Complete Summary

GUIDELINE TITLE

Assessment and management of foot ulcers for people with diabetes.

BIBLIOGRAPHIC SOURCE(S)

Registered Nurses Association of Ontario (RNAO). Assessment and management of foot ulcers for people with diabetes. Toronto (ON): Registered Nurses Association of Ontario (RNAO); 2005 Mar. 112 p. [193 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

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SCOPE

DISEASE/CONDITION(S)

Diabetic foot ulcers

GUIDELINE CATEGORY

Evaluation
Management

CLINICAL SPECIALTY

Dermatology
Endocrinology
Family Practice
Internal Medicine

Nursing
Pediatrics
Plastic Surgery
Podiatry

INTENDED USERS

Advanced Practice Nurses
Nurses

GUIDELINE OBJECTIVE(S)

- To assist nurses and patients in decision-making about appropriate health care
- To address the question of how to assess and manage patients with established diagnosis of diabetic foot ulcers
- To provide direction to practicing nurses (registered nurses [RNs] and registered practical nurses [RPNs]) who provide care in all health care settings to patients (>15 years old) with type 1 and/or type 2 diabetes who have diabetic foot ulcers

TARGET POPULATION

Patients (>15 years old) with type 1 and/or type 2 diabetes who have diabetic foot ulcers

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation

1. Obtain and document a health history
2. Assess bilateral extremities for vascular supply
3. Facilitate appropriate diagnostic testing
4. Assess signs and symptoms of infection
5. Assess sensory, autonomic, and motor changes for signs of peripheral neuropathy
6. Assess for foot deformity, pressure, gait, footwear, and devices
7. Perform comprehensive foot ulcer assessment

Management

1. Provide patient education
2. Define the goals of care
3. Identify, and modify factors that may influence and/or interfere with wound healing
4. Provide local wound care
5. Provide pressure redistribution
6. Implement treatment options for non-healable wounds
7. Assess effectiveness of treatment plan and additional correctable factors, if applicable

8. Consider other therapies including biological agents, adjunctive therapies, and/or surgery

MAJOR OUTCOMES CONSIDERED

- Incidence of foot ulcers and amputation
- Incidence of complications associated with diabetic foot ulcers
- Effectiveness of interventions on diabetic foot ulcer outcomes

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A database search for existing diabetes foot ulcer guidelines was conducted by a university health sciences library. A computerized search of the Medline, Embase, and CINAHL databases for guidelines and other literature published from January 1, 1995 to December 2003 was conducted using the following search terms: "diabetic foot ulcers," "foot ulceration," NOT "venous leg ulcers or arterial ulcers," "peripheral neuropathy," "diabetes complications," "prevention," "assessment," "management," "amputation," "factors influencing wound healing," "patient/family education," "randomized controlled trials," "systematic reviews," "practice guideline(s)," "clinical practice guideline(s)," "standards," "consensus statement(s)," "consensus," "evidence-based guidelines," and "best practice guidelines."

One individual searched an established list of Web sites for content related to the topic area. This list of sites, reviewed and updated in October 2002, was compiled based on existing knowledge of evidence-based practice Web sites, known guideline developers, and recommendations from the literature. Presence or absence of guidelines was noted for each site searched as well as date searched. The Web sites at times did not house a guideline but directed to another Web site or source for guideline retrieval. Guidelines were either downloaded if full versions were available or were ordered by phone/e-mail.

A Web site search for existing diabetic foot ulcer guidelines was conducted via the search engine "Google," using the search terms identified above. One individual conducted this search, noting the results of the search term results, the Web sites reviewed, date, and a summary of the results. The search results were further critiqued by a second individual who identified guidelines and literature not previously retrieved.

Additionally, panel members were already in possession of a few of the identified guidelines. In some instances, a guideline was identified by panel members and not found through the previous search strategies. These were guidelines that were

developed by local groups or specific professional associations and had not been published to date.

The panel identified a total of eight clinical practice guidelines related to diabetic foot ulcers. These guidelines were reviewed according to a set of initial inclusion criteria, which resulted in elimination of one guideline. The inclusion criteria were:

- Guideline was in English, international in scope.
- Guideline was dated no earlier than 1997.
- Guideline was strictly about the topic area.
- Guideline was evidence-based (e.g., contained references, description of evidence, sources of evidence).
- Guideline was available and accessible for retrieval.

Seven guidelines were critically appraised with the intent of identifying existing guidelines that were current, developed with rigour, evidence-based and which addressed the scope identified by the panel for the best practice guideline. A quality appraisal was conducted on these seven clinical practice guidelines using the *Appraisal of Guidelines for Research and Evaluation Instrument* (AGREE Collaboration, 2001). This process yielded a decision to work primarily with seven guidelines.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia Evidence obtained from meta-analysis or systematic review of randomized controlled trials

Ib Evidence obtained from at least one randomized controlled trial

IIa Evidence obtained from at least one well-designed controlled study without randomization

IIb Evidence obtained from at least one other type of well-designed quasi-experimental study, without randomization

III Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

In January of 2004, a panel of nurses with expertise in practice, education, and research related to diabetic foot ulcers was established by the Registered Nurses Association of Ontario (RNAO). At the onset, the panel discussed and came to consensus on the scope of the best practice guideline.

The panel members divided into subgroups to undergo specific activities using the short-listed guidelines, other literature, and additional resources for the purpose of drafting recommendations for nursing interventions. This process yielded a draft set of recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

An advisory panel was recruited to review and provide feedback on the draft recommendations. The advisory panel represented physicians, other health care disciplines, as well as professional associations. An acknowledgement of the advisory panel is provided at the front of the original guideline document. Feedback on the recommendations was obtained from health care consumers through a focus group. The panel members as a whole reviewed the recommendations and the feedback from the advisory panel and consumers,

discussed gaps and available evidence, and came to a consensus on a draft guideline.

This draft was submitted to a set of external stakeholders for review and feedback of the content. It was also critiqued using the Appraisal of Guidelines for Research and Evaluation Instrument (AGREE) instrument. An acknowledgement of these reviewers is provided at the front of the original guideline document. Stakeholders represented health care consumers, various health care disciplines, as well as professional associations. External stakeholders were provided with specific questions for comments, as well as the opportunity to give overall feedback and general impressions. The results were compiled and reviewed by the development panel. Discussion and consensus resulted in revision to the draft document prior to publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The levels of evidence supporting the recommendations (Ia, Ib, IIa, IIb, III, IV) are defined at the end of the "Major Recommendations" field.

Practice Recommendations

Patient Empowerment and Education

Recommendation 1.0

All patients with diabetic foot ulcer(s) (PWDFU) or caregivers should have an understanding of their condition and the resources available to optimize their general health, diabetes management, and ulcer care.

(Level of Evidence = Ia)

Recommendation 1.1

Education is essential as an empowerment strategy for diabetes self-management and prevention or reduction of complications.

(Level of Evidence = IV)

Recommendation 1.2

Education is based on identified individual needs, risk factors, ulcer status, available resources, and ability to heal.

(Level of Evidence = IV)

Holistic Assessment

Recommendation 2.0

Complete and document a health history, including diabetes management, allergies, medications, functional assessment, and physical examination (vascular status, infection, callus, neuropathy, foot deformity/pressure, ulcer).

(Level of Evidence = Ib-IV)

Vascular Status

Recommendation 2.1

Clinically assess bilateral lower extremities for vascular supply and facilitate appropriate diagnostic testing.

(Level of Evidence = IIb-IV)

Infection

Recommendation 2.2

Assess all patients with diabetic foot ulcers for signs and symptoms of infection and facilitate appropriate diagnostic testing and treatment.

(Level of Evidence = IIa)

Neuropathy

Recommendation 2.3

Identify peripheral neuropathy by assessing for sensory, autonomic, and motor (S.A.M.) changes.

(Level of Evidence = II-IV)

Foot Deformity and Pressure

Recommendation 2.4

Assess for foot pressure, deformity, gait, footwear, and devices. Facilitate appropriate referrals.

(Level of Evidence = Ia-IV)

Foot Ulcer Assessment

Recommendation 3.0

Describe and document the ulcer characteristics.

(Level of Evidence = IV)

Recommendation 3.1

Identify the location, length, width, depth and classify the ulcer(s).

(Level of Evidence = Ia-IV)

Recommendation 3.2

Assess ulcer bed, exudate, odour, and peri-ulcer skin.

(Level of Evidence = IV)

Goals of Care

Recommendation 4.0

Define goals based on clinical findings, expert opinion, and patient preference.

(Level of Evidence = IV)

Recommendation 4.1

Determine the potential of the ulcer to heal.

(Level of Evidence = IV)

Recommendation 4.2

Develop goals mutually agreed upon by the patient and health care professionals.

(Level of Evidence = IV)

Management

Recommendation 5.0

Identify and optimize systemic, local, and extrinsic factors that can influence wound healing.

(Level of Evidence = IV)

Systemic Factors

Recommendation 5.1

Modify systemic factors and co-factors that may interfere with or impact on healing.

(Level of Evidence = IV)

Local Factors

Recommendation 5.2

Provide local wound care considering debridement, infection control, and a moist wound environment.

(Level of Evidence = Ia-III)

Extrinsic Factors

Recommendation 5.3

Provide pressure redistribution.

(Level of Evidence = IIa)

Non-Healing Diabetic Foot Wounds

Recommendation 5.4

Evaluate and implement treatment options for non-healable wounds.

(Level of Evidence = IV)

Evaluation

Recommendation 6.0

Evaluate the impact and effectiveness of the treatment plan.

(Level of Evidence = IV)

Reassess

Recommendation 6.1

Reassess for additional correctable factors if healing does not occur at the expected rate.

(Level of Evidence = III - IV)

Other Therapies

Recommendation 6.2

Consider the use of biological agents, adjunctive therapies, and/or surgery if healing has not occurred at the expected rate. Review each specific modality for recommendations.

(Level of Evidence = Ia-IV)

Education Recommendations

Continuing Professional Development

Recommendation 7.0

Nurses and other members of the interdisciplinary team need specific knowledge and skills in order to competently assess and participate in the treatment of diabetic foot ulcers.

(Level of Evidence = IV)

Curriculum Support and Resources

Recommendation 8.0

Educational institutions are encouraged to incorporate the Registered Nurses Association of Ontario (RNAO) Nursing Best Practice Guideline *Assessment and Management of Foot Ulcers for People with Diabetes* into basic RN, RPN, MD and allied health professional curricula.

(Level of Evidence = IV)

Organization & Policy Recommendations

System Support

Recommendation 9.0

Nursing best practice guidelines can be successfully implemented only where there are adequate planning, resources, organizational and administrative support, as well as appropriate facilitation. Organizations may wish to develop a plan for implementation that includes:

- An assessment of organizational readiness and barriers to education
- Involvement of all members (whether in a direct or indirect supportive function) who will contribute to the implementation process
- Dedication of qualified individual(s) to provide the support needed for the development and implementation process
- Ongoing opportunities for discussion and education to reinforce the importance of best practices
- Opportunities for reflection on personal and organizational experience in implementing guidelines

In this regard, RNAO (through a panel of nurses, researchers and administrators) has developed the *Toolkit: Implementation of Clinical Practice Guidelines*, based on available evidence, theoretical perspectives and consensus. The RNAO strongly recommends the use of this *Toolkit* for guiding the implementation of the best

practice guideline on *Assessment and Management of Foot Ulcers for People with Diabetes*.

(Level of Evidence = IV)

Resources

Recommendation 9.1

Organizations are encouraged to develop policies that acknowledge and designate human, material, and fiscal resources to support the nurse and the interdisciplinary team in diabetic foot ulcer management.

(Level of Evidence = IV)

Team Development

Recommendation 9.2

Organizations are encouraged to establish and support an interdisciplinary, inter-agency team comprised of interested and knowledgeable persons to address and monitor quality improvement in the management of diabetic foot ulcers.

(Level of Evidence = IV)

Partnerships

Recommendation 9.3

Organizations are encouraged to work with community and other partners to develop a process to facilitate patient referral and access to local diabetes resources and health professionals with specialized knowledge in diabetic foot ulcer management.

(Level of Evidence = IV)

Financial Support

Recommendation 9.4

Organizations are encouraged to advocate for strategies and funding to assist patients in obtaining appropriate pressure redistribution devices.

(Level of Evidence = IV)

Advocacy

Recommendation 9.5

Organizations are encouraged to advocate for an increase in the availability and accessibility of diabetic foot ulcer care for all residents of Ontario.

(Level of Evidence = IV)

Definitions:

Levels of Evidence

Ia Evidence obtained from meta-analysis or systematic review of randomized controlled trials

Ib Evidence obtained from at least one randomized controlled trial

IIa Evidence obtained from at least one well-designed controlled study without randomization

IIb Evidence obtained from at least one other type of well-designed quasi-experimental study, without randomization

III Evidence obtained from well-designed non-experimental descriptive studies, such as comparative studies, correlation studies, and case studies

IV Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for the pathway to diabetic foot ulcers

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Accurate and adequate assessment and management of patients with established diagnosis of diabetic foot ulcers

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- This nursing best practice guideline is a comprehensive document providing resources necessary for the support of evidence-based nursing practice. The document needs to be reviewed and applied, based on the specific needs of the organization or practice setting/environment, as well as the needs and wishes of the client. Guidelines should not be applied in a "cookbook" fashion but used as a tool to assist in decision making for individualized client care, as well as ensuring that appropriate structures and supports are in place to provide the best possible care.
- It is acknowledged that individual competencies of nurses vary between nurses and across categories of nursing professionals (registered nurses [RNs] and registered practical nurses [RPNs]) and are based on knowledge, skills, attitudes and judgement enhanced over time by experience and education. It is expected that individual nurses will perform only those aspects of care for which they have received appropriate education and experience. Both registered nurses and registered practical nurses should seek consultation in instances where the patient's care needs surpass the individual nurse's ability to act independently.
- Caring for patients with diabetic foot ulcers is an interdisciplinary endeavour. Effective care depends on a coordinated interdisciplinary approach incorporating ongoing communication between health professionals and patients. It is however acknowledged that personal preferences and unique needs as well as the personal and environmental resources of each individual patient must always be kept in mind.
- These best practice guidelines are related only to nursing practice and not intended to take into account fiscal efficiencies. These guidelines are not binding for nurses and their use should be flexible to accommodate client/family wishes and local circumstances. They neither constitute a liability nor discharge from liability. While every effort has been made to ensure the accuracy of the contents at the time of publication, neither the authors nor the Registered Nurses Association of Ontario (RNAO) give any guarantee as to the accuracy of the information contained in them nor accept any liability, with respect to loss, damage, injury or expense arising from any such errors or omission in the contents of this work. Any reference throughout the document to specific pharmaceutical products as examples does not imply endorsement of any of these products.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Best practice guidelines can only be successfully implemented if there are: adequate planning, resources, organizational and administrative support as well as appropriate facilitation. Registered Nurses Association of Ontario (RNAO), through a panel of nurses, researchers and administrators has developed the *Toolkit: Implementation of Clinical Practice Guidelines* based on available evidence, theoretical perspectives and consensus. The *Toolkit* is recommended for

guiding the implementation of any clinical practice guideline in a health care organization.

The *Toolkit* provides step-by-step directions to individuals and groups involved in planning, coordinating, and facilitating the guideline implementation. Specifically, the *Toolkit* addresses the following key steps in implementing a guideline:

1. Identifying a well-developed, evidence-based clinical practice guideline
2. Identification, assessment and engagement of stakeholders
3. Assessment of environmental readiness for guideline implementation
4. Identifying and planning evidence-based implementation strategies
5. Planning and implementing evaluation
6. Identifying and securing required resources for implementation

Implementing guidelines in practice that result in successful practice changes and positive clinical impact is a complex undertaking. The *Toolkit* is one key resource for managing this process.

Evaluation and Monitoring

Organizations implementing the recommendations in this nursing best practice guideline are encouraged to consider how the implementation and its impact will be monitored and evaluated. A table found in the original guideline document, based on a framework outlined in the Registered Nurses Association of Ontario *Toolkit: Implementation of Clinical Practice Guidelines* (2002b), illustrates some indicators for monitoring and evaluation.

Implementation Strategies

The Registered Nurses Association of Ontario and the guideline development panel have compiled a list of implementation strategies to assist health care organizations or health care disciplines who are interested in implementing this guideline. See the original guideline document for a summary of strategies.

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms
Clinical Algorithm
Patient Resources
Quick Reference Guides/Physician Guides
Tool Kits

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Registered Nurses Association of Ontario (RNAO). Assessment and management of foot ulcers for people with diabetes. Toronto (ON): Registered Nurses Association of Ontario (RNAO); 2005 Mar. 112 p. [193 references]

ADAPTATION

The Registered Nurses Association of Ontario (RNAO) panel selected the following guidelines to adapt and modify for the current guideline:

- Australian Centre for Diabetes Strategies. (2001). National evidence based guidelines for the management of type 2 diabetes mellitus--Draft for public consultation. 6 April 2001 for the identification & management of diabetic foot disease. Australian Centre for Diabetes Strategies [Electronic version].
- Clinical Resource Efficiency and Support Team (CREST). (1998). Guidelines for the management of the diabetic foot: recommendations for practice. [Electronic version].
- American College of Foot and Ankle Surgeons. (2000). Diabetic foot disorders: a clinical practice guideline. [Electronic version].
- Royal College of General Practitioners. (2000) Clinical guidelines and evidence review for type 2 diabetes: prevention and management of foot problems. [Electronic version].
- Inlow, S., Orsted, H., & Sibbald, R.G. (2000). Best practices for the prevention, diagnosis and treatment of diabetic foot ulcers. *Ostomy/Wound Management, 46*(11),55-68.
- Ministry of Health Malaysia (2003). Clinical practice guidelines: management of diabetic foot. [Electronic version].
- Royal Melbourne Hospital (2002). Evidence based guidelines for the inpatient management of acute diabetes related foot complications. Melbourne Health [Electronic version].

DATE RELEASED

2005 Mar

GUIDELINE DEVELOPER(S)

Registered Nurses Association of Ontario - Professional Association

SOURCE(S) OF FUNDING

Funding was provided by the Ontario Ministry of Health and Long Term Care.

GUIDELINE COMMITTEE

Not stated

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Declarations of interest and confidentiality were made by all members of the guideline development panel. Further details are available from the Registered Nurses Association of Ontario.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Registered Nurses Association of Ontario (RNAO) Web site.

Print copies: Available from the Registered Nurses Association of Ontario (RNAO), Nursing Best Practice Guidelines Project, 158 Pearl Street, Toronto, Ontario M5H 1L3.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Summary of recommendations. Assessment and management of foot ulcers for people with diabetes. Toronto (ON): Registered Nurses Association of Ontario (RNAO); 2005 Mar. 3 p. Electronic copies: Available in Portable Document Format (PDF) from the Registered Nurses Association of Ontario (RNAO) Web site.
- Toolkit: implementation of clinical practice guidelines. Toronto (ON): Registered Nurses Association of Ontario (RNAO); 2002 Mar. 88 p. Electronic copies: Available in Portable Document Format (PDF) from the Registered Association of Ontario (RNAO) Web site.

Print copies: Available from the Registered Nurses Association of Ontario (RNAO), Nursing Best Practice Guidelines Project, 158 Pearl Street, Toronto, Ontario M5H 1L3.

PATIENT RESOURCES

The following are available:

- Patient information booklet. Charcot arthropathy. 2002. 24 p. Electronic copies: Available in Portable Document Format (PDF) from the Registered Nurses Association of Ontario (RNAO) Web site.
- Appendix F: Diabetic foot care--patient handout and checklist Assessment and management of foot ulcers for people with diabetes. Toronto (ON): Registered Nurses Association of Ontario (RNAO); 2005 Mar. 2 p. Electronic copies: Available in Portable Document Format (PDF) from the Registered Nurses Association of Ontario (RNAO) Web site.

Print copies: Available from the Registered Nurses Association of Ontario (RNAO), Nursing Best Practice Guidelines Project, 158 Pearl Street, Toronto, Ontario M5H 1L3.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This summary was completed by ECRI on June 3, 2005. The updated information was verified by the guideline developer on June 21, 2005.

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