admission and regularly thereafter by a registered nurse or registered practical nurse. No standardized time frame or tool for reassessment currently exists. Normally, front-line nursing staff notify an APN if further assessment is required for patients either with a foot ulcer or believed to be at risk of developing a foot ulcer.

Three APNs who have experience in wound care and diabetic foot assessment served as assessors. Education on the use of the tool was provided to the assessors through a face-to-face education session from an experienced healthcare professional with expertise on foot assessments and knowledge and experience with the instrument. Education focused on clarification of the tool’s domains, assessment procedures, and the completion of study documentation.

Persons selected to participate from across the facility were randomly divided into three groups, assigned an identification code, and allocated a primary assessor. The three primary assessors completed the initial screen within a 30-day period, dividing the participants as follows: assessor A = 12, assessor B = 12, and assessor C = 11. At the completion of each assessment, the assessor calculated the time it took to complete the screening process, completed the tool’s evaluation questionnaire, and documented all findings in the medical record. The primary assessor subsequently updated the password-protected schedule, indicating the initial assessment was completed. This resulted in initiating the 72-hour time frame for the second assessment to be completed by a second assessor, independent of the first. In total, each participant received two assessments within 72 hours by two separate assessors. This time period was believed to be short enough for little to no change to have had occurred on the foot since the initial screening in the CCC setting. No communication between the assessors regarding the screening assessments and the use of the tool occurred.

The amount of time to administer the screening was calculated for each patient’s assessment using the formula: Completion Time (the moment the assessor completed the calculation for the total composite score of the tool) minus the Start Time (moment when the exposed foot was ready to be assessed) minus the Number of Interrupted Minutes (lost minutes during the screening process due to toileting, receiving a phone call, nursing care or visitor) = Total Administration Time in Minutes.

Assessors’ expert opinion on the content of the screening tool and its application in the study setting were documented on the tool’s evaluation questionnaire at the time of each assessment. Assessors were asked YES/NO questions regarding the screening tool’s design, ease of understanding, mutual exclusivity of responses, and whether all parameters of a foot assessment had been covered. General instructions were assessed for level of
helpfulness (YES/NO). Space also was provided for assessors to provide comments on each domain and general comments on the usefulness of the tool.

Determining sample size. Three APNs who had knowledge in wound care and diabetes and were available at the time of the study were chosen as the assessors to administer the tool and complete the evaluation form on the tool’s ease of use and content applicability to CCC. Experts typically chosen to review the content of potential tools are selected for their diversity and ability to review several versions and make refinements as required.22

All three assessors were used to evaluate the inter-rater reliability of the tool. Based on three raters, $H_1 < 0.60$ (the minimum value considered acceptable), versus $H_2 > 0.60$, with alpha level of 0.05 and beta of 0.20, and an expectation that the population value of reliability will be 0.80, a minimum of 35 participants was required.23

Statistical analysis. Descriptive statistics were used to report the time of completion and the feedback provided by the assessors about the tool’s content and general instruction. All qualitative comments were tabulated and grouped into themes by the expert panel. Inter-rater reliability was described using the Intraclass Correlation Coefficient (ICC) and 95% confidence interval (CI)24, the highest possible correlation being 1.0.24

Results

Thirty-five patients (15 [43%] women and 20 [57%] men, mean age 66.8 ± 13.8 years) participated in the study. Amputations (lower limb amputation of one limb) had occurred in six of the 35 participants (17%) before the onset of the study and ESRD in six out of 35 participants (17%). Seventy in low’s 60-second Diabetic Foot Screening assessments were completed over a 30-day period by three assessors on all participants. The mean time to complete a patient assessment was 7 minutes (range 2 to 21 minutes); 39% of assessments required between 6 and 7 minutes to complete. The mean time between assessments was 15 hours (range 0.2 to 66 hours). The ICC measuring inter-rater reliability was 0.608 (95% CI 0.349 to 0.781), which is relatively low.

Results from the ease-of-use and content evaluation indicate all assessors found the tool’s content terms to be easily understandable and the tool itself “easy to neutral” to use in 90% of their completed assessments. However, all three assessors’ comments indicated the instructions provided lacked important content needed to complete an accurate assessment in the CCC population (see Table 1).

Content analysis. Content analysis of the second portion of the assessor’s comments and the tool’s application in CCC resulted in the emergence of four primary themes: 1) significance of comorbidities, 2) ability to complete the assessment, 3) clarity of instructions, and 4) recommended interval screening times.

Significance of comorbidities. The assessors all commented on the importance of considering comorbidities when screening the diabetic foot. The inpatient population of CCC often lives with comorbidities affecting muscular and/or neurological systems, which in turn cause partial or complete loss of sensation or movement of one or both lower limbs. For the participants in this study, this primarily included quadriplegia, paraplegia, multiple sclerosis, and hemiplegia secondary to stroke. When allocating scores assessing sensation, range of motion, and foot deformities, all assessors questioned whether the impairments scored in these areas accurately reflected changes in the foot secondary to diabetes, because they are also the result of coexisting comorbidities. The items in these categories affected the overall scores, and in some circumstances the assessors felt this resulted in overestimating the recommended frequency of future assessments. The addition of a section for comments to capture such information was recommended. Assessors also indicated that for study patients, the scoring of the tool did not capture comorbidities known to increase the risk for amputations to the lower limb, such as ESRD or a current infected foot ulcer at the time of assessment. As a result, in these situations, the assessors found the tool underestimated the recommended interval screening time for such patients.

Ability to complete assessment. Key factors that interfered with the assessors’ ability to complete assessment were identified. Immobility was a primary limitation in the assessment of dependent rubor in 46 of the 70 (66%) assessments. To resolve this problem, the term dependent rubor was occasionally described to the patient in laymen’s terms, and a score was allocated based on how the patient responded to the question. Inability to raise the patient’s legs high enough to test for pallor also was identified as a limitation. Foot dressings covering all or part of the foot that could not be readily removed may have impaired the assessors’ ability to assess the patient’s foot, pedal pulses, sensations using monofilament testing, and erythema. In the event of an amputation of the metatarsal heads, the “nail” section of the screen tool was omitted, and the monofilament testing section was not completed, resulting in a score that could not be accurately calculated for the affected limb.

Clarity of instructions. All assessors noted instructions were reasonably clear; however, clarification consistently was needed concerning the general instructions and the descriptions of the scores for the specific parameters. The instructions did not guide the assessors when they encountered limitations already noted regarding ability to complete assessment, and clinical judgment was implemented to assign a score to the parameter in question. For example, if the assessor was unable to ask or test a patient for dependent rubor, a score of 0 was given. Although foot
dressings covering all or part of the foot impaired the assessors’ ability to assess the patient’s foot, pedal pulses, sensations using monofilament testing, and/or erythema, a score still was allocated based on that assessment. Assessors commented that specific detailed instructions differentiating the scores 0 and 1 for skin and nails would have been beneficial. In addition, clarification of the definition of deformity is needed, and the inclusion or exclusion of foot deformities unrelated to diabetes (foot drop, gross edema) provided in the descriptions and scores.

Recommended intervals screening times. Screening time intervals based on the composite score from the initial assessments are reported in Table 2. Fifty-seven percent of patients had composite scores ranging from six to 12, suggesting further screening every 6 months. All assessors agreed that for some of these patients, 6 months was too long a reassessment interval; however, monthly assessments would have been too frequent. All assessors suggested that an interim period of 3 months would be beneficial.

**Discussion**

Inlow’s 60-second Diabetic Foot Screen has potential application in the CCC setting. However, revisions to the tool parameters and instruction sheet would be beneficial to better reflect the screening needs of this population and reduce the need for clinical judgment and interpretation.

When evaluating the diabetic foot, the care process should include a thorough medical history that includes comorbidities. ESRD is an example of a comorbidity that increases the risk to developing a diabetic foot ulcer, which in turn increases the risk for lower extremity amputation. A cross-sectional prevalence study by Hill et al of 60 PWD with ESRD and 72 PWD without ESRD identified a 25% rate of foot problems in patients with diabetes receiving renal replacement therapy compared with a 10% rate for nondiabetic patients. This has been further discussed by Richbourg, whose review of the literature linked PWD with foot complications and indicated that routine foot screening results in fewer lower extremity complications and amputations. MacDonald’s discussion paper recommended that any tool used for assessment should help the assessor recognize problems to trigger referrals appropriately while indicating the urgency. Modifications to the tool that better reflect the importance of comorbidities and immobility in the CCC population, along with clearer instructions on how to deal
with variation when administering the tool, need to be considered. The addition of a 3-month screening interval category also would be beneficial and lessen the gap between screening recommendations that currently exists.

A history of previous amputation is a strong predictor for the development of foot ulcers or foot complications.29,30 The tool allowed the assessors to complete a comprehensive foot assessment on patients at risk. However, the Inlow screen does not include previous amputation of one lower limb as risk factor, and previous amputation does not impact the overall score. Instructions as to whether the stump should be assessed were unclear, because some of the parameters did not apply, and it was not clear whether an additional score of two (indicating deformity) when assessing the remaining limb should be added. Future consideration of the clinical importance of a previous lower limb amputation is needed. Revisions also may include additional scoring for foot assessments that reveal conditions such as pedal edema, which is an important finding as a predictor of ulceration and an important component of the foot examination.25

Inter-rater reliability, which was lower than expected, reduced the assessors’ confidence in the ability of the current tool to produce similar results across different users. The complexity of the population and the variation in assessors’ decision-making concerning the interpretation of assessment parameters may have been factors. Some assessors also had more patient history information than others if they had been previously consulted on the case. This may have affected their overall score results and may be seen as a limitation. Recent work by Murphy et al31 on the Inlow tool using a prospective, observational design in the acute and long-term care setting found strong inter-(long-term care 0.92 [0.86–0.96] and dialysis 0.83 [0.65–0.92]) and intra-rater reliability in a sample of 69 patients and residents in acute and long-term care across two assessors; intra-reliability was assessed after only a 3-hour interval between the initial and second assessment made by the same assessor, which could have introduced recall bias into the completion of the tool. The study also investigated the predictive validity over a 5-month period on 64 participants. Two significant events occurred — one ulcer and one amputation — both of which had initial high-risk composite scores of 17 to 20.31 Further work on the predictive value of the tool in the CCC environment is required.

Inclusion of intra-rater reliability in the research design of the current study was considered but not included, primarily due to the assessors knowing the participants quite well. Researchers believed that to reduce the effect of recall bias, the second assessment would have to be done at least 4 to 5 days post initial assessment, which could potentially be long enough to see a change in the participant’s condition.

The tool completion time was >60 seconds in this study population. Although each assessor made every attempt to keep track of interruption time in order to determine the actual time required for the assessment, this proved difficult. Assessors often were required to answer questions and provide simple explanations pertaining to the assessment, such as explaining why the shoe was being examined and what was found. This slowed the assessment and resulted in variability in completion times. Talkative patients, education during the screening, and the increased time required when examining patients with cognitive impairment varied the results. Communication barriers related to language, or as a result of aphasia or cognitive impairment, required adapting to patients needs. Assessors often were required to speak very slowly, provide simple to understand instructions repeatedly, and wait for delayed or nonverbal responses such as eye blinking, all of which affected time to complete the assessment. These factors reflect the reality of completing a foot assessment in this population.

It must be recognized that initially the tool was developed for quick and easy use in a primary care setting. The intention of the exam was a minimum standard for any healthcare professional to use on a PWD yet to be identified as being

Table 2: Recommended screening intervals based on initial composite scores (n = 35)

<table>
<thead>
<tr>
<th>Recommended screening interval by score</th>
<th>0 – 5 Yearly</th>
<th>6–12 Every 6 months</th>
<th>13 – 17 Monthly</th>
<th>18–23 Weekly and specialist referral required</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assessors A (n=12)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial composite score</td>
<td>1 (8%)</td>
<td>5</td>
<td>3 (25%)</td>
<td></td>
</tr>
<tr>
<td><strong>Assessor B (n=12)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial composite scores</td>
<td>2 (17%)</td>
<td>2</td>
<td>2 (17%)</td>
<td></td>
</tr>
<tr>
<td><strong>Assessor C (n=11)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Initial composite scores</td>
<td>1 (9%)</td>
<td>4</td>
<td>5 (45%)</td>
<td>1 (9%)</td>
</tr>
</tbody>
</table>

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at risk for foot complications.\(^\text{20}\) An extensive literature search by Evan and Chance\(^\text{32}\) emphasized that foot assessments in PWD are important. Inlow’s 60-second Diabetic Foot Screen provides a comprehensive tool to help caregivers identify patients at risk for developing foot complications and prompting interventions with the additional benefit of providing documentation. Despite the fact that evidence suggests routine foot screening results in fewer lower limb complications, studies reviewed by Richbourg\(^\text{27}\) demonstrated a lack of documentation, suggesting the level of care could be improved. The Inlow Foot Screen potentially provides an easy, practical method of documenting foot examinations and recommendations; however, for patients with complex needs, the tool needs some refinement.

**Conclusion**

Inlow’s 60-second Diabetic Foot Screen in CCC has many benefits. It is a comprehensive, practical, economical screening method that could be used on all newly admitted patients with diabetes to provide a baseline assessment and guide further screening intervals. Revisions to the tool to ensure that comorbidities such as ESRD and amputations are reflected in the overall score would strengthen the tool’s application in this CCC setting. Modifications to the screening intervals to support more frequent screening of patients at risk of ulcer development are needed. Clearer instructions to assist the assessor would add to the ease and consistency of use. Further validation of the translation of the sensation questions is required. Following revision of the tool, additional testing in CCC would be warranted, along with further study in other healthcare settings and on the impact of patient outcomes.

**References**