Registered Nurses' Association of Ontario
Diabetic foot ulcers: Prevention, assessment and management
Third Edition
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Best practice guideline development methods

This document presents an overview of the Registered Nurses' Association of Ontario's (RNAO) guideline development process and methods. RNAO is unwavering in its commitment that every best practice guideline (BPG) be based on the best available evidence. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) method has been implemented to provide a rigorous framework and meet international standards for guideline development. RNAO also aims to meet international reporting standards for clinical practice guidelines, including the standards outlined in the Appraisal of Guidelines for Research and Evaluation (AGREE II) Instrument and the Reporting Items for practice Guidelines in HealThcare (RIGHT) statement (1,2).

Scoping the best practice guideline

The scope defines what an RNAO BPG will and will not cover (see **Purpose and scope**). To determine the purpose and scope of this particular BPG, the RNAO best practice guideline development and research team conducted the following steps:

1. **A review of previous BPGs.** The RNAO BPGs *Reducing foot complications for people with diabetes* (3) and *Assessment and management of foot ulcers for people with diabetes* (4) were reviewed.

2. **An environmental scan of guidelines**. Two guideline development methodologists searched an established list of websites for guidelines and other relevant content published between January 2013 and June 2021. The purpose of the guideline search was to gain an understanding of existing guidelines on the prevention and management of diabetic foot ulcers (DFU) to identify opportunities to develop the purpose and scope of this BPG. The resulting list was compiled based on knowledge of evidence-based practice websites and recommendations from the literature. RNAO expert panel members were asked to suggest additional guidelines (see the **Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)** diagram online). A PRISMA diagram is a diagram that depicts the flow of information throughout the different phases of a systematic review. It maps the number of articles identified, included and excluded (5). For more detailed information, please see the search strategy for existing guidelines, including the list of websites searched and the inclusion criteria used.

   The guidelines were reviewed for content, applicability to nursing scope of practice, accessibility and quality. The two guideline development methodologists appraised three international guidelines using the AGREE II tool (1). Guidelines with an overall score of 6 or 7 (on a 7-point Likert scale) were considered high quality.

   The following guidelines were appraised as indicated:

- National Institute for Health and Care Excellence (NICE). Diabetic foot problems: Prevention and management [Internet]. Manchester (UK): NICE; 2015 Aug [updated 2019 Oct 11]. Available from: https://www.nice.org.uk/guidance/ng19
    - Score: 6 out of 7.
    - This guideline was used as a supporting resource for this BPG.

- Schaper NC, van Netten JJ, Apelqvist J, et al.; International Working Group on the Diabetic Foot (IWGDF). IWGDF guidelines on the prevention and management of diabetic foot disease [Internet]. [place unknown]: IWGDF; 2019. Available from: https://iwgdfguidelines.org/wp-content/uploads/2019/05/IWGDF-Guidelines-2019.pdf
  Schaper NC, van Netten JJ, Apelqvist J, et al.; International Working Group on the Diabetic Foot (IWGDF). IWGDF guidelines on the prevention and management of diabetic foot disease [Internet]. [place unknown]: IWGDF; 2023. Available from: https://iwgdfguidelines.org/wp-content/uploads/2023/07/IWGDF-Guidelines-2023.pdf

    - Both scores: 6 out of 7.
    - The 2023 edition of this guideline was used as a supporting resource for this BPG.

- Malaysian Health Technology Assessment Section (MaHTAS). Clinical practice guidelines 2018: Management of diabetic foot [Internet]. 2nd ed. Putrajaya (MY): MaHTAS; 2018. Available from: https://www.moh.gov.my/moh/resources/penerbitan/CPG/CPG%20Management%20of%20Diabetic%20Foot%20%20(Second%20Edition).pdf

    - Score: 4 out of 7.
    - This guideline was not used as a supporting resource.

3. **An environmental scan of standards.** Two guideline development methodologists also searched for standards published within Canada between January 2013 and June 2021 to gain an understanding of existing standards on DFUs and to identify their scope. The standards were reviewed for content, applicability to nursing scope of practice and accessibility. The standards were not quality appraised.

   The following standard was reviewed as indicated:
    - Health Quality Ontario (HQO). Diabetic foot ulcers: care for patients in all settings [Internet]. Toronto (ON): HQO; 2017. Available from: https://www.hqontario.ca/Portals/0/documents/evidence/quality-standards/qs-diabetic-foot-ulcers-clinical-guide-en.pdf

        - This standard was used as a supporting resource.

4. **A review of the literature.** A literature review was undertaken to determine interventions and outcomes related to the prevention and management of DFUs. Two guideline development methodologists searched for literature published between January 2013 and February 2022. Common findings across studies were summarized and shared with the expert panel during the initial planning meetings.

5. **Key informant interviews.** Fifteen interviews were conducted virtually with experts in the field — including direct care health providers, researchers and patient advocates — to understand the needs of members of the interprofessional health team and persons with lived experience and their care partners in relation to the prevention and management of DFUs.

6. **Discussion groups were convened**. Two virtual sessions were convened with a total of six health providers to understand the needs of nurses, members of the interprofessional health team and persons with lived experience and their care partners in relation to the prevention and management of DFUs.

Assembly of the expert panel

RNAO aims for diversity in membership of an expert panel; this is in alignment with its Organizational Statement on Diversity and Inclusivity, which is part of the RNAO Mission and Values (6). RNAO also aims for persons impacted by BPG recommendations, especially persons with lived experiences and families, to be included as expert panel members.

There are numerous ways in which RNAO finds and selects members of an expert panel. These include the following:

- searching the literature for researchers in the topic area;
- soliciting recommendations from key informant interviews;
- drawing from established professional networks, such as RNAO Interest Groups, the Best Practice Champions Network® and Best Practice Spotlight Organizations® (BPSO); and
- contacting other nursing and health provider associations, topic-relevant technical associations or organizations, and advocacy bodies.

For this BPG, the RNAO best practice guideline development and research team assembled a panel of experts from nursing practice, research and education, policy, as well as members of the interprofessional team, and persons with lived experience representing a range of sectors and practice areas (see the **RNAO best practice guideline expert panel**).

The expert panel engaged in the following activities:

- developed and approved the purpose and scope of this BPG
- determined the recommendation questions and outcomes to be addressed in this BPG
- participated in a development process to finalize recommendation statements
- provided feedback on the draft of this BPG
- participated in the development of evaluation indicators
- helped develop BPG Order Sets
- identified appropriate external reviewers to review the draft guideline prior to publication

In addition to the above, the expert panel co-chairs also participated in the following activities:

- engaged in meetings with the guideline development methodologists and guideline development project coordinator
- facilitated expert panel meetings
- provided in-depth guidance on clinical and/or research issues
- moderated consensus processes (and voting if necessary)

Declaration of conflict of interest

In the context of RNAO best practice guideline development, the term "conflict of interest" (COI) refers to situations in which an RNAO staff member's or expert panel member's financial, professional, intellectual, personal, organizational or other relationships may compromise their ability to conduct panel work independently. Declarations of COI that might be construed as constituting a perceived and/or actual conflict were made by all members of the RNAO expert panel prior to their participation in guideline development work using a standard form. Expert panel members also updated their COI at the orientation meeting, the recommendation build meetings, and prior to guideline publication. Any COI declared by an expert panel member was reviewed by the RNAO best practice guideline development and research team and expert panel co-chairs. No limiting conflicts were identified by members of the expert panel. For COI declarations, refer to supplementary materials under the "methodology documents" tab on the BPG webpage.

Identifying priority recommendation questions and outcomes

RNAO systematic review questions are developed in accordance with the PICO format (population, intervention, comparison and outcomes).

In April and May 2022, the RNAO best practice guideline development and research team and the expert panel convened virtually three times to determine the priority recommendation questions and outcomes for this BPG. The three meetings included an orientation meeting and two planning meetings. A comprehensive list of recommendation questions and good practice areas that the BPG could potentially address was developed at the meeting. This list was informed by:

- the environmental scan of guidelines
- the review of the literature
- key informant interviews and discussion groups
- expert panel discussion during the planning meetings

During planning meeting two, the expert panel determined that four recommendation areas would be best suited as good practice statements. For further details, see "Developing good practice statements."

The list of remaining potential recommendation areas was sent via email to the expert panel in a confidential online survey after they had an opportunity to discuss them during the first and second planning meetings. Expert panel members were asked to rank order the recommendation areas from highest to lowest priority. The top six recommendation areas were deemed to be the final recommendation questions. Expert panel co-chairs did not participate in the rank ordering. The results were presented to the expert panel in an email. Based on the survey results, the expert panel determined that systematic reviews would be conducted for the top six recommendation areas.

In alignment with GRADE standards for assessing and presenting the evidence, potential outcomes were brainstormed by the expert panel for each recommendation question that would be the focus of a systematic review. The list of outcomes was informed by a review of the literature, the key informant interviews and discussion groups, and expert panel discussion. Outcomes were chosen based on what was considered important to people for decision-making.

It was deemed feasible to have three to five outcomes per recommendation question. During the brainstorming session at the second planning meeting, the expert panel identified between nine and 12 potential outcomes per recommendation question. As a next step, the RNAO guideline development and research team consulted with RNAO's monitoring and evaluation team to review all the outcomes. During the consultation, the following factors were considered to refine outcomes: which outcomes are measurable; overlap between outcomes; consistency in outcomes across recommendation areas; and outcomes that could be captured through other means (e.g., implementation tips or values and preferences associated with each recommendation area). After this internal review process, the team narrowed down the initial list and modified some outcomes.

Following the internal review process, the expert panel was sent a confidential online survey to rate the relative importance of each outcome (per recommendation question). The RNAO guideline development and research team then reviewed the results and calculated the top three to five most critical and important outcomes per recommendation question. The expert panel was provided with an update via email regarding the final list of outcomes prioritized for each recommendation question.

The six recommendation questions and their respective PICO research questions are presented below.

Recommendation question #1: Should person-engagement strategies be recommended or not for health providers delivering self-management support for diabetic foot care (e.g., motivational interviewing, cognitive behavioral therapy or other psychosocial interventions)?

> **PICO research question #1**
> **Population:** Health providers supporting persons at risk of or living with a DFU
> **Intervention:** Person-engagement strategies
> **Comparison:** Usual DFU care
> **Outcomes:** Person satisfaction, self-efficacy, person adherence, DFU occurrence/recurrence, amputation rates*
>
> * For recommendation question 1, the outcome "amputation rates" was not found in the literature.

Recommendation question #2: Should self-screening for DFU risk assessment be recommended or not for persons at risk of or living with DFUs and their care partners?

> **PICO research question #2**
> **Population:** Persons at risk of a DFU and their care partners
> **Intervention: S**elf-screening performed by persons or care partners to prevent DFUs
> **Comparison:** No self-screening by persons or care partners to prevent DFUs
> **Outcomes:** DFU occurrence/recurrence, screening rates, person satisfaction*, neuropathy screening*, amputation rates*
>
> * For recommendation question 2, the outcomes "person satisfaction," "neuropathy screening" and "amputation rates" were not found in the literature.

Recommendation question #3: Should support from a specialized wound care team be recommended or not for persons at risk or living with DFUs?

> **PICO research question #3**
> **Population:** Persons at risk of or living with DFUs

Intervention: Support from a specialized wound care team
Comparison: No support from a specialized wound care team (i.e., standard care or care by one individual provider)
Outcomes: DFU healing rates, amputation rate, DFU occurrence/recurrence, readmission rates, person satisfaction*

* For recommendation question #3, the outcome "person satisfaction" was not found in the literature.

Recommendation question #4: Should virtual care (e.g., telepractice, social media) be recommended or not to support/supplement (in conjunction with in-person service) the delivery of diabetic foot care services?

PICO research question #4
Population: Persons at risk of or living with DFUs
Intervention: Use of virtual technology (e.g., telemedicine, telehealth, social media) to support/supplement in-person DFU prevention or management strategies
Comparison: No use of virtual technology in DFU care delivery
Outcomes: Self-efficacy, screening rates, DFU occurrence/recurrence, provider satisfaction*, person satisfaction*, neuropathy screening*

* For recommendation question 4, the outcomes "provider satisfaction," "person satisfaction" and "neuropathy screening" were not found in the literature.

Recommendation question #5*: What cultural safety strategies should be recommended for health providers supporting persons at risk of or living with DFUs?

PICO research question #5
Population: Persons at risk of or living with a DFU (Indigenous populations, 2SLGTBTQI+ communities, other BIPOC)
Intervention: Use of cultural safety strategy to DFU prevention or management
Comparison: Usual care/no cultural safety strategy to DFU prevention or management
Outcomes: Person engagement, improved provider knowledge, person satisfaction (trust, empowerment, feeling safe), self-efficacy, person adherence (number of visits)

* The expert panel initially brainstormed outcomes for this question in order to conduct a systematic review. However, upon further discussion, a scoping review was preferred. See **Updates to the recommendation questions and outcomes** (below) for further explanation.

Recommendation question #6*: Should structured foot screening (preventive) and DFU risk assessment be conducted annually or not?

PICO research question #6
Population: Persons at risk of or living with DFUs
Intervention: Structured foot screening performed on an annual basis for risk factors of DFU to prevent a primary or recurrent/subsequent DFU
Comparison: Usual DFU screening care (e.g., unstructured or less frequent screening for DFU risk factors)
Outcomes: Neuropathy screening, ulcer occurrence/recurrence, screening rates, amputation rates, person satisfaction

* The expert panel initially brainstormed outcomes for this question in order to conduct a systematic review. However, upon further discussion, the expert panel determined preventive foot screening to be part of **Good practice statement 1.0**. See **Updates to the recommendation questions and outcomes** (below) for further explanation.

Updates to the recommendation questions and outcomes

Systematic reviews were conducted for **Recommendation questions 1, 2, 3** and **4.** Following consultation with the expert panel, it was determined that **Recommendation question 6** would be better integrated into **Good practice statement 1.0**, and the topic of **Recommendation question 5** would be better addressed through a scoping review.

For **Recommendation question 6**, a systematic review was initially conducted, and no new evidence was found. The question asked whether diabetic foot screening should be conducted or not on an annual basis to prevent a primary or recurrent DFU. It was noted that the frequency of screening would be best suited as an implementation tip. Since **Good practice statement 1.0** is about foot screening, the panel decided to discuss the frequency of screening in the implementation tips for **Good practice statement 1.0**.

For **Recommendation question 5**, a systematic review was originally conducted to determine whether a cultural safety strategy should be used or not when providing care to persons at risk of or living with a DFU to improve self-efficacy, person adherence, person satisfaction, person engagement and provider knowledge. Only one study was identified through the systematic review that examined the prioritized outcomes. Given the limited amount of evidence examining the prioritized outcomes, the expert panel suggested the guideline development and research team to conduct a broader scoping review to examine cultural safety strategies that have been used in diabetes care, without limiting the search to select outcomes and study designs.

Developing good practice statements

The RNAO best practice guideline development and research team developed four good practice statements to capture the need for health providers to conduct a preventative screening and risk assessment and a wound assessment before carrying out interventions or treatment plans for adults at risk of and or living with diabetic foot ulcers and their care partners. The third good practice statement was written about self-management support for persons and their care partners. The fourth good practice statement was written about implementing a plan of care with the person living with a DFU and their care partners that utilizes appropriate treatment options. Good practice statements are actionable statements that should be done in practice and the benefits of the action clearly outweigh the harms (7). Consensus was reached through discussion with the panel on each of the following five questions:

1. Is collecting and summarizing the evidence a poor use of time and energy?
2. Is the message necessary to communicate?
3. Would implementing the action result in large benefits and very small harms?
4. Is there a clear rationale for the action?
5. Is the statement clear and actionable?

Through discussion, the expert panel determined that each of the five criteria had been met, so these areas became good practice statements.

Systematic retrieval of the evidence

Strong and conditional recommendations are based on a comprehensive and systematic review of the literature.

For this BPG, a search strategy was developed by RNAO's best practice guideline development and research team and a health sciences librarian for each of the aforementioned PICO research questions. In August 2022, a search for relevant research studies published in English between January 2017 and August 2022 was applied to the following databases: Cumulative Index to Nursing and Allied Health (CINAHL), Medline, Medline in Process, Cochrane Central, Cochrane Database of Systematic Reviews, Embase, Emcare, and PsycInfo. The systematic reviews were also registered in PROSPERO (PROSPERO 2022 CRD42022358847).

Expert panel members were asked to review their personal libraries for key studies not found through the above search strategies. Detailed information on the search strategy for the systematic reviews, including the inclusion and exclusion criteria and search terms, can be found in supplementary materials under the "methodology documents" tab on the BPG webpage.

Systematic review search dates were limited to the last 5 years to capture the most up-to-date evidence. All study designs were included in the search.

All studies were independently assessed for relevance and eligibility by two guideline development methodologists based on the inclusion and exclusion criteria. Any disagreements were resolved through consensus.

All included studies were independently assessed for risk of bias by study design using validated and reliable tools. Randomized controlled trials were assessed using the Risk of Bias 2.0 tool (8); cluster randomized controlled trials were assessed using the Revised Cochrane risk-of-bias tool for cluster-randomized trials (9); non-randomized controlled trials were assessed using the ROBINS-I tool (10); and systematic reviews were assessed using the ROBIS tool (11). The two guideline development methodologists reached consensus on all scores through discussion.

For data extraction, the included studies were divided equally between the guideline development methodologists who each extracted information from their assigned studies; each reviewed the other's work for accuracy.

In March 2024, the health science librarian conducted an update search for relevant systematic reviews published in English between August 2022 and March 2024 that answered **Recommendations questions 1, 2, 3** and **4**. The search was applied to the following databases: Cumulative Index to Nursing and Allied Health (CINAHL), Medline, Medline in Process, Cochrane Central, Cochrane Database of Systematic Reviews, Embase, Emcare and PsycInfo. Results from 5 studies were incorporated into the discussions of evidence for **Recommendations 1, 2, 3** and **4**. See PRISMA diagrams online for studies included in the update search.

Note: If randomized-controlled trials or non-randomized-controlled trials were found when conducting the initial systematic review, non-randomized single arm studies found during the update search that examined the same outcome were not included. However, if there were no studies found during the initial

systematic review that examined an outcome, non-randomized single arm studies found during the update search that examined the same outcome were included.

Determining certainty and confidence of evidence

Certainty of evidence

The certainty of quantitative evidence (i.e., the extent to which one can be confident that an estimate of an effect is true) is determined using GRADE methods (12). First, the certainty of the evidence is rated for each prioritized outcome across studies (i.e., for a body of evidence) per recommendation (12). This process begins with the study design and then requires an examination of five domains — risks of bias, inconsistency, imprecision, indirectness and publication bias — to potentially downgrade the certainty of evidence for each outcome (12). For example, a body of quantitative evidence for one priority outcome may begin with high certainty, but due to serious limitations in one or more of the five GRADE criteria, it will be rated down by one or two levels (12). See Table 1 for a definition of each of these certainty criteria.

Table 1. GRADE certainty criteria

Certainty Criteria	Definition
Risk of bias	Limitations in the study design and execution that may bias study results. Valid and reliable quality appraisal tools are used to assess the risk of bias. First, risk of bias is examined for each individual study and then examined across all studies per defined outcome.
Inconsistency	Unexplained differences (heterogeneity) of results across studies. Inconsistency is assessed by exploring the magnitude of difference, and possible explanations in the direction and size of effects reported across studies for a defined outcome.
Indirectness	Variability between the research and review question and context within which the recommendations would be applied (applicability). Four sources of indirectness are assessed: • differences in population • differences in interventions • differences in outcomes measured • differences in comparators
Imprecision	The degree of uncertainty around the estimate of effect. This is usually related to sample size and number of events. Studies are examined for sample size, number of events and confidence intervals.
Publication bias	Selective publication of studies based on study results. If publication bias is strongly suspected, downgrading is considered.

Source: Adapted with permission from: Schünemann HJ, Brozek J, Guyatt G, Oxman A, editors. Handbook for grading the quality of evidence and the strength of recommendations using the GRADE approach [Internet]. [place unknown: publisher unknown]; 2013 Oct. Available from: https://gdt.gradepro.org/app/handbook/handbook.html#h.svwngs6pm0f2.

Following the initial consideration for rating down the certainty of quantitative evidence, three factors are assessed that can potentially enable rating up the certainty of evidence for non-randomized studies:

1. **Large magnitude of effect**: If the body of evidence has not been rated down for any criteria other than risk of bias and a large estimate of the magnitude of intervention effect is present, there is consideration for rating up.
2. **Dose–response gradient**: If the body of evidence has not been rated down for any criteria other than risk of bias and a dose–response gradient is present, there is consideration for rating up.
3. **Effect of plausible confounding**: If the body of evidence has not been rated down for any criteria other than risk of bias and all residual confounders would result in an underestimation of treatment effect, there is consideration for rating up (12).

GRADE categorizes the overall certainty of evidence as high, moderate, low or very low. See Table 2 for the definitions of these categories.

For this BPG, the five GRADE quality criteria for potentially downgrading quantitative evidence — and the three GRADE quality criteria for potentially rating up evidence — were independently assessed by the two guideline development methodologists. Any disagreements were resolved through consensus. An overall certainty of evidence per recommendation was assigned based on these assessments. The certainty of evidence assigned to each recommendation was based on the certainty of prioritized outcomes in the studies that informed the recommendation.

Table 2: Certainty of evidence

Overall certainty of evidence	Definition
High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low	We have very little confidence in the effect estimate: the true effect is likely to be substantially different from the estimate of effect.

Source: Reprinted with permission from: Schünemann HJ, Brozek J, Guyatt G, Oxman A, editors. Handbook for grading the quality of evidence and the strength of recommendations using the GRADE approach [Internet]. [place unknown: publisher unknown]; 2013 Oct. Chapter 5, Quality of evidence. Available from: https://gdt.gradepro.org/app/handbook/handbook.html#h.9rdbelsnu4iy

Formulating recommendations

Summarizing the evidence

The guideline development methodologists analyzed all studies pertaining to each research question and drafted recommendations that answer the research questions accordingly. Draft recommendation statements were developed based on the themes. For each draft recommendation, the two guideline development methodologists constructed GRADE evidence profiles. GRADE evidence profiles are used to present decisions on determining the certainty of evidence and to present general information about the body of research evidence, including key statistical or narrative results (12).

The evidence profiles for the body of quantitative studies presented the decisions made by the two guideline development methodologists on the five key GRADE certainty criteria for downgrading the population included in the studies, the countries where the studies were conducted, the key results and the transparent judgments about the certainty underlying the evidence for each outcome (12). The evidence profiles for quantitative studies presented the relative importance of outcomes as determined by the expert panel through a confidential online vote using a 9-point Likert scale that ranged from 1 (less important) to 9 (most important). For this BPG, meta-analyses were not performed.

For more detail, please see the GRADE evidence profiles for each recommendation, organized per outcome under the "methodology documents" tab of the webpage.

Evidence-to-Decision frameworks

Evidence-to-Decision (EtD) frameworks outline proposed recommendations and summarize all necessary factors and considerations based on available evidence and expert panel judgments for formulating the recommendation statements. EtD frameworks are used to help ensure that all important factors (i.e., certainty or confidence of the evidence, benefits/harms, values and preferences, and health equity) required to formulate recommendation statements are considered by the expert panel (12). Both quantitative and qualitative evidence are incorporated into the frameworks. The guideline development methodologists draft the EtD frameworks with available evidence from the systematic reviews.

For this BPG, the EtD frameworks included the following areas of consideration for each drafted recommendation statement (see Table 3):

- background information on the magnitude of the problem
  - includes the PICO question and general context related to the research question
- the balance of benefits and harms of an intervention
- certainty and/or confidence of the evidence
- values and preferences
- health equity

Decision making: Determining the direction and strength of recommendations

Expert panel members are provided with the EtD frameworks to review prior to the recommendation build meetings to determine the direction (i.e., a recommendation for or against an intervention) and the strength (i.e., strong or conditional) of a BPG's recommendations. Expert panel members are also given access to the complete evidence profiles and full-text articles.

The expert panel co-chairs and the two guideline development methodologists facilitated the meeting to allow for adequate discussion for each proposed recommendation.

The decision on the direction and strength of each recommendation statement was determined by discussion of the judgments made for each of the factors in the EtD frameworks and a consensus-building process facilitated by the co-chairs and the RNAO guideline development and research team (13). Since the recommendations are explicitly linked to the body of evidence, agreement was reached (13). In determining the strength of a recommendation statement, the following was considered (see Table 3):

- the balance of benefits and harms of an intervention
- certainty and/or confidence of the evidence
- values and preferences
- health equity

If the expert panel deemed there was insufficient evidence to develop a recommendation (i.e., limited number of studies and/or very low certainty evidence), they also had the option not to proceed with a recommendation.

Table 3: Key considerations for determining the strength of recommendations

Factor	Definition	Sources
Benefits and harms	Potential desirable and undesirable outcomes reported in the literature when the recommended practice or intervention is used. "The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a conditional recommendation is warranted" (14).	Includes research exclusively from the systematic review.
Certainty and confidence of evidence	The extent of confidence that the estimates of an effect are adequate to support a recommendation. The extent of confidence that a review finding is a reasonable representation of the phenomenon of interest (15). Recommendations are made with different levels of certainty or confidence; the higher the certainty or confidence, the higher the likelihood that a strong recommendation is warranted (14).	Includes research exclusively from the systematic review.
Values and preferences	The relative importance or worth of the health outcomes of following a particular clinical action from a person-centred perspective. "The more values and preferences vary or the greater the uncertainty in values and preferences, the higher the likelihood that a conditional recommendation is warranted" (14).	Includes evidence from the systematic review (when available) and other sources, such as insights from the expert panel. During the systematic review screening process, if studies did not directly answer the research question (i.e., they did not discuss the outcomes of interest) but were relevant to preferences for the intervention from a person-centred perspective, those studies were also included in this section.
Health equity	Represents the potential impact of the recommended practice or intervention on health outcomes or health quality across different populations.	Includes evidence from the systematic review (when available) and other

	The greater the potential for increasing health inequity, the higher the likelihood that a conditional recommendation is warranted (16).	sources, such as insights from the expert panel.

Source: Adapted by the RNAO expert panel with permission from: Schünemann HJ, Brozek J, Guyatt G, Oxman A, editors. Handbook for grading the quality of evidence and the strength of recommendations using the GRADE approach [Internet]. [place unknown: publisher unknown]; 2013 Oct. Available from: https://gdt.gradepro.org/app/handbook/handbook.html#h.svwngs6pm0f2

Scoping review

For this BPG, a scoping review was conducted according to the Arksey and O'Malley framework (17) to identify and map the evidence describing culturally safe strategies that could assist persons (and care partners) at risk of or living with diabetes. RNAO's best practice guideline development and research team and a health sciences librarian developed the search strategy. A search for relevant articles published in English between 2018 and 2023 was applied to the following databases: ProQuest Dissertations and Theses Open Access, Theses Canada, Medline, CDSR, APA PsychINFO, CINHAL and ERIC. The search was limited to the last five years in order to capture the most up-to-date evidence. All study designs were included in the search. The scoping review was registered in Open Science Framework (available from: osf.io/2ay7g).

Expert panel members were asked to review their personal libraries for key studies not found through the search strategy. Articles related to cultural safety, cultural humility, cultural competence, and cultural awareness in the context of diabetes care and/or DFUs were included. Detailed information on the search strategy for the scoping review, including the inclusion and exclusion criteria and search terms, is also available online under the "methodology documents" tab of the webpage.

All studies were independently assessed for relevance and eligibility by two guideline development methodologists based on the inclusion and exclusion criteria. Any disagreements were resolved through consensus.

For data extraction, the included studies were divided equally between the guideline development methodologists. Each guideline development methodologist extracted information from their assigned studies, and this was reviewed by the other guideline development methodologist for accuracy. The guideline development methodologists analyzed and grouped studies according to themes.

Supporting resources and appendices

Content for the supporting resources and appendices was submitted throughout the guideline development process by expert panel members and external reviewers. The two guideline development methodologists reviewed the content based on the following five criteria:

1. **Relevance:** Supporting resources and appendices should be related to the subject of the BPG or recommendation. In other words, the resource or appendix should be suitable and appropriate in relation to the purpose and scope of the BPG or the specific recommendation(s).

2. **Timeliness:** Resources should be timely and current. Resources should be published within the last 10 years or in line with current evidence.

3. **Credibility:** When assessing credibility, the trustworthiness and expertise of the source material's author or authoring organization is considered. Potential biases are also assessed, such as the presence of advertising or the affiliation of the authors with a private company selling health-care products.

4. **Quality:** This criterion assesses the accuracy of the information and the degree to which the source is evidence informed. The assessment of quality is in relation to the subject of the resource. For example, if a tool is being suggested, is that tool reliable and/or valid?

5. **Accessibility:** This criterion considers whether the resource is freely available and accessible online.

Drafting the guideline

The guideline development methodologists wrote the draft of this BPG. The expert panel reviewed the draft and provided written feedback. The BPG then proceeded to external review.

Quality assurance

RNAO staff carry out quality assurance of the guideline, including reviews of the evidence profiles, evidence-to-decision frameworks and drafts of the BPG. The associate director of guideline development is responsible for ensuring that the guideline is produced in accordance with the RNAO BPG development methods outlined in the BPG, GRADE methods, and international guideline standards such as AGREE II and the RIGHT reporting standards (1,2,12). One senior manager and the associate director review the evidence profiles, evidence-to-decision frameworks and BPG drafts to ensure adherence to the established methodology. An external review of an early draft of the BPG, along with the evidence profiles, is conducted to ensure adherence to GRADE methodology.

External review

As part of the guideline development process, RNAO is committed to obtaining feedback from: a) nurses and members of the interprofessional team from a wide range of practice settings and roles; b) persons with lived experience; and c) knowledgeable educators and administrators, throughout Canada and around the world.

External reviewers for RNAO BPGs are identified in two ways. First, external reviewers are recruited through a public call issued on the RNAO website. Second, individuals and organizations with expertise in the guideline topic area are identified by the RNAO best practice guideline development and research team and the expert panel, and they are directly invited to participate in the review.

External reviewers are individuals with subject matter expertise in the guideline topic or those who may be affected by its implementation. Reviewers may be nurses, members of the interprofessional team, nurse executives, administrators, research experts, educators, nursing students or persons with lived experience and their family members. External panel reviewers were asked to declare any conflicts of interest. See supplementary materials under the "methodology documents" tab on the BPG webpage.

External reviewers are asked to read a full draft of the BPG and participate in its review prior to its publication. External reviewer feedback is submitted online by completing a survey questionnaire.

The external reviewers are asked the following questions about each good practice statement:

- Is this statement clear?
- Do you agree with this statement?

- Is there a clear and explicit rationale to support this good practice statement?

The external reviewers are asked the following questions about each recommendation:

- Is this recommendation clear?
- Do you agree with this recommendation?
- Is the discussion of evidence for this recommendation thorough and clear, and does the evidence support the recommendation?

In addition, the external reviewers are asked:

- Do you have any additional comments/suggestions about the background/guiding principles section of this guideline?
- Do you agree with the wording of the key concepts and accompanying definitions?
- Are the results from the scoping review clear?
- Are the supporting resources and appendices included in this guideline appropriate?
- Do you agree with the wording of the key concepts and accompanying definitions?

With respect to the evaluation indicators, the external reviewers are asked:

- Will the indicator measure best practice guideline implementation in your practice setting?
- Is the indicator important to measure?
- Does it have the potential to demonstrate improvements in patient care and outcomes?
- Can the indicator be collected with the resources in your practice setting?
- Is the indicator measurable?

Survey submissions are compiled, and feedback is summarized by the RNAO best practice guideline development and research team. The RNAO best practice guideline research and development team reviews the feedback received, consults the expert panel where necessary, and modifies the BPG content.

For this BPG, the external review process was completed between April 17, 2024, and May 2, 2024. External reviewers with diverse perspectives provided feedback (see **External reviewer acknowledgement**).

The Canadian Association of Foot Care Nurses, Ontario Health and the Ontario Society of Chiropodists were also provided with the opportunity to review the draft guideline and provide feedback.

Limitations

- Due to feasibility, only four systematic reviews were conducted. Since the expert panel prioritized prevention and assessment-focused questions, there is less content on the management of DFUs. Therefore, the BPG refers to other national and international guidelines for management recommendations.
- The expert panel lacked a physician's perspective, which led to a lack of treatment perspectives in the recommendations and good practice statements.
- The systematic review searches were conducted from 2017-2022 with update search conducted until 2024, only in the English language. The scoping review search was conducted from 2017-2023, only in the English language.

Procedure for updating the guideline

The RNAO commits to updating all BPGs, as follows:

1. Each BPG will be reviewed by the RNAO every five years following publication of the previous edition.
2. Whether it is a new BPG topic or an update to an existing BPG, careful consideration needs to be made regarding selection of the BPG for development. For new editions, an assessment of the uptake of the existing BPG is conducted, such as asking:
    - Is this a mandatory guideline that BPSOs need to implement?
    - How many BPSOs are actively implementing this BPG?
    - How many times has the BPG been downloaded?
3. Further, an assessment of existing, recent and/or in-production high quality guidelines of the same topic by other organizations is completed. If the uptake of a BPG is high and there are no existing high quality BPGs on the same topic, this may indicate a higher priority for the next edition to be completed. However, if the uptake is low and/or there is another high-quality guideline on the same topic, the BPG may be retired.
4. New BPG topics are determined by a set of criteria to guide the systematic assessment of a selected list of suggested topics and feedback from a range of stakeholders. Any group or individual may propose a BPG topic to RNAO through a variety of methods such as the following:
    - "Suggest a guideline topic" on the RNAO website;
    - writing to RNAO's CEO or director/associate directors of the International Affairs and Best Practice Guidelines (IABPG) Centre;
    - a rapid review or environmental scan (i.e., scoping search for trends, hot topics, practice concerns);
    - a survey requesting that individuals rank identified topics on a five-point Likert scale; and
    - report sources (e.g., coroner's inquest, government or related agency).
5. RNAO selects topics for BPG development annually. All topics submitted are identified, and priority topics are chosen based on the following systematic assessment criteria:
    - key priority areas identified by the Government of Ontario, request from major public health agency, Coroner's inquest;
    - within the scope of nursing practice (RN, NP, RPN/LPN), and applicable in a range of practice settings;
    - based on a multidisciplinary approach;
    - builds on previously developed BPGs or general topic areas;
    - potential for partnerships in BPG development with other agencies;
    - perceived need for the guideline, as identified by those submitting a topic for consideration;
    - evidence to support the guideline recommendations is available; and
    - no other high-quality guideline exists on the topic area.

6. Upon reviewing all submissions based on the above criteria, the results are shared with the BPG guideline development and research team, the Director of the IABPG Centre, and the CEO of RNAO, who reports the selected topics to the Government of Ontario.

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