Complete Summary

GUIDELINE TITLE

Reducing foot complications for people with diabetes.

BIBLIOGRAPHIC SOURCE(S)

Registered Nurses Association of Ontario (RNAO). Reducing foot complications for people with diabetes. Toronto (ON): Registered Nurses Association of Ontario (RNAO); 2004 Mar. 80 p. [63 references]

GUIDELINE STATUS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

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SCOPE

DISEASE/CONDITION(S)

Foot complications including foot ulceration and/or amputation

GUIDELINE CATEGORY

Management
Risk Assessment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Nursing

INTENDED USERS

Advanced Practice Nurses
Nurses

GUIDELINE OBJECTIVE(S)

To support nurses as they help people with diabetes reduce their risk of foot complications. Specifically, this guideline assists nurses who are not specialists in diabetes care to:

- Conduct a risk assessment for foot ulcers
- Provide basic education for prevention of foot ulcers for all clients with diabetes
- Implement appropriate interventions when clients are assessed as higher risk for foot ulcers and/or amputations

TARGET POPULATION

Adults with diabetes who are at risk for developing foot complications

INTERVENTIONS AND PRACTICES CONSIDERED

Risk Assessment/Prognosis

1. Annual foot examinations
2. Assessment of risk factors, including history of previous foot ulcers, sensation, structural and biomechanical abnormalities, circulation, and self-care and knowledge
3. Risk classification

Management

Patient education

MAJOR OUTCOMES CONSIDERED

Incidence of foot ulceration and amputation

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

An initial database search for existing diabetes guidelines was conducted in early 2001 by an external company that specializes in searches of the literature for

health related organizations, researchers, and consultants. A subsequent search of the MEDLINE, Embase, and CINAHL databases for articles published from January 1, 1998 to February 28, 2001 was conducted using the following search terms and key words: "diabetes," "diabetes education," "self-care," "self-management," "practice guideline(s)," "clinical practice guideline(s)," "standards," "consensus statement(s)," "consensus," "evidence-based guidelines," and "best practice guidelines." In addition, a search of the Cochrane Library database for systematic reviews was conducted concurrently using the above search terms.

A metacrawler search engine (www.metacrawler.com) plus other available information provided by the project team was used to create a list of Web sites known for publishing or storing clinical practice guidelines.

Panel members were asked to review personal archives to identify guidelines not previously identified. In a rare instance, a guideline was identified by panel members and not found through the database or Internet search. These guidelines were developed by local groups and had not been published to date. Results of this strategy revealed no additional clinical practice guidelines.

This search method revealed 16 guidelines, several systematic reviews, and numerous articles related to diabetes education. The final step in determining whether the clinical practice guideline would be critically appraised was to apply the following criteria:

- Guideline was in English
- Guideline was dated 1998 or later
- 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.

At a later date, the panel was able to identify one additional existing guideline that was also added for the purpose of ensuring content clarity as well as currency of the recommendations.

After reviewing the existing guidelines, the panel decided to focus the scope of their work on reducing the risk of foot complications for people with diabetes. This preventable problem is serious as well as costly, and there is potential for all nurses to contribute to risk reduction. A second phase to the literature search was required, as many of the issues relevant for nursing practice were not sufficiently addressed in the existing guidelines.

NUMBER OF SOURCE DOCUMENTS

Five guidelines were selected as foundation documents for this guideline.

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

Level Ia: Evidence obtained from meta-analysis of randomized controlled trials, plus consensus

Level Ib: Evidence obtained from at least one randomized controlled trial, plus consensus

Level II: Evidence obtained from at least one well-designed controlled study without randomization or evidence obtained from at least one other type of well-designed quasi-experimental study, plus consensus

Level III: Evidence obtained from well-designed nonexperimental descriptive studies, such as comparative studies, correlation studies, and case studies, plus consensus

Level IV: Evidence obtained from expert committee reports of opinions and/or clinical experiences of respected authorities, plus consensus

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Following the initial literature search, members of the development panel critically appraised eight guidelines using the "Appraisal Instrument for Clinical Guidelines" from Cluzeau et al. (1997). This instrument allows for evaluation in three key dimensions: rigour, content and context, and application. From this appraisal process, four documents were identified as high quality, relevant guidelines and were selected as "foundation" documents for this guideline.

Following a second phase of the literature search, a critique of systematic review articles, technical reviews, and other pertinent literature was conducted to update and/or validate recommendations in the existing guidelines.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

In February of 2001, a panel of nurses with expertise in diabetes care, education, and research representing institutional, community, and academic settings was convened under the auspices of the Registered Nurses Association of Ontario (RNAO). The first task of the group was to review existing clinical practice guidelines in order to build on the current understanding of diabetes care and management and to reach consensus on the scope of the guideline.

The first strategy undertaken to develop the recommendations was a review of the literature to identify risk factors for diabetes foot complications that were consistently supported by research studies utilizing strong methodologies. Once the panel identified the risk factors, small task groups were formed to further study each of the risk indicators. The small groups conducted an in-depth search for evidence to validate the risk factors, as well as to identify evidence-based processes for risk assessment. The subgroups further identified assessment tools, mechanisms, and/or educational resources for each of the risk factors. Through an iterative process of discussion and validation, consensus was reached on the final draft recommendations for the guideline.

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

Clinical Validation-Pilot Testing
External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

A draft document was submitted to a set of external stakeholders for review and feedback. Stakeholders represented various health care professional groups, clients and families, as well as professional associations. External stakeholders were asked to provide feedback using a questionnaire consisting of open and closed-ended questions. The results were compiled and reviewed by the development panel; discussion and consensus resulted in revisions to the draft document prior to pilot testing.

A pilot implementation practice setting was identified through a "Request for Proposal" (RFP) process. Practice settings in Ontario were asked to submit a proposal if they were interested in pilot testing the recommendations of the guideline. The proposals underwent an external review process and the successful applicant (practice setting) selected. This guideline was implemented by a hospital and a community care organization in northern Ontario between April 2002 and July 2003. Four participating medical/oncology hospital units located at two sites in one community participated, as did the diabetic education and care centre, located at a third site. Nurses participating from the community care organization were located in three geographically separate communities. An evaluation of the implementation process was conducted during this period by an evaluation team that was external to the pilot site.

The development panel reconvened following completion of the pilot to review the experiences of the pilot sites, consider the evaluation results and review any new

literature published since the initial development phase. All these sources of information were used to update and revise the document prior to publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary. The recommendations that follow are based on the previous version of the guideline.

Levels of evidence supporting the recommendations (Level Ia, Ib, II, III, IV) are defined at the end of the "Major Recommendations" field.

Practice Recommendations

Recommendation 1.0

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)*

Recommendation 1.1

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)*

Recommendation 2.0

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 biomechanical abnormalities
- Circulation
- Self-care behaviour and knowledge

(Level of Evidence IV)

Recommendation 3.0

Based on assessment of risk factors, clients should be classified as "lower" or "higher" risk for foot ulceration/amputation. *(Level of Evidence IV)*

Recommendation 4.0

All people with diabetes should receive basic foot care education. *(Level of Evidence Ib)*

Recommendation 4.1

Foot care education should be provided to all clients with diabetes and reinforced at least annually. *(Level of Evidence IV)*

Recommendation 5.0

Nurses in all practice settings should provide or reinforce basic foot care education, as appropriate. *(Level of Evidence IV)*

Recommendation 5.1

The basic foot care education for people with diabetes should include the following six elements:

- Awareness of personal risk factors
- Importance of at least annual inspection of feet by a health care professional
- Daily self inspection of feet
- Proper nail and skin care
- Injury prevention
- When to seek help or specialized referral

(Level of Evidence IV)

Recommendation 5.2

Education should be tailored to client´s current knowledge, individual needs, and risk factors. Principles of adult learning must be used. *(Level of Evidence IV)*

Recommendation 6.0

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)*

Education Recommendations

Recommendation 7.0 *(Level of Evidence IV)*

Nurses need knowledge and skills in the following areas in order to competently assess a client´s risk for foot ulcers and provide the required education and referral:

- Skills in conducting an assessment of the five risk factors
- Knowledge and skill in educating clients
- Knowledge of sources of local referral

Recommendation 8.0

Educational institutions should incorporate the Registered Nurses Association of Ontario (RNAO) Nursing Best Practice Guideline *Reducing Foot Complications for People with Diabetes* into basic nursing education curriculum as well as provide continuing education programs in this topic area. *(Level of Evidence IV)*

Organization and Policy Recommendations

Recommendation 9.0

Organizations should develop a policy that acknowledges and designates human and fiscal resources to support nursing´s role in assessment, education, and referral of clients for appropriate foot care. It is the organization´s responsibility to advocate with policy makers and develop policy that facilitates implementation. *(Level of Evidence IV)*

Recommendation 10.0

Organizations should ensure that resources for implementation are available to clients and staff. Examples of such resources include policies and procedures, documentation forms, educational materials, referral processes, workload hours, and monofilaments. *(Level of Evidence IV)*

Recommendation 11.0

Organizations should work with community partners to develop a process to facilitate client referral and access to local diabetes resources and health professionals with specialized knowledge in diabetes foot care. *(Level of Evidence IV)*

Recommendation 12.0

Organizations are encouraged to establish or identify a multidisciplinary, interagency team comprised of interested and knowledgeable persons to address and monitor quality improvement in diabetes foot complication prevention. *(Level of Evidence IV)*

Recommendation 13.0

Organizations should consult an infection control team to define appropriate care, maintenance, and replacement of the Semmes-Weinstein monofilament. Such a process may include setting up a protocol for the appropriate maintenance and replacement of the monofilaments. *(Level of Evidence IV)*

Recommendation 14.0

Organizations should advocate for strategies and funding to assist clients to obtain appropriate footwear and specialized diabetes education. For example, the inclusion of funding support through the Assistive Devices Program (ADP) for appropriate footwear and orthotics. *(Level of Evidence IV)*

Recommendation 15.0

Organizations should advocate for an increase in the availability and accessibility of diabetes care and education services for all residents of Ontario. *(Level of Evidence IV)*

Recommendation 16.0

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 a qualified individual to provide the support needed for the education 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

(Level of Evidence IV)

Refer to the "Description of the Implementation Strategy" field for more information.

Definitions:

Level Ia: Evidence obtained from meta-analysis of randomized controlled trials, plus consensus

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Level II: Evidence obtained from at least one well-designed controlled study without randomization or evidence obtained from at least one other type of well-designed quasi-experimental study, plus consensus

Level III: Evidence obtained from well-designed nonexperimental descriptive studies, such as comparative studies, correlation studies, and case studies, plus consensus

Level IV: Evidence obtained from expert committee reports of opinions and/or clinical experiences of respected authorities, plus consensus

CLINICAL ALGORITHM(S)

An algorithm is provided in the original guideline document for risk assessment.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence is provided for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

A program of risk assessment, self-care education, and regular reinforcement of self-care may reduce the incidence of foot ulceration and amputation.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- 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.
- 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 a 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 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. In this light, the Registered Nurses Association of Ontario (RNAO), through a panel of nurses, researchers, and administrators, has developed a *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 healthcare organization.

The "Toolkit" provides step-by-step directions to individuals and groups involved in planning, coordinating, and facilitating 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 an evaluation
6. Identifying and securing required resources for implementation and evaluation

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

IMPLEMENTATION TOOLS

Clinical Algorithm
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

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Registered Nurses Association of Ontario (RNAO). Reducing foot complications for people with diabetes. Toronto (ON): Registered Nurses Association of Ontario (RNAO); 2004 Mar. 80 p. [63 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 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

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Guideline Development Panel Members:

Cheri Ann Hernandez, RN, PhD, CDE
Team Leader
Associate Professor
Faculty of Nursing, University of Windsor
Windsor, Ontario

Catherine A. Arnott, RPN
President –
Arnott Lightens Your Load, Inc/Footloose
Certified Footcare Nurse/RPNAO Educator
Toronto, Ontario

Grace Bradish, RN, MScN, CDE
Advanced Practice Nurse
Integrated Cancer Program
London Health Sciences Centre
London, Ontario

Sharon Brez, RN, BScN, MA(Ed), CDE
Advanced Practice Nurse
The Ottawa Hospital
Ottawa, Ontario

Lillian Delmas, RN, BScN, CRRN
Nurse Clinician
The Rehabilitation Centre
Ottawa, Ontario

Penny Fredrick, RN, CDE
Diabetes Nurse Educator
Peterborough Regional Health Centre
Peterborough, Ontario

Robin Hokstad, RN, CDE
Diabetes Nurse Educator
Nipissing Diabetes Resource Centre
North Bay, Ontario

Margaret Hume, RN, MScN, CDE
Clinical Nurse Specialist (retired)
Endocrine-Metabolic Clinic
University Health Network
Toronto, Ontario

Sharon Jaspers, RN, HBScN, CDE
Diabetes Nurse Educator
Diabetes Health Thunder Bay
Thunder Bay, Ontario

Helen Jones, RN, MSN, CDE
Clinical Nurse Specialist/Manager
Leadership Sinai Centre for Diabetes
Mount Sinai Hospital
Toronto, Ontario

Barbara Martin, RN, CDE
Clinic Nurse/Diabetes Educator
Gane Yohs Community Health Centre
Six Nations, Ontario

Heather McConnell, RN, BScN, MA(Ed)
RNAO Project Staff – Facilitator
Project Manager, Nursing Best Practice Guidelines Project
Registered Nurses Association of Ontario
Toronto, Ontario

Alwyn Moyer, RN, MSc(A), PhD
Health Care Consultant
Adjunct Professor, University of Ottawa
Ottawa, Ontario

Ruth Ruttan, RN, CDE
Foot Care Educator
President – Ruth Ruttan & Associates
Sharon, Ontario

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

Note: This guideline has been updated. The National Guideline Clearinghouse (NGC) is working to update this summary.

GUIDELINE AVAILABILITY

Electronic copies of the addended guideline: 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 is available:

- 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 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.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on September 20, 2004. The information was verified by the guideline developer on October 14, 2004.

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