TITLE: Screening and Risk Stratification for Diabetic Foot Ulcers: A Review of Clinical Effectiveness, Cost-effectiveness, and Guidelines

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CONTEXT AND POLICY ISSUES

The rising prevalence of diabetes mellitus (DM) and associated complications represent a global public health care problem and financial burden.[1,2] The estimated prevalence of DM in Canada was 6.8% (2.4 million) in 2009, a 230% increase from estimates in 1998. Increasing prevalence and associated costs to Canada's publically funded healthcare system is projected to continue. As of 2010 the estimated economic burden of DM and its complications in Canada was $12.2 billion.[3] The most common chronic complication of DM is diabetic foot ulcers (DFUs), with a prevalence of four to ten percent among DM patients.[1,4] Several factors predispose DM patients to DFUs including long duration of diabetes, trauma, infection, poor glycemic control, improper footwear, old age, smoking, low socioeconomic status, and psychological factors, however neuropathy and peripheral vascular disease (PVD) may be the most significant causative factors.[1] The presentation of DFUs varies considerably with underlying pathogenesis and with the presence or absence of infection and ischemia. Along with serious complications including wound infection, osteomyelitis, and cellulitis, DFU patients also suffer from complications associated with DM including nephropathy, retinopathy, ischemic heart disease, and cerebrovascular disease. Furthermore, the potentially preventable endpoint of untreated DFU is amputation, which is itself associated with immense social and psychological consequences, in addition to significant morbidity, mortality and financial impact on healthcare.[1,2]

Assessment of risk factors such as neuropathy and PVD in a primary care setting can be used to stratify DM patients based on risk of developing DFU and can inform suitable preventive measures based on risk stratification. Risk stratification is one component of a screening program. A screening program also includes the deployment of interventions to effectively prevent DFU, such as patient education and referral to secondary care. By focusing preventive interventions based on risk, a significant reduction in DFU occurrence and related complications might be expected. The inference that DFU and complications can be prevented with a screening program because risk stratification is predictive and effective preventative interventions exist requires evidence. Additionally, screening and risk stratification of the large

DM patient population requires considerable resources that might be more effectively utilized for DFU treatment.[5]

The purpose of this report is to retrieve and review existing evidence of clinical and cost-effectiveness of screening programs in primary care for DFUs. Additionally this report aims to retrieve and review the existing primary care guidelines for DFU prevention strategies.

RESEARCH QUESTIONS

1. What is the clinical effectiveness of screening programs for preventing foot ulcerations in adults with diabetes?

2. What is the cost-effectiveness of screening programs for preventing foot ulcerations in adults with diabetes?

3. What are the evidence-based guidelines on screening and risk stratification of foot ulcers in adults with diabetes?

KEY FINDINGS

This report presents evidence that support the efficacy of screening programs to reduce diabetic foot ulcer occurrence and related complications in high-risk populations. The identified evidence is of uncertain applicability to a screening program of a general diabetic population in a primary care setting. The identified guidelines unanimously recommend assessment of diabetic patients for diabetic foot ulcer risk factors. While the recommendations are consistent, the strength of similar recommendations varies significantly between the identified guidelines. Five of the eight included guidelines, two of which are Canadian, recommend secondary care referral for diabetic patients identified as high-risk for foot ulceration. There was no cost-effectiveness studies identified and cost and benefit analysis of relevant guideline implementation was lacking.

METHODS

Literature Search Strategy

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2014 August, Issue 8), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were used to limit retrieval by publication type for research questions 1 and 2. A methodological filter was applied to limit retrieval to guidelines for question 3. The search was limited to English language documents published between Jan 1, 2009 and August 22, 2014.

Selection Criteria and Methods

One reviewer screened the titles and abstracts of the retrieved publications. Full-text publications of potentially relevant articles were retrieved and evaluated for inclusion, according to selection criteria presented in Table 1.

Table 1: Selection Criteria	
Population	Adults (18+) with diabetes without a current DFU (with or without prior DFU) in a primary care setting.
Intervention	Primary screening or risk stratification scheme aimed at preventing DFU. Must be applicable to all adults with diabetes, in rural/remote settings.
Comparator	Standard medical care and surveillance, no comprehensive foot screening program.
Outcomes	Prevalence or recurrence of DFU, lower limb amputations. Cost and cost-effectiveness of screening program. Guidelines.
Study Designs	Health Technology Assessments (HTA)/ Systematic review (SR)/Meta-analysis (MA); Randomized controlled trials (RCTs); non-randomized studies; Economic evaluations; and Evidence-based Guidelines

Exclusion Criteria

Studies were excluded if they did not meet the selection criteria, were duplicate publications, included only one metric for risk stratification, were not generally applicable to adults with diabetes including in rural or remote settings, or were published prior to 2009. Studies evaluating screening programs by specialists in diabetes clinics were also excluded, as the focus was on primary care settings. SRs were excluded if a more recently published SR included the same studies.

Critical Appraisal of Individual Studies

The quality of the included systematic reviews (SR) were assessed using the Assessing the Methodological Quality of Systematic Reviews (AMSTAR) tool.[6] Critical appraisal of the included guidelines used the Appraisal of Guidelines for Research and Evaluation (AGREE II) instrument.[7] For all critical assessments strengths and limitations were described narratively instead of assigning a numerical score.

SUMMARY OF EVIDENCE

Quantity of Research Available

Initially, 233 citations were identified after the literature search was conducted as outlined in the literature search strategy. These titles and abstracts were further screened for potential relevance and 19 articles were selected for full-text retrieval. The full-text articles were examined along with 13 articles identified and retrieved from grey literature. After screening the 32 articles, nine met the inclusion criteria. Of the 23 excluded articles, two examined an irrelevant population, 13 examined an irrelevant intervention, three were narrative reviews, two were SRs that had trials included in a subsequent SR, one was published in a language other than English, and two examined an irrelevant outcome. After selection one SR[5] and eight sets of guidelines met the selection criteria[3,8-14] and were included in this report. No cost-effectiveness studies of screening programs for DFU prevention were identified. A Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flowchart describes the selection

procedure of the studies included in this review (Appendix 1).[15] A summary of the available evidence included in the identified SR and guidelines is outlined in Appendix 2.

Summary of Study Characteristics

Clinical Effectiveness

Characteristics of the included SR are summarized in Appendix 3, Table A3.1.

Population

The identified SR, published in 2013, focused on examining the evidence to support screening programs for the prevention of lower extremity complications in diabetic patients. The SR included two RCTs,[16,17] and four historically controlled studies.[18-21] One RCT examined a diabetes screening and protection program in a secondary care setting where 13% percent were identified as high-risk for DFU based upon neuropathy, PVD, ankle brachial pressure index (ABPI), foot pressure, and foot radiographs.[16] No other baseline patient demographic data was reported.[16] The other RCT examined a population where 70% were identified as high-risk for DFU based upon peripheral neuropathy, history, and PVD assessments. These patients were from a renal dialysis unit and averaged 21.25 years of diagnosed diabetes.[17] The historically controlled studies examined a population before and after implementation of a screening program.[18-21] The included studies ranged in size from 83 to 2,738 DM patients. One study examined screening program efficacy in a population of aboriginal North Americans,[21] and two studies included patients with a current DFU.[19,21] This SR examines the evidence and its implications for screening in a primary care setting; however, three out of the six studies included in the SR, including both RCTs, take place outside of a primary care setting.[16,17,19]

Interventions and Comparators

The SR was not focused on the evidence for a method of risk stratification, or evidence for particular interventions used for DFU prevention, but on the evidence for the effectiveness of a screening program to reduce DFU and related complications. Both RCTs in the SR compared a population that was stratified by risk factors into high-risk and low-risk groups, to a control population that was not assessed for DFU risk. One RCT used assessments of PVD, neuropathy, ABPI, foot pressure, and foot radiographs, while the other used patient history, peripheral neuropathy and PVD for determining risk category. Details on the criteria for risk categories based on the assessments were not reported in the SR.[5] The high-risk group in both studies was given preventive interventions. In one RCT the high-risk group was assigned to a diabetes foot clinic review for chiropody, hygiene maintenance, given support hosiery, protective shoes, and education. The low-risk and control groups in this RCT were given no special care.[5] The high-risk group in the other RCT was given weekly to monthly foot assessments, education, and non-foot-related diabetes interventions. The low-risk group in this study was given three monthly assessments and the control group was given no special care.[5]

The historically controlled studies compared standard care before implementation of a screening program, to a variety of preventive interventions after implementation of a screening program. Preventative interventions were prescribed to patients based upon the determined risk category. Foot assessments evaluated history,[18-21] neuropathy,[18-21] PVD,[18-20] and peak foot pressure[19] to determine risk category. Details on the criteria for risk categories based upon the assessments were not reported in the SR.[5] Interventions in these studies included referral and

treatment at the discretion of physical therapists and podiatrists,[18,19,21] structured follow-up,[21] protective footwear,[19-21] patient education,[19,20] and medical management of PVD.[19] Two of these 'before and after' studies also assigned different protective footwear based upon DFU risk stratification.[19,20]

Outcomes

Outcomes reported in the included SR were ulceration,[16,20] minor amputation,[16,18,21] major amputation,[16,18,21] total amputation,[16-21] hospitalization,[17-20] and death.[17,20] Outcomes from different studies were not pooled because of heterogeneity of study design, subject, setting, and screening methodology.[5]

Cost Effectiveness

No cost-effectiveness studies on screening programs for DFU prevention were identified.

Guidelines and Recommendations

Characteristics of the included guidelines are tabulated and summarized in Appendix 3, Table A3.2.

Origin of Guidelines

Two guidelines are from Canada, one published in 2013 from the Canadian Diabetes Association (CDA),[3] and one published in 2011 from the Registered Nurses Association of Ontario (RNAO).[13] The American Diabetes Association (ADA) published guidelines in 2012 which are included in this report.[8] The most recent guidelines, published in 2014, are from the UK's North West Podiatry Services (NWPS).[11] The Scottish Intercollegiate Guidelines Network (SIGN) published relevant guidelines in 2011.[14] Two sets of guidelines published in 2011 are from Australia, one from the National Health and Medical Research Council (NHMRC),[12] and one from the University of Adelaide.[10] One set of guidelines was from the Basque Office for Health Technology Assessment (BOHTA) in Madrid, Spain and published in English in 2012.[9]

Interventions

All of the guidelines have recommendations for assessing risk of DFU in DM patients.[3,8-14] Five included guidelines have recommendations that include a recommended frequency of risk assessment.[3,8,9,11,13] Two guidelines provide criteria for risk groups.[9,12] One guideline has recommendations for risk stratification of two indigenous populations of DM patients in Australia.[12] Five guidelines have recommended interventions for those patients identified as high-risk.[3,8,10,11,13]

Grading of recommendations and levels of evidence

Both guidelines originating in Australia use the same grading scheme of the NHMRC. Both have recommendations graded A to D and expert opinion (EO), and levels of evidence assigned from I to IV.[10,12] Two guidelines, one from SIGN and one from BOHTA, use the grading system from SIGN where recommendations are graded A to D and EO, and levels of evidence assigned from 1++ to 4.[9,14] The guidelines published from the CDA grade recommendations from A to D, based on supporting levels of evidence from 1 to 4.[3] Guidelines from the RNAO do not grade

recommendations but assign a level of evidence of Ia to IV that supports the recommendations.[13] Guidelines from the NWPS grade recommendations from A to D and DS for evidence from diagnostic studies, and assign levels of evidence from Ia to IV and DS.[11] The ADA do not grade recommendations, instead assigning a level of evidence that supports each recommendation from A to C and E for expert opinion.[8]

The grading systems used in the included guidelines to assign levels of evidence and grades of recommendations are summarized in greater detail in Appendix 4.

Summary of Critical Appraisal

The included SR, Ozdemir et al. (2013), has a focused objective examining the clinical evidence to support population-based screening programs.[5] While studies that examined the evidence for population-based screening programs outside of a primary care setting were included, the SR discusses the relevancy of this evidence to primary care based screening. The literature search covered a period of 42 years in two electronic databases, but was limited to English language articles and did not include mention of a grey literature search. Studies that did not report clinical efficacy outcomes such as amputation and ulceration were excluded. While a PRISMA flow diagram was provided outlining the selection process there was no references to excluded studies, or examination of publication bias. The SR tabulated available study characteristics and patient demographic data and also included a statement of no conflict of interest (COI). Heterogeneity was not statistically examined but it was stated that the studies were too heterogeneous to combine the trial data. Study quality was assessed quantitatively using the Consolidated Standards of Reporting Trials (CONSORT) checklist for the RCTs, and the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist for the historically controlled studies. These quality assessments were converted to a percentage. Some quality relevant information was also discussed. While informative to the overall study quality, a numerical quality score without a complete narrative assessment makes identifying specific strengths and weaknesses of the evidence difficult.[5] A summary of the critical appraisal of the included SR, using the AMSTAR tool,[6] is available in Appendix 5, Table A5.1.

The clinical efficacy evidence for a DFU screening program identified by the SR consisted of two RCTs and four historically controlled trials. The RCTs were evaluated as having a CONSORT score of 65% for McCabe et al. (1998)[16] and 57% for McMurray et al., 2002.[17] The authors of the SR also state that the RCT by McCabe et al. (1998)[16] did not provide any information concerning baseline characteristics of the populations, the index group was subdivided and reallocated multiple times on the basis of neuropathy and PVD, and the allocation protocol was breached.[5] The end points, blinding, and statistical methods were also unclear.[16,22] The SR provided in the guidelines from the University of Adelaide stated that this RCT had a moderate risk of bias and was of average quality.[10] The other RCT included in this SR, McMurray et al. (2002),[17] had a frequency of follow-up with a large proportion of DM patients that would be difficult to maintain outside the setting of a trial.[5] This RCT examined a population that had a much higher percentage of high-risk patients than the general diabetes population limiting the generalizability of the findings.[5] The STROBE percentages of the historically controlled studies, as determined by the SR, were 77% for Rith-Najarian et al. (1998),[21] 71% for Lavery et al. (2005),[19] 74% for Patout et al. (2000),[20] and 63% for Anchini et al. (2007).[18]

This report identified eight sets of guidelines with recommendations for risk assessment. Two guidelines based recommendations for assessment of risk on evidence that risk assessment

was predictive of DFU occurrence,[11,14] while the remaining guidelines did not describe evidence linking risk assessment to development of an ulcer. Two guidelines, from the RNAO and from the ADA, did not clearly link the recommendations to the evidence used to support them.[8,13] The remaining four guidelines cited evidence of the clinical efficacy of screening programs to support the recommendations.[3,9,10,12] Two sets of guidelines used previously published recommendations and therefore are dependent on the rigour of development of those recommendations, which was not described.[11,13] Four of the included guidelines stated a clear scope and purpose.[9,10,12,14] Stakeholder involvement in the development of the guidelines was comprehensive in four guidelines,[9,12-14] while the contributions to one set of guidelines was predominantly from podiatrists.[11] The remainder of the guidelines do not mention involvement of stakeholders in guideline development.[3,8,10]

Two guidelines had almost no description of guideline development methodology and it was unclear if a methodology description was available elsewhere.[8,11] Three guidelines provided details of a comprehensive literature search and selection,[3,9,10] however one of these guidelines had no specific inclusion/exclusion criteria or specific search queries.[3] A brief search methodology, without inclusion of used search terms, was provided by SIGN,[14] while guidelines from the NHMRC had literature search methodology described in a separate source.[12] Guidelines from the RNAO provided a literature search methodology however only previously published guidelines were included.[13] One set of guidelines, from the University of Adelaide, provided a flow diagram for literature selection.[10] The strengths and limitations of evidence supporting recommendations was best examined in three guidelines that provided a quality assessment of the supporting evidence.[9,10,12] The guidelines from ADA refer to many previously published guidelines, placing their independently formulated recommendations in context with other guideline development group recommendations.[8] The NWPS guidelines provide a source for the recommendations, as formulated by another guideline development group,[11] while the remaining guidelines all provide graded recommendations that are explicitly linked to the evidence level.[3,9,10,12-14] Four of those guidelines also made the primary source for that evidence level clear.[3,9,10,12,14] An external review by experts was clearly done in four guidelines,[3,9,11,14] and three of those also provided at least some mention of a method for updating the guidelines.[3,9,14]

All of the included guidelines made the recommendations clearly identifiable, however guidelines from the NWPS had recommendations that were repetitive and slightly ambiguous.[11] Two guidelines were from Canada and thus may have recommendations more readily applicable to a Canadian healthcare setting.[3,13] Most of the guidelines do not specify the setting in which the recommendations are to be followed,[3,9,13,14] however two guidelines recommend trained personnel conduct risk assessment,[11,12] one guideline recommends that risk assessment is performed by a specialist,[10] and one suggests a clinician conduct assessment.[8] The guidelines from NWPS and RNAO include some assessment tools for primary care givers to aid in implementation of the guidelines.[11,13] Five guidelines also provided some level of guidance on guideline implementation and also provided at least some mention of resource implications of implementation.[9,10,12-14] Suggestions for further research were included in three guidelines.[9,12,14] Guidelines from BOHTA provided information on potential COIs,[9] while CDA guidelines provided details on the methods used to avoid potential COIs.[3] Three guidelines did not mention potential COIs,[10,11,13] while three others state that information regarding potential COIs is available from other sources.[8,12,14] Other potentially important guideline limitations include a focus on type I diabetes in the BOHTA guidelines,[9] and potentially outdated information in the RNAO guidelines as the scope of recent updates was unclear.[13] A summary of the critical appraisal of the identified guidelines is available in Appendix 5, Table A5.4.

Summary of Findings

Major findings and authors conclusions of the included SR are summarized in Appendix 6, Table A6.1.

The identified SR included the results of two RCTs and four historically controlled studies. All of these studies found statistically significant improvements in clinical effectiveness outcomes for patient groups receiving DFU risk stratification and preventive interventions based upon risk assessment.[5] The highest-quality RCT, as determined by the SR, found that there were statistically significant improvements in major amputation and total amputation in the group receiving risk stratified intervention.[5] In this study, McCabe et al. (1998),[16] the assessments placed 13% of the index group in a high-risk group. There was no statistically significant decrease in ulcerations or in minor amputations in the group receiving DFU risk stratification during the two year follow-up.[5] The other RCT included in the SR, McMurray et al. (2002),[17] found a statistically significant decrease in total amputations and foot-related hospitalizations in the group receiving DFU risk stratified interventions. No statistically significant differences were identified in the number of deaths during the 1 year follow-up. In this study 70% of the index group from a renal dialysis unit was stratified as high-risk. It has been estimated that 10% of the primary care DM population are high-risk.[5] In the historically controlled studies a statistically significant reduction was observed in all four studies for total amputation.[18-21] A statistically significant reduction was found in all three studies examining hospitalization,[18-20] in both studies examining inpatient length of stay,[19,20] in the one study examining admission to a skilled nursing facility,[19] and in one of two studies examining major amputation.[18] One historically controlled study observed there was no statistically significant difference in major amputation between groups,[21] and another did not observe a statistically significant difference in the number of deaths between groups.[20] The SR also discussed the McCabe et al. (1998)[16] demonstration of cost-effectiveness for the combined screening and care package for high-risk patients compared with standard care. The cost per patient for this secondary care-based program was estimated at £100 in 1995. Cost-effectiveness was out of the scope of the SR and was not examined systematically; however a brief review with additional citations is presented. Based on the applicability and quality of the identified studies the authors conclude that the evidence to support the introduction of comprehensive diabetes foot-screening programs in primary care is weak and that further studies are required to demonstrate efficacy and cost-effectiveness.[5]

Relevant recommendations of the included guidelines are in Appendix 6, Table 6.2. The levels of evidence and grades of recommendations referenced in the following text are described in Appendix 4.

There was a consensus in the identified guidelines that DM patients should be examined for DFU risk factors.[3,8-14] While this recommendation was quite similar between the guidelines it was graded A from the NWPS,[11] graded C from the CDA,[3] assigned a level of evidence B from the ADA,[8] graded A from BOTHA,[9] graded C from the NHMRC and the University of Adelaide,[10,12] assigned a level of evidence Ib from the RNAO,[13] and graded B from SIGN.[14] Six of the included guidelines provided evidence-based recommendations that included a statement about the recommended frequency of DFU risk assessment. Two guidelines recommended a risk assessment at least annually for DM patients one from the NWPS graded A and one from the ADA graded a level B.[8,11] Four guidelines, including both Canadian guidelines, suggested a frequency of foot inspection based upon risk assessment. These recommendations were all graded as based upon expert opinion or evidence from non-analytic studies.[3,9,12,13] Two guidelines did not provide a recommendation on the frequency of risk assessment.[10,14] Two

guidelines lack evidence-based recommendations for risk-stratified DFU prevention interventions.[9,14] Five guidelines recommended referral to secondary care for patients identified as high-risk for developing DFU.[3,8,10,11,13] This recommendation was graded A by the NWPS,[11] grade C by the CDA,[3] grade C by the University of Adelaide,[10] given a level of evidence B by the ADA,[8] and a level of evidence IV by the RNAO.[13] The CDA also recommended providing education and professionally fitted footwear to patients at high-risk of DFU, in addition to specialist foot care if complications occur. This recommendation was graded C based upon non-RCT or cohort studies.[3] SIGN presented a 'good practice point' that suggested foot assessment results be entered into an online screening tool (SCI-DC) that provides a recommended risk stratified management plan.[14] Two guidelines provided criteria for risk stratification. One from the NHMRC that included low, intermediate, and high risk categories,[12] and one from BOHTA that included low, increased, high, and ulcerated categories.[9] The criteria for these categories was consistent between guidelines in that low-risk patients had no risk factors, the intermediate category patients had one of PVD or neuropathy, and the high-risk patients had both PVD and neuropathy.[9,12] Although five of the eight guidelines mentioned the resource implications of guideline implementation,[9,10,12-14] only one set of guidelines mentioned the implications for implementing guidelines relevant to DFU screening. Guidelines from BOHTA stated that while the recommended risk stratification is feasible, the required time for training and consultation increases the difficulty of implementation.[9]

Limitations

There was a lack of evidence supporting the effectiveness of DFU screening programs for a general DM population in a primary care setting. The identified SR stated that the applicability of the identified evidence to a general DM population in a primary care setting was questionable.[5] There was no data in the identified SR examining the predictive accuracy of the risk-assessment used in the investigated DFU screening programs. The clinical efficacy and cost-effectiveness of a DFU screening program is likely dependent on accurate risk stratification. No cost-effectiveness studies were identified. While the identified guidelines all provided evidence-based recommendations for DFU risk stratification the strength of these recommendations varied significantly. Confidence in the strength of the evidence used to support DFU screening guidelines was therefore limited. One set of guidelines was focused on DM type 1 which may limit the applicability to a general diabetic population.[9] The guidelines do not provide sufficient analysis of the costs and benefits of implementing DFU risk assessment and screening recommendations for the general DM population. Recommendations often included referral to specialist services for patients identified as at high-risk for DFU that may not be available in some healthcare settings.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING

All identified evidence from one SR supported DFU screening programs for improved clinical outcomes. The recent SR included in this report found evidence from two RCTs demonstrating improved clinical outcomes in DM patient populations where DFU preventive interventions were implemented based upon stratified risk. This evidence had methodological limitations and the applicability to a general DM population in a primary care setting was unclear.

No evidence was identified for the cost-effectiveness of DFU screening programs. The included SR contained a short narrative review of the cost effectiveness of screening programs and concluded that further research is required.[5] One set of guidelines also stated that while the implementation of DFU screening programs are feasible there are considerable associated

resource, training, and cost implications for healthcare systems.[9] The cost-effectiveness of screening programs for the prevention of diabetic foot ulcers remains unclear.

Guidelines containing relevant recommendations identified in this report were unanimous that DM patients should be assessed for DFU risk factors, although the strength of the recommendations varied considerably. For patients stratified as low-risk of developing DFU, six of the eight identified guidelines recommended at least annual assessments for DFU risk factors. Two Canadian guidelines were identified that supported at least annual risk assessment and preventive interventions based upon stratified risk.

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LIST OF ABBREVIATIONS

ADA	American Diabetes Association
AGREE	Appraisal of Guidelines for Research and Evaluation
AMSTAR	Assessing the Methodological Quality of Systematic Reviews
BOHTA	Basque Office for Health Technology Assessment
CDA	Canadian Diabetes Association
COI	conflict of interest
CONSORT	Consolidated Standards of Reporting Trials
CRD	Centre for Reviews and Dissemination
DFU	diabetic foot ulcer
DM	diabetes mellitus
DPY	diabetic person years
EO	expert opinion
FU	follow-up
HTA	health technology assessment
LOPS	loss of protective sensation
MA	meta-analysis
NHMRC	National Health and Medical Research Council
NICE	National Institute for Health and Care Excellence
NWPS	North West Podiatry Services
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PVD	peripheral vascular disease
RCT	randomized controlled trial
RNAO	Registered Nurses Association of Ontario
SIGN	Scottish Intercollegiate Guidelines Network
SR	systematic review
SSD	statistically significant difference
STROBE	Strengthening the Reporting of Observational Studies in Epidemiology
UK	United Kingdom

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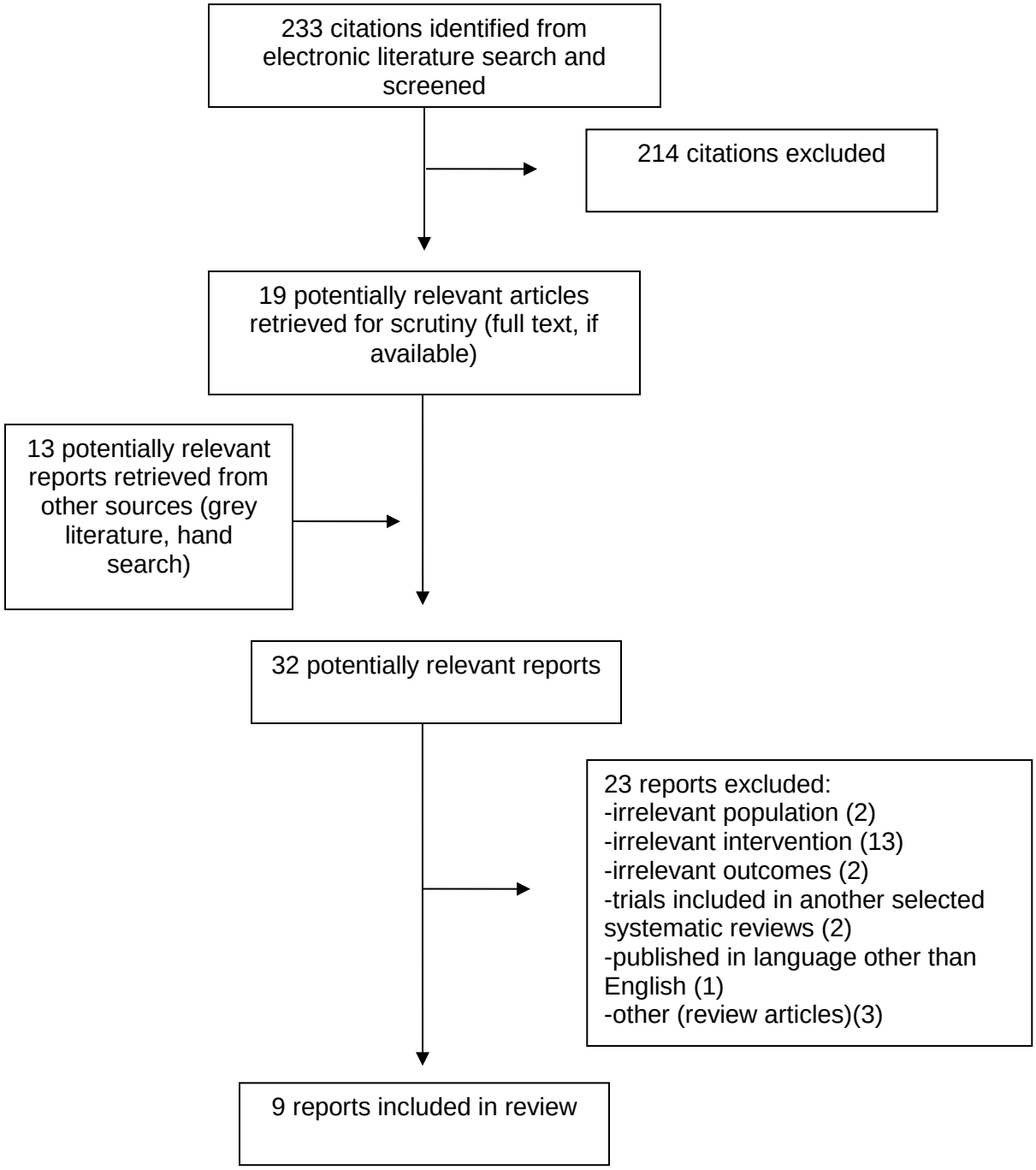
APPENDIX 1: Selection of Included Studies



APPENDIX 2: SUMMARY OF INCLUDED STUDIES

Table A2.1: Trials/Guidelines Included in Identified Studies

		Included Trials and Guidelines											
		Feng et al., 2011[23]	Boulton et al., 2008[24]	Anchini et al., 2007[18]	Crawford et al., 2007[25]	Lavery et al., 2005[19]	Singh et al., 2005[26]	NICE 2004[27]	McMurray et al., 2002[17]	Abbot et al., 2002[28]	Patout et al., 2000[20]	McCabe et al., 1998[16]	Rith-Najarian et al., 1998[21]
SRs	Ozdemir et al., 2013[5]			X		X			X		X	X	X
	Arad et al., 2011[22]											X	
	Hunt et al., 2009[29]											X	
Guidelines	NWPS 2014[11]							X					
	CDA 2013[3]	X	X		X							X	
	ADA 2012[8]		X										
	BOTHA 2012[9]			X		X		X				X	
	NHMRC 2011[12]											X	
	University of Adelaide 2011[10]								X			X	
	RNAO 2011[13]											X	
	SIGN 2010[14]				X	X	X			X			

*not all identified SRs have been reviewed in this report, Arad et al., (2011) and Hunt et al., (2004) have been superseded by the more recent and comprehensive Ozdemir et al., (2013). All identified guidelines have been reviewed in this report.

ADA=American Diabetes Association; **BOHTA**=Basque Office for Health Technology Assessment; **CDA**=Canadian Diabetes Association; **NHMRC**=National Health and Medical Research Council; **NWPS**=North West Podiatry Services; **RNAO**=Registered Nurses Association of Ontario; **SIGN**=Scottish Intercollegiate Guidelines Network;

APPENDIX 3: SUMMARY OF STUDY CHARACTERISTICS

Table A3.1: Summary of Study Characteristics of Included SR

Study Design	Population (sample size of trials)	Intervention	Comparator(s)	Outcomes
Ozdemir et al., 2013[5]				
SR: DFU prevention (2 RCTs, 4 historically controlled trials)	DM patients (n = 83 to 2738)	Screening tests and interventions dependent upon stratified risk	Before stratification, or index group	• Ulceration • Minor amputation • Major amputation • Total amputation • Hospitalization • Death
DM=diabetes mellitus; **RCT**=randomized controlled trial; **SR**=systematic review				

Table A3.2: Summary of Study Characteristics of Included Guidelines

Origin, Publication Year	Interventions of Interest	Grading (See Appendix 4)	Target Users
NWPS 2014[11]			
North West Podiatry Services, Diabetes Clinical Effectiveness Group, UK, 2014	Risk assessment and appropriate intervention(s)	Used grades and levels of evidence from supporting reference. For relevant recommendation used scheme from NICE, 2004.[27] Levels of Evidence Ia - IV Recommendations Graded A - D	NHS Podiatrists, managers and commissioners
CDA 2013[3]			
Canadian Diabetes Association Clinical Practice Guidelines Expert Committee, Canada, 2013	Risk assessment and appropriate intervention(s)	Levels of Evidence 1A – 4 Recommendations Graded A - D	Healthcare professionals
ADA 2012[8]			
American Diabetes Association, Diabetes Care, USA, 2012	Risk Assessment and appropriate intervention(s)	Levels of Evidence A - E	NR
BOHTA 2012[9]			
BOHTA, Working Group of the Clinical Practice Guideline on Diabetes Mellitus Type 1, Madrid, Spain, 2012	Risk Assessment	Levels of Evidence Ia - IV Recommendations Graded A - D	Healthcare professionals, specialist care professionals, patients, families and caregivers
NHMRC 2011[12]			
National Health and Medical Research Council, Melbourne, Australia,	Risk Assessment and appropriate intervention(s)	Levels of Evidence I - IV Recommendations Graded A - D	Broad range of Health Professionals and Healthcare Workers in urban and rural/remote primary care and specialist foot

Origin, Publication Year	Interventions of Interest	Grading (See Appendix 4)	Target Users
2011			centers
University of Adelaide, 2011[10]			
School of Population Health and Clinical Practice, University of Adelaide, Australia, 2011	Diabetic foot screening program	Levels of Evidence I – IV Recommendations Graded A -D	NR
RNAO 2011[13]			
RNAO, Ontario Ministry of Health and Long-Term Care, Ontario, Canada, 2011	Risk Assessment and appropriate intervention(s)	Levels of Evidence Ia - IV	Nurses, other health care professionals, and administrators
SIGN 2010[14]			
National Health Service Quality Improvement Scotland, Scottish Intercollegiate Guidelines Network, Scotland, 2010	Risk Assessment	SIGN classification Levels of Evidence 1 – 4 Recommendation Grades A - D	All healthcare professionals involved in the care of people with diabetes Diabetic Patients Diabetic Caregivers

ADA=American Diabetes Association; **BOHTA**=Basque Office for Health Technology Assessment; **CDA**=Canadian Diabetes Association; **NHMRC**=National Health and Medical Research Council; **NR**=not reported; **NWPS**=North West Podiatry Services; **RNAO**=Registered Nurses Association of Ontario; **SIGN**=Scottish Intercollegiate Guidelines Network;

APPENDIX 4: SUMMARY OF GUIDELINE GRADING AND RECOMMENDATIONS AND LEVELS OF EVIDENCE

Table A4.1: Guideline Grading of Recommendations and Levels of Evidence

Recommendation	Levels of Evidence
NWPS 2014[11]	
A Evidence from Level I **B** Evidence from Level II or extrapolated from Level I **C** Evidence from Level III or extrapolated from Level I or II **D** Evidence from Level IV or extrapolated from Level I, II, or III **DS** Evidence from diagnostic studies	**Ia** MA of RCTs **Ib** RCTs (n≥1) **IIa** Controlled study without randomization (n≥1) **IIb** Quasi-experimental study (n≥1) **III** Non-experimental descriptive studies, comparative studies, correlation studies, and case control studies **IV** Expert opinion **DS** Evidence from diagnostic studies
CDA 2013[3]	
A Evidence from Level **1** **B** Evidence from Level **2** **C** Evidence from Level **3** **D** Evidence from Level **4** or consensus	**1A** SR or MA of high quality RCTs **1B** non-RCT or cohort study with indisputable results **2** moderate quality RCT or SR **3** non-RCT or cohort study or SR, MA of Level 3 studies **4** Other
ADA 2012[8]	
N/A	**A** Clear evidence, or supporting evidence from adequately powered, well-conducted, multicenter RCTs **or** MAs that include quality ratings **or** compelling non-experimental evidence i.e., "all or none" rule **B** Supportive evidence from well-conducted prospective cohort studies **or** well conducted MA of cohort studies **C** Supportive evidence from poorly controlled or uncontrolled studies, RCTs with one or more major or three or more minor methodological flaws **or** observational studies with a high risk of bias **or** case series **or** conflicting evidence with the weight of evidence supportive **E** Expert consensus
BOHTA 2012[9]	
A At least one relevant MA, SR, or RCT rated as **1++**, or multiple overall consistent relevant studies rated as **1+** **B** Relevant consistent studies rated as **2++** or extrapolated evidence from studies rated as **1++** or **1+** **C** Relevant consistent studies rated as **2+**	**1++** High quality MAs, SRs of RCTs, or RCTs - very low risk of bias **1+** Well conducted MAs, SRs, or RCTs - low risk of bias **1 -** MAs, SRs, or RCTs - high risk of bias **2++** High quality SRs of case control or cohort studies or high quality case control or cohort studies - very low risk of confounding or bias

Recommendation	Levels of Evidence
or extrapolated evidence from studies rated as **2++** **D** Evidence level **3** or **4** or Extrapolated evidence from studies rated as **2+** **EO** Expert opinion	and a high probability of a causal relationship **2+** Well conducted case control or cohort studies - low risk of confounding or bias and a moderate probability of a causal relationship **2 -** Case control or cohort studies - high risk of confounding or bias and a significant risk that the relationship is not causal **3** Non-analytic studies (e.g. case reports, case series) **4** Expert opinion
NHMRC 2011[12]	
A Level **I** (n≥1) or Level **II** (n≥2) with a low risk of bias **B** Level **II** (n≤2) with a low risk of bias or SR or several level **III** studies with low bias risk **C** Level **III** (n≤2) with low bias risk or Level **I** or **II** studies with moderate bias risk **D** Level **IV** (n≥1) or Level **I** – **III**, SRs with high bias risk **EO** Expert opinion	**I** SR of Level **II** **II** RCT **III-1** pseudo-randomized controlled trial **III-2** non-RCT, cohort study, case-control study, interrupted time series with control group **III-3** historical control study, two or more single arm studies, or interrupted time series without parallel control group **IV** Case series
University of Adelaide, 2011[10]	
A Level **I** (n≥1) or Level **II** (n≥2) with a low risk of bias **B** Level **II** (n≤2) with a low risk of bias or SR or several level **III** studies with low bias risk **C** Level **III** (n≤2) with low bias risk or Level **I** or **II** studies with moderate bias risk **D** Level **IV** (n≥1) or Level **I** – **III**, SRs with high bias risk **EO** Expert opinion	**I** SR of Level **II** **II** RCT **III-1** pseudo-randomized controlled trial **III-2** non-RCT, cohort study, case-control study, interrupted time series with control group **III-3** historical control study, two or more single arm studies, or interrupted time series without parallel control group **IV** Case series
RNAO 2011[13]	
N/A	**Ia** MA of RCTs plus consensus **Ib** RCT (n≥1) plus consensus **II** Well-designed controlled study without randomization, or well-designed quasi-experimental study, plus consensus **III** Well-designed non-experimental descriptive studies, such as comparative studies, correlation studies and case studies, plus consensus **IV** Expert opinion, committee reports, plus consensus
SIGN 2010[14]	
A At least one relevant MA, SR, or RCT rated as **1++**, or multiple overall consistent relevant studies rated as **1+** **B** Relevant consistent studies rated as **2++**	**1++** High quality MAs, SRs of RCTs, or RCTs - very low risk of bias **1+** Well conducted MAs, SRs, or RCTs - low risk of bias **1 -** MAs, SRs, or RCTs - high risk of bias

Recommendation	Levels of Evidence
or extrapolated evidence from studies rated as **1++** or **1+** **C** Relevant consistent studies rated as **2+** or extrapolated evidence from studies rated as **2++** **D** Evidence level **3** or **4** or Extrapolated evidence from studies rated as **2+** **EO** Expert opinion	**2++** High quality SRs of case control or cohort studies or high quality case control or cohort studies - very low risk of confounding or bias and a high probability of a causal relationship **2+** Well conducted case control or cohort studies - low risk of confounding or bias and a moderate probability of a causal relationship **2 -** Case control or cohort studies - high risk of confounding or bias and a significant risk that the relationship is not causal **3** Non-analytic studies (e.g. case reports, case series) **4** Expert opinion
ADA=American Diabetes Association; **BOHTA**=Basque Office for Health Technology Assessment; **CDA**=Canadian Diabetes Association; **MA**=meta-analysis; **NHMRC**=National Health and Medical Research Council; **NR**=not reported; **NWPS**=North West Podiatry Services; **RNAO**=Registered Nurses Association of Ontario; **RCT**=randomized controlled trial; **SIGN**=Scottish Intercollegiate Guidelines Network; **SR**=systematic review	

APPENDIX 5: SUMMARY OF CRITICAL APPRAISAL

Table A5.1: Critical Appraisal Summary for SR using AMSTAR tool[6]

Strengths	Limitations
Ozdemir et al., 2013[5]	
• Focused objective • Statement of no COIs • Literature search selection/inclusion/exclusion methodology outlined • PRISMA flowchart • Study quality quantified (CONSORT or STROBE score) • Study heterogeneity mentioned • Tabulated study conclusions • Patient demographics tabulated	• No descriptions for study quality assessments • No list of excluded studies • Examined studies in different settings however discussed relevancy to a primary care setting • No grey literature search • No examination of publication bias
COI=conflict of interest; **CONSORT**=Consolidated Standards of Reporting Trials; **PRISMA**=Preferred Reporting Items for Systematic Reviews and Meta-Analyses	

Table A5.4: Critical Appraisal Summary for Guidelines using AGREE II tool[7]

Strengths	Limitations
NWPS 2014[11]	
• Assessment tools for primary care givers and podiatrists • Source for recommendation explicitly linked to recommendation • Externally reviewed by experts • Clearly identifiable recommendations	• Recommendations not independently developed but derived from other guidelines • No guideline development methodology • No mention of COIs • No statement of limitations • Limited professional group stakeholder representation • No mention of resource implications for guideline implementation • Guidelines are based on evidence for risk factors
CDA 2013[3]	
• Graded recommendations explicitly linked to evidence level • Guideline development methodology described • Statement regarding avoidance of potential COIs • Guideline update process outlined • Target audience described • Externally reviewed by experts • Canadian perspective	• Very broad focus • Literature search methodology lacks specificity to screening programs • No detailed description of stakeholder representation • No statement of limitations • No mention of resource implications for guideline implementation
ADA 2012[8]	
• Graded recommendations • Potential COI disclosures available • Provides information on recommendations from many other sources	• No guideline development methodology • No literature search information • Evidence used to formulate recommendations not clearly linked • No detailed description of stakeholder representation • No statement of limitations • No mention of resource implications for guideline implementation • Guidelines are based on evidence for risk factors
BOHTA 2012[9]	
• Graded recommendations • Grades of recommendations linked to a level of evidence • Search methodology detailed and included Spanish, English, French and German language literature • Quality of supporting literature evaluated • Explicit scope and purpose • Guideline development methodology described • Externally reviewed by experts	• Guidelines developed for DM type 1 • No statement of limitations

Strengths	Limitations
• Potential COIs stated • Comprehensive stakeholder involvement • Guideline update process mentioned • Guidance for guideline implementation • Mention of resource implications of guideline implementation • Suggestions for needed future research	
NHMRC 2011[12]	
• Graded recommendations • Grades of recommendations linked to a level of evidence • Literature search methodology provided in separate source • Quality of supporting literature evaluated and discussed • Explicit scope and purpose • Guideline development methodology described • Comprehensive stakeholder involvement • Guideline update process outlined • Mention of resource implications of guideline implementation • Guidance for guideline implementation • Suggestions for needed future research	• Broad focus • COI statement only available in external document • No statement of limitations
University of Adelaide, 2011[10]	
• Graded recommendations • Grades of recommendations linked to a level of evidence • Literature search methodology detailed including inclusion/exclusion criteria • Explicit scope and purpose • Guideline development methodology described • Quality of supporting literature evaluated • COI statements of included literature reported • QUOROM flowchart of literature selection provided • List of excluded studies with reason provided • Mention of resource implications of guideline implementation • Guidance for guideline implementation	• Broad focus • No COI statement • No statement of limitations • No mention of stakeholder representation
RNAO 2011[13]	
• Recommendations linked to a supporting level of evidence • Literature search methodology detailed including inclusion/exclusion criteria	• Recommendations not independently developed but derived from other guidelines • No quality assessment of supporting literature • Guidelines originally published in 2004 with

Strengths	Limitations
• Explicit scope and purpose • Provides risk assessment algorithm and assessment tools for primary care givers • Statement of independence • No statement of COI • Comprehensive stakeholder involvement • Guidance for guideline implementation • Mention of resource implications of guideline implementation • Canadian perspective	minimal updates in 2007. Updates from 2011 are unclear. • No statement of limitations • Evidence used to formulate recommendations not clearly linked
SIGN 2010[14]	
• Explicit scope and purpose • Graded recommendations • Grades of recommendations linked to a level of evidence • Guideline development methodology described • Externally reviewed by experts • Comprehensive stakeholder involvement • Guidance for guideline implementation • Guideline update process outlined • Mention of resource implications of guideline implementation • Suggestions for needed future research	• Very broad scope • Statement of COIs available upon request • Literature search methodology vague • Guidelines are based on evidence for risk factors
ADA=American Diabetes Association; **BOHTA**=Basque Office for Health Technology Assessment; **CDA**=Canadian Diabetes Association; **COI**=conflict of interest; **DM**=Diabetes mellitus; **NHMRC**=National Health and Medical Research Council; **NWPS**=North West Podiatry Services; **RNAO**=Registered Nurses Association of Ontario; **SIGN**=Scottish Intercollegiate Guidelines Network;	

APPENDIX 6: SUMMARY OF FINDINGS

Table A6.1: Summary of Main Findings and Author's Conclusions of SRs/MAs/RCTs

Main Findings	Author's Conclusions
Ozdemir et al., 2013[5]	
Clinical Effectiveness RCTs McCabe et al., 1998[16] 13% of intervention group evaluated as high-risk for DFU (2 year FU) **Major Amputation ($p < 0.01$)** Intervention 1/999 (0.1%) Control 12/1000 (1.2%) **Total Amputation ($p < 0.04$)** Intervention 7/999 (0.7%) Control 23/1000 (2.3%) **Ulceration - no SSD ($p > 0.14$)** Intervention 24/999 (2.4%) Control 35/1000 (3.5%) **Minor Amputation - no SSD ($p > 0.15$)** Intervention 6/999 (0.6%) Control 13/1000 (1.3%) McMurray et al., 2002[17] 70% of the intervention group evaluated as high-risk for DFU (1 year FU) **Total Amputation ($p < 0.05$)** Intervention 0/45 (0%) Control 5/38 (13.2%) **Foot-related hospitalizations ($p < 0.002$)** Intervention 1/45 (2.2%) Control 10/38 (26.3%) **Death - no SSD** Historically controlled studies Rith-Najarian et al., 1998[21] **Total Amputation** No formalized care 29/1000 DPY Diabetes foot screening program 21/1000 DPY* Staged diabetes management 15/1000 DPY* * ($p = 0.016$) **Major Amputation - no SSD** Lavery et al., 2005[19]	"The evidence base for formal national primary care-based foot screening of all patients with diabetes is weak. Focused research is needed to confirm that general population-based screening in the community is effective and cost-effective. Limited evidence suggests that screening of high-risk populations of patients may be justified." (pp. 173) "The recommendation for screening has become a consistent feature of diabetes foot care recommendations internationally based on consensus opinion rather than evidence." (pp. 181)

Main Findings		Author's Conclusions
Total Amputation ($p < 0.05$)		
Before	12.89/1000 patients/year	
After	6.18/1000 patients/year	
Hospital Admissions ($p < 0.05$)		
Before	22.86/1000 patients/year	
After	14.23/1000 patients/year	
Inpatient Length of Stay ($p < 0.05$)		
Before	4.75/1000 days	
After	3.72/1000 days	
Skilled Nursing Facility Admission ($p < 0.05$)		
Before	8.72 days/1000 patients/year	
After	6.52 days/1000 patients/year	
Patout et al., 2000[20]		
Ulceration ($p < 0.01$)		
Before	74 days/patient year	
After	38 days/patient year	
Total Amputation ($p < 0.01$)		
Before	0.096/patient year	
After	0.020/patient year	
Hospital Admissions ($p < 0.01$)		
Before	0.35/patient year	
After	0.04/patient year	
Inpatient Length of Stay ($p < 0.01$)		
Before	3.76 days/patient year	
After	0.37 days/patient year	
Death - no SSD		
Anchini et al., 2007[18]		
Total Amputation ($p < 0.05$)		
Before	10.7/100 000	
After	6.24/100 000	
Major Amputation ($p < 0.05$)		
Before	6.3/100 000	
After	3.1/100 000	
Minor Amputation ($p < 0.05$))		
Before	4.4/100 000	
After	3.12/100 000	

Main Findings		Author's Conclusions
Hospitalization ($p < 0.05$)		
Before	80	
After	65	
DPY=diabetic person years; **FU**=follow-up; **RCT**=randomized controlled trial; **SSD**=statistically significant difference;		

Table A6.2: Summary of Recommendations by Source (see Appendix 4 for grading schemes)

NWPS 2014[11]
Recommendation: "As part of an annual review, trained personnel should examine patient's feet to detect risk factors for ulceration." NICE, 2004 - **Grade A** (pp. 7) **Recommendation:** "Regular (at least annual) 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." NICE, 2004 - **Grade A** (pp. 9) **Recommendation:** "Patients with risk factors for ulceration should be referred to a foot protection team." NICE, 2004 - **Grade A** (pp. 14)
CDA 2013[3]
Recommendation: "In people with diabetes, foot examinations by healthcare providers should be an integral component of diabetes management to identify persons at risk for ulceration and lower-extremity amputation [**Grade C, Level 3**] and should be performed at least annually and at more frequent intervals in those at high risk. [**Grade D, Level 4**]" (pp. S148) **Recommendation:** "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 healthcare professional trained in foot care management if foot complications occur." [**Grade C, Level 3**] (pp. S148)
ADA 2012[8]
Recommendation: "For all patients with diabetes, perform an annual comprehensive foot examination to identify risk factors predictive of ulcers and amputations. The foot examination should include inspection, assessment of foot pulses, and 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)." **Level B** (pp. S38) **Recommendation: "**A multidisciplinary approach is recommended for individuals with foot ulcers and high-risk feet, especially those with a history of prior ulcer or amputation. **Level B** (pp. S38)
BOHTA 2012[9]
Recommendation: "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." **Grade A** (pp. 237) **Recommendation:** "The diabetic foot screening in people with diabetes mellitus type 1 should start after 5 years of disease progression from puberty." **Grade EO** (pp. 237) **Recommendation:** "The diabetic foot screening should include a thorough annual examination of the feet to identify risk factors, predict ulcers and amputations, inspect the foot and soft tissues, assess footwear, carry out a musculoskeletal exploration, assess 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." **Grade B** (pp. 237)

Recommendation: Grade D (pp. 237)

Risk (Classification)	Features	Inspection Frequency
Low Risk	Preserved sensitivity, palpable pulses	Annual
Increased Risk	Neuropathy, absence of pulses and other risk factors	Every 3-6 months (monitoring visits)
High Risk	Neuropathy or absent pulses together to deformity or skin changes or previous ulcer	Every 1-3 months
Ulcerated foot		Individualized treatment, possible referral

NHMRC 2011[12]

Recommendation: "Assess all people with diabetes and stratify their risk of developing foot complications." **Grade C** (pp. 5)

Recommendation: "Any suitably trained healthcare professional may perform the risk assessment." **Grade EO** (pp. 5)

Recommendation: "Assess risk stratification by 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 10g monofilament and palpating foot pulses." **Grade C** (pp. 5)

Recommendation: "Stratify foot risk in the following manner:

> **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"
> **Grade C** (pp. 5)

Recommendation: "Until adequately assessed all Aboriginal and Torres Strait Islander people with diabetes are considered to be at high risk of developing foot complications and therefore will require foot checks at every clinical encounter and active follow-up." **EO** (pp. 5)

Recommendation: "In people stratified as having low-risk feet (where no risk factors or previous foot complications have been identified), foot examination should occur annually." **EO** (pp. 20)

Recommendation: "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." **EO** (pp. 20)

University of Adelaide, 2011[10]

Recommendation: "The evidence suggests that a two-stage foot screening program, followed by a protection program for those patients identified with a high risk foot for patients visiting a general diabetes clinic may reduce the incidence of major amputation." **Grade C** (pp. 9)

Evidence Grade C "The evidence suggests that foot screening, performed by a registrar, should take place in two direct sequential stages to identify those patients at high risk of lower extremity amputation followed by a protection program to prevent amputation." (pp. 119)
RNAO 2011[13]
Recommendation: "Physical examination of the feet to assess risk factors for foot ulceration/amputation should be performed by a health care professional." **Level of Evidence Ib** (pp. 11) **Recommendation:** "This examination should be performed at least annually in all people with diabetes over the age of 15 and at more frequent intervals for those at higher risk." **Level of Evidence IV** (pp. 11) **Recommendation:** "Based on assessment of risk factors, clients should be classified as "lower" IV or "higher" risk for foot ulceration/amputation." **Level of Evidence IV** (pp. 11) **Recommendation:** "Nurses should conduct a foot risk assessment for clients with known diabetes. This risk assessment includes the following: • history of previous foot ulcers; • sensation; • structural and biomedical abnormalities; • circulation; and • self-care behaviour and knowledge." (pp. 11) **Recommendation:** "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." **Level of Evidence IV** (pp. 32)
SIGN 2010[14]
Recommendation: "All patients with diabetes should be screened to assess their risk of developing a foot ulcer." **Grade B** (pp. 104) Good Practice Point "The result of a foot screening examination should be entered onto an online screening tool, such as SCI-DC, to provide automatic risk stratification and a recommended management plan, including patient information." The online screening tool provides a recommended management plan based upon risk stratification. (pp. 104)
ADA=American Diabetes Association; **BOHTA**=Basque Office for Health Technology Assessment; **CDA**=Canadian Diabetes Association; **EO**=expert opinion; **NICE**=National Institute for Health and Care Excellence; **NHMRC**=National Health and Medical Research Council; **NWPS**=North West Podiatry Services; **RNAO**=Registered Nurses Association of Ontario; **SIGN**=Scottish Intercollegiate Guidelines Network;