



Registered Nurses' Association of Ontario L'Association des infirmières et infirmières autorisés de l'Ontario

NURSING BEST PRACTICE GUIDELINES PROGRAM





# Greetings from Doris Grinspun Executive Director Registered Nurses' Association of Ontario

It is with great excitement that the Registered Nurses' Association of Ontario (RNAO) disseminates this nursing best practice guideline to you. Evidence-based practice supports the excellence in service that nurses are committed to deliver in our day-to-day practice.

We offer our endless thanks to the many institutions and individuals that are making RNAO's vision for Nursing Best Practice Guidelines (NBPGs) a reality. The Government

of Ontario recognized RNAO's ability to lead this program and is providing multi-year funding. Tazim Virani – NBPG program director – with her fearless determination and skills, is moving the program forward faster and stronger than ever imagined. The nursing community, with its commitment and passion for excellence in nursing care, is providing the knowledge and countless hours essential to the creation and evaluation of each guideline. Employers have responded enthusiastically to the request for proposals (RFP), and are opening their organizations to pilot test the NBPGs.

Now comes the true test in this phenomenal journey: Will nurses utilize the guidelines in their day-to-day practice?

Successful uptake of these NBPGs requires a concerted effort of four groups: nurses themselves, other healthcare colleagues, nurse educators in academic and practice settings, and employers. After lodging these guidelines into their minds and hearts, knowledgeable and skillful nurses and nursing students need healthy and supportive work environments to help bring these guidelines to life.

We ask that you share this NBPG, and others, with members of the interdisciplinary team. There is much to learn from one another. Together, we can ensure that Ontarians receive the best possible care every time they come in contact with us. Let's make them the real winners of this important effort!

RNAO will continue to work hard at developing and evaluating future guidelines. We wish you the best for a successful implementation!

Doris Grinspun, RN, MSN, PhD(cand), OOnt

Executive Director Registered Nurses' Association of Ontario

# How to Use this Document

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.

Nurses, other healthcare professionals and administrators who are leading and facilitating practice changes will find this document valuable for the development of policies, procedures, protocols, educational programs, assessments and documentation tools. It is recommended that the nursing best practice guidelines be used as a resource tool. Nurses providing direct client care will benefit from reviewing the recommendations, the evidence in support of the recommendations and the process that was used to develop the guidelines. However, it is highly recommended that practice settings/environments adapt these guidelines in formats that would be user-friendly for daily use. This guideline has some suggested formats for such local adaptation and tailoring.

Organizations wishing to use the guideline may decide to do so in a number of ways:

- Assess current nursing and healthcare practices using the recommendations in the guideline.
- Identify recommendations that will address identified needs or gaps in services.
- Systematically develop a plan to implement the recommendations using associated tools and resources.

RNAO is interested in hearing how you have implemented this guideline. Please contact us to share your story. Implementation resources will be made available through the RNAO website at <u>www.rnao.org/bestpractices</u> to assist individuals and organizations to implement best practice guidelines.

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Nursing Best Practice Guideline

# Assessment and Management of Foot Ulcers for People with Diabetes

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Stakeholders representing diverse perspectives were solicited for their feedback and the Registered Nurses' Association of Ontario wishes to acknowledge the following for their contribution in reviewing this Nursing Best Practice Guideline.

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Nursing Best Practice Guideline

# Assessment and Management of Foot Ulcers for People with Diabetes

#### Disclaimer

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 or 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.

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# Summary of Recommendations

	RECOMMENDATION *LEVEL C	OF EVIDENC
Practice Recon	nmendations	
Patient Empowerment and Education	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.	la
	1.1 Education is essential as an empowerment strategy for diabetes self-management and prevention or reduction of complications.	IV
	1.2. Education is based on identified individual needs, risk factors, ulcer status, available resources and ability to heal.	IV
Holistic Assessment	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).	lb – IV
Vascular Status	2.1 Clinically assess bilateral lower extremities for vascular supply and facilitate appropriate diagnostic testing.	IIb – IV
Infection	2.2 Assess all patients with diabetic foot ulcers for signs and symptoms of infection and facilitate appropriate diagnostic testing and treatment.	lla
Neuropathy	2.3 Identify peripheral neuropathy by assessing for sensory, autonomic II - and motor (S.A.M.) changes.	
Foot Deformity and Pressure	2.4 Assess for foot pressure, deformity, gait, footwear and devices. Facilitate appropriate referrals.	la – IV
Foot Ulcer	3.0 Describe and document the ulcer characteristics.	IV
Assessment	3.1 Identify the location, length, width, depth and classify the ulcer(s).	la – IV
	3.2 Assess ulcer bed, exudate, odour and peri-ulcer skin.	IV
Goals of Care	4.0 Define goals based on clinical findings, expert opinion and patient preference.	IV
	4.1 Determine the potential of the ulcer to heal.	IV
	4.2 Develop goals mutually agreed upon by the patient and healthcare professionals.	IV
Management	5.0 Identify and optimize systemic, local and extrinsic factors that can influence wound healing.	IV
Systemic Factors	5.1 Modify systemic factors and co-factors that may interfere with or impact on healing.	IV
Local Factors	5.2 Provide local wound care considering debridement, infection control and a moist wound environment.	la-III
Extrinsic Factors	5.3 Provide pressure redistribution.	lla

\*See page 12 for details regarding "Interpretation of Evidence".

	RECOMMENDATION LEVEL	OF EVIDENC
Non-healing diabetic foot wounds	5.4 Evaluate and implement treatment options for non-healable wounds.	IV
Evaluation	6.0 Evaluate the impact and effectiveness of the treatment plan.	IV
Reassess	<b>6.1</b> Reassess for additional correctable factors if healing does not occur at the expected rate.	III-IV
Other therapies	<b>6.2</b> 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.	la-IV
Education Reco	ommendations	
Continuing Professional Development	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.	IV
Curriculum Support and Resources	8.0 Educational institutions are encouraged to incorporate the 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.	IV
Organization &	& Policy Recommendations	
System Support	<ul> <li>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: <ul> <li>An assessment of organizational readiness and barriers to education.</li> <li>Involvement of all members (whether in a direct or indirect supportive function) who will contribute to the implementation process.</li> <li>Dedication of qualified individual(s) to provide the support needed for the development and implementation process.</li> <li>Ongoing opportunities for discussion and education to reinforce the importance of best practices.</li> <li>Opportunities for reflection on personal and organizational experience in implementing guidelines.</li> </ul> </li> <li>In this regard, RNAO (through a panel of nurses, researchers and administrators) has developed the <i>Toolkit: Implementation of Clinical Practice Guidelines</i>, based on available evidence, theoretical perspectives and consensus. The RNAO strongly recommends the use of this <i>Toolkit</i> for guiding the implementation of the best practice guideline on <i>Assessment and Management of Foot Ulcers for People with Diabetes</i>.</li> </ul>	IV
Resources	<ul> <li>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.</li> </ul>	IV
Team Development	<b>9.2</b> 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.	IV

	RECOMMENDATION LEVEL	OF EVIDENCE
Partnerships	<b>9.3</b> 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.	IV
Financial Support	<b>9.4</b> Organizations are encouraged to advocate for strategies and funding to assist patients in obtaining appropriate pressure redistribution devices.	IV
Advocacy	<b>9.5</b> Organizations are encouraged to advocate for an increase in the availability and accessibility of diabetic foot ulcer care for all residents of Ontario.	IV

# Interpretation of Evidence

# Levels of Evidence

- la Evidence obtained from meta-analysis or systematic review of randomized controlled trials.
- lb Evidence obtained from at least one randomized controlled trial.
- lla 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.

# Responsibility for Guideline Development

**The Registered Nurses' Association of Ontario (RNAO),** with funding from the Government of Ontario, has embarked on a multi-year program of nursing best practice guideline development, pilot implementation, testing, evaluation and dissemination. In this fifth cycle of the program, one of the areas of emphasis is on the assessment and management of diabetic foot ulcers. This guideline was developed by a panel of nurses convened by the RNAO conducting its work independent of any bias or influence from the Government of Ontario.

# Purpose & Scope

**Best practice guidelines (BPG)** are systematically developed statements to assist nurses and patients in decision-making about appropriate healthcare (Field & Lohr, 1990). This guideline has been developed to address the question of how to assess and manage patients with established diagnosis of diabetic foot ulcers. It will provide direction to practicing nurses (RNs and RPNs) who provide care in all healthcare settings to patients (>15 years old) with type 1 and/or type 2 diabetes who have diabetic foot ulcers.

The guideline focuses its recommendations on four areas: (1) Practice Recommendations directed at the nurse and other interdisciplinary healthcare professionals; (2) Educational Recommendations directed at the competencies required for practice; (3) Organization and Policy Recommendations directed at practice settings and the environment in order to facilitate nurses' practice and (4) Evaluation and monitoring indicators.

It is acknowledged that individual competencies of nurses vary between nurses and across categories of nursing professionals (RNs and 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 RNs and RPNs 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.

# **Guideline Development Process**

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

A search of the literature for systematic reviews, clinical practice guidelines, relevant articles and websites was conducted. See Appendix A for a detailed outline of the search strategy employed.

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 the following seven guidelines.

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].

Available: http://www.diabetes.net.au/PDF/evidence\_based\_healtcare/FootProblems.pdf

- CREST Clinical Resource Efficiency and Support Team (1998). Guidelines for the management of the diabetic foot: Recommendations for practice. Clinical Resource Efficiency and Support Team [Electronic version]. Available: <u>http://www.crestni.org.uk/publications/diabetic\_foot.pdf</u>
- Frykberg, R. G., Armstrong, D. G., Giurini, J., Edwards, A., Kravette, M., Kravitz, S. et al. (2000). Diabetic foot disorders: A clinical practice guideline. American College of Foot and Ankle Surgeons [Electronic version]. Available: <u>http://www.acfas.org/diabeticcpg.html</u>

- Hutchinson, A., McIntosh, A., Feder, R.G., Home, P. D., Mason, J., O'Keefee, C. et al. (2000). Clinical guidelines and evidence review for type 2 diabetes: Prevention and management of foot problems. Royal College of General Practitioners [Electronic version]. Available: <a href="http://www.rcgp.org.uk/rcgp/clinspec/guidelines/diabetes/contents.asp">http://www.rcgp.org.uk/rcgp/clinspec/guidelines/diabetes/contents.asp</a>
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- Ministry of Health Malaysia (2003). Clinical practice guidelines: Management of diabetic foot. Ministry of Health Malaysia [Electronic version]. Available: http://www.acadmed.org.my/cpg/Draft%20CPG%20%20management%20of%20diabetic%20foot.pdf
- Royal Melbourne Hospital (2002). Evidence based guidelines for the inpatient management of acute diabetes related foot complications. Melbourne Health [Electronic version]. Available: http://www.mh.org.au/ClinicalEpidemiology/new\_files/Foot%20guideline%20supporting.pdf

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.

An advisory panel was recruited to review and provide feedback on the draft recommendations. The advisory panel represented physicians, other healthcare disciplines as well as professional associations. An acknowledgement of the advisory panel is provided at the front of this document. Feedback on the recommendations was obtained from healthcare 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 AGREE instrument (AGREE Collaboration, 2001). An acknowledgement of these reviewers is provided at the front of this document. Stakeholders represented healthcare consumers, various healthcare 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.

# **Definition of Terms**

An additional Glossary of Terms related to clinical aspects of the document is located in Appendix B.

**Clinical Practice Guidelines or Best Practice Guidelines:** Systematically developed statements (based on best available evidence) to assist practitioner and patient decisions about appropriate healthcare for specific clinical (practice) circumstances (Field & Lohr, 1990).

**Consensus:** A process for making policy decisions, not a scientific method for creating new knowledge. At its best, consensus development merely makes the best use of available information, be that of scientific data or the collective wisdom of the participants (Black et al., 1999).

**Education Recommendations:** Statements of educational requirements and educational approaches/strategies for the introduction, implementation and sustainability of the best practice guideline.

**Evidence:** "An observation, fact or organized body of information offered to support or justify inferences or beliefs in the demonstration of some proposition or matter at issue" (Madjar & Walton, 2001, p.28).

**Meta-Analysis:** The use of statistical methods to summarize the results of independent studies, thus providing more precise estimates of the effects of healthcare than those derived from the individual studies included in a review (Alderson, Green & Higgins, 2004).

**Organization & Policy Recommendations:** Statements of conditions required for a practice setting that enable the successful implementation of the best practice guideline. The conditions for success are largely the responsibility of the organization, although they may have implications for policy at a broader government or societal level.

**Practice Recommendations:** Statements of best practice directed at the practice of healthcare professionals that are evidence-based.

**Randomized Controlled Trial:** For the purposes of this guideline, a study in which subjects are assigned to conditions on the basis of chance, and where at least one of the conditions is a control or comparison condition.

**Stakeholder:** A stakeholder is an individual, group, or organization with a vested interest in the decisions and actions of organizations that may attempt to influence decisions and actions (Baker et al., 1999). Stakeholders include all individuals or groups who will be directly or indirectly affected by the change or solution to the problem. Stakeholders can be of various types, and can be divided into opponents, supporters, and neutrals (Ontario Public Health Association, 1996).

**Systematic Review:** Application of a rigorous scientific approach to the preparation of a review article (National Health and Medical Research Council, 1998). Systematic reviews establish where the effects of healthcare are consistent and research results can be applied across populations, settings, and differences in treatment (e.g., dose); and where effects may vary significantly. The use of explicit, systematic methods in reviews limits bias (systematic errors) and reduces chance effects, thus providing more reliable results upon which to draw conclusions and make decisions (Alderson et al., 2004).

# **Background Context**

**Diabetes mellitus is serious,** complex, life-long condition affecting 4.2% of the world's population and 1.5 million Canadians (Boulton, Meneses, & Ennis, 1999; Canadian Diabetes Association (CDA), 1998). Diabetes seriously burdens individuals, their families and society. It is estimated that the cost of diabetes and its chronic complications range from 4.6 to 13.7 billion U.S. dollars annually (Dawson, Gomes, Gerstein, Blanchard & Kahler, 2002; Gordois, Scuffham, Shearer, Oglesby & Tobian, 2003). The aboriginal (First Nations, Metis and Inuit) population in Canada demonstrates a prevalence of type 2 diabetes that is at least three times the national average (Health Canada, 2000; 2002; Indian and Inuit Health Committee & Canadian Pediatric Society, 1994). This increased incidence is reflected in high rates across all age groups. It is important to note that Aborignal ancestry has been identifed as an independent risk factor for diabetes and despite this fact, little is known of this particular group (Health Canada, 2000; 2002; Young, 2003; Young, Szathmary, Evers & Wheatley, 1990).

There are two major classifications of diabetes; Type 1 and Type 2. Type 1 diabetes, which affects 10-15% of all people with diabetes, is primarily the result of the inability to produce insulin due to beta cell destruction in the pancreas. While Type I diabetes accounts for fewer individuals with diabetes, it results in a disproportionately higher frequency of diabetes related complications. Type 2 diabetes, affecting over 80% of those diagnosed with diabetes, results from a combination of insufficient insulin production and/or resistance of the cells of the body to the actions of insulin (RNAO, 2004).

Control of blood glucose levels is paramount to minimizing complications related to diabetes (Diabetes Control and Complication Trial (DCCT) Research Group, 1993; United Kingdom Prospective Diabetes Study (UKPDS) Group 33, 1998). This is achieved through lowering serum glucose using oral hypoglycemic agents, and/or subcutaneous injections of insulin, dietary restriction and regular exercise. Other factors contributing to delayed onset of complications include control of hypertension, hyperlipidemia and hyperinsulinemia. Unfortunately, these treatments may not completely control the progression of diabetes-related changes including neuropathy (CDA, 1998).

Regardless of the type of diabetes classification, over time, failure to achieve optimal glycemic control can cause damage to the body's small and large blood vessels and nerves. Damage to these vessels and nerves can affect all organs in the body; however, the eyes, heart, kidneys, and skin are most commonly affected in patients with diabetes.

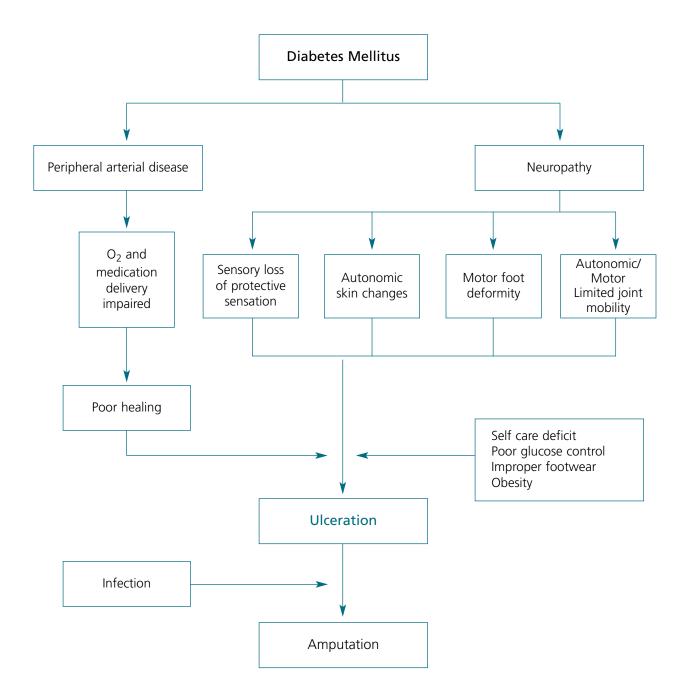
These changes along with those previously mentioned lead to a cascade of events resulting in changes to the foot itself. According to Boulton, Kirsner, & Vileikyte (2004), the "triad of neuropathy, deformity and trauma is present in almost two thirds of patients with foot ulcers" (p. 49). The structural changes discussed along with vascular insufficiency, infection and pressure predispose the person with diabetes (PWD) to develop a foot ulceration (See Figure 1: Pathway to Diabetic Foot Ulcers).

In industrialized countries, diabetes is the leading cause of non-traumatic, lower extremity amputations (American Diabetes Association (ADA), 1999; Foundation for Accountability, 1996). Approximately 15% of all persons with diabetes (PWD) will develop a foot ulcer at some time during the course of their disease (ADA, 1999). Eighty-five percent of lower extremity amputations are preceded by foot ulcers (Reiber, Boyko & Smith, 1995). Of these, 14% to 24% will proceed to major amputation (Ramsey, Newton, Blough, McCulloch, Sandhu, Reiber et al., 1999). Neuropathy is most commonly associated with the development of diabetic foot ulcers, but the presence or co-existence of peripheral vascular disease and infection can also lead to skin breakdown. It is widely known that diabetic foot ulceration is a significant end-stage complication of diabetes (Boulton et al., 1999). Moreover, the risk of amputation increases 10-fold in patients with diabetes and concurrent end–stage renal disease (ESRD)(Eggers, Gohdes & Pugh, 1999).

It should be emphasized that the most common offending agent or cause of traumatic foot ulceration is footwear (Birke, Patout Jr. & Foto, 2000; Tyrrell, 2002). The use of ill-fitting shoes are instrumental in the development of blisters, callus and corns which can lead to ulceration in patients with diabetes. In particular, peripheral neuropathy in people with diabetes leads to a cascade of events resulting in changes to the foot itself. These changes, along with those previously mentioned, predispose the patient with diabetes to the development of ulceration.

Given the data on the burden of illness and the significant long-term impact on health of people with diabetes, care of persons with diabetic foot ulcers demands a systematic, team approach from healthcare professionals (Dargis, Pantlejeva, Jonushaite, Vileikyte & Boulton, 1999; Sumpio, 2000). The development panel recognizes the complexity of the treatment of individuals with diabetic foot ulcers, and acknowledges the stressful conditions in which nurses work, in particular, the demands on the time of nurses in various practice settings. To this end, the recommendations serve as a guide for nurses to identify and assess patients in high risk groups who would benefit from specialized wound care. A specialized interdisciplinary team should work closely with patients and their families to address the complex lifestyle, self-care and multiple treatment demands of patients who have a diabetic foot ulcer. It is acknowledged that this level of care is not yet accessible to or accessed by all people with diabetes. Moreover, fewer patients with foot ulcerations receive optimal wound management (Boulton et al., 2004). Nurses can facilitate and positively influence wound healing outcomes by promoting, collaborating and participating in interdisciplinary care teams who follow best practice guidelines similar to those presented in this document.





Adapted with permission of Dr. M. E. Levin.

Levin, M. E. (2001). Pathogenesis and general management of foot lesions in the diabetic patient. In J. H. Bowker & M. A. Pfeifer (Eds.), *Levin and O'Neals The Diabetic Foot*. (6th ed.) (pp.222). St. Louis, MO: Mosby, Inc.

# *Guiding Principles in the Care* of Patients with Diabetic Foot Ulcers

- 1. Diabetic foot ulcers are complex wounds, best treated with a team approach.
- 2. Nurses and their interdisciplinary colleagues require knowledge and collaboration to provide care.
- **3**. Successful management of foot ulcers can significantly improve quality of life for patients with diabetes, their family and caregivers.
- 4. Patients are empowered through education and involvement in the planning and implementation of their care.
- 5. The V. I. P. principle (Vascular supply, Infection, and Pressure redistribution) guides the assessment and management of diabetic foot ulcers.
- 6. Nurses and their interdisciplinary colleagues demonstrate integration of the best evidence for practice and expertise in local wound care.
- 7. Patients with diabetes who are aware of their risk category and management strategies can reduce ulcer re-ocurrence. Nurses and their interdisciplinary colleagues have a role in educating their patients about reducing ulcer recurrence and further foot complications. Hence, it is highly recommended by the development panel to implement this guideline in conjuction with the RNAO (2004) Best Practice Guideline entitled *Reducing Foot Complications for People with Diabetes*. This guideline is available to download at www.rnao.org/bestpractices.
- 8. Ulcer healing of patients with diabetes, improvement of quality of life and reduction in amputation rate requires the successful implementation of a comprehensive foot ulcer program.
- 9. The development and implementation of a successful diabetic foot ulcer program involves collaboration with practice leaders, educators and administrators.
- 10. Diabetic foot ulcer program outcomes should be evaluated and benchmarked for continuous quality improvement.

# **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* =1a)

## **Discussion of Evidence:**

In order to address the many individual variables involved in learning, the process of educating patients with diabetes has become participative rather than didactic (Whittemore, 2000). Evidence supports educational intervention for improvement in foot care knowledge and behaviour in the short term for people with diabetes (Hutchinson et al., 2000; Valk, Kriegsman, & Assendelft, 2002). There is additional evidence to support that people with diabetes who are at a higher risk for foot ulceration significantly benefit from education and regular reinforcement of that education (ADA, 2001; CDA, 1998; 2003; Mason, O'Keefee, Hutchinson, McIntosh, Young & Booth, 1999a; The University of York – NHS Centre for Reviews and Dissemination, 1999; New Zealand Guidelines Group (NZGG), 2000). A three-fold increased amputation risk was demonstrated by Reiber, Pecoraro & Koepsell (1992) for those people with diabetes who had not received formal diabetes education, suggesting significant prevention is possible with appropriate teaching strategies.

Expert opinion supports the need for reinforcement of basic foot care education in patients with diabetes and established foot ulcers. Nurses, as the single largest group of health professionals working in a range of settings, are well positioned to monitor risk status for re-occurrence, identify new or deteriorating ulcers and provide and/or reinforce basic foot care education. They may act as the primary diabetes foot care educator, or as a link between patients and their primary care providers or within specialized diabetes care teams (RNAO, 2004).

### **Recommendation 1.1:**

Education is essential as an empowerment strategy for diabetes self-management and prevention or reduction of complications. (*Level of Evidence = IV*)

# **Discussion of Evidence:**

Diabetes education should be interactive, solution-focused and based on the experiences of the learner. It should be staged and tailored to meet individual needs and abilities. The education of patients should be in keeping with the principles of adult learning using a client-centred approach (Glasgow, 1999). The nurse should be sensitive to socioeconomic, cultural, psycho-social and other individual domains when planning all interventions.

Randomized controlled trials evaluating education for people with diabetes are of poor quality and have significant methodological issues (Valk, Kriegsman & Assendelft, 2004). The existing evidence, however, does indicate that foot care knowledge and patient behaviour is positively influenced, albeit for a short time period, and education may be of particular benefit to those patients at high risk (Valk et al., 2004). Group education and sustained long-term follow-up have both been shown to enhance knowledge and produce positive outcomes (CDA, 2003).

#### **Recommendation 1.2:**

Education is based on identified individual needs, risk factors, ulcer status, available resources and ability to heal. (*Level of Evidence* = *IV*)

## **Discussion of Evidence:**

As visible care providers across the continuum, nurses are in a unique position to promote the maintenance of healthy feet, identify problems at any stage, positively influence self-care practices, and refer higher risk individuals for expert care (RNAO, 2004).

There is evidence that diabetes self-care behaviours influence blood glucose control. Improved glycemic control facilitates healing of foot ulcers and delays and/or prevents diabetes related complications that further contribute to peripheral neuropathies and reduced lower extremity circulation (DCCT Research Group, 1993; RNAO, 2004; UKPDS Group 33, 1998).

The needs assessment should be the driving force for individual program planning and management. These assessments need to be tailored to determine appropriate allocation of personnel and resources to ensure the education and healthcare needs of the individual are met (ADA, 1999). Personal attitudes and cultural beliefs, level of literacy, age and physical condition will all influence the individual's ability to carry out the recommended regimen (American Association of Diabetes Educators, 1999; Canadian Diabetes Association – Diabetes Educator Section, 2000).

Although education seems to have short term positive impact on foot care knowledge and patient behaviour, it is uncertain whether it can prevent foot ulceration and amputation. In a systematic review examining patient education regarding diabetic foot ulceration, Valk et al. (2002), conclude that further research is required to recognize the impact of patient education on ulcer incidence and whether education has different effects for individuals with different levels of risk of ulcer development.

As discussed in the best practice guideline *Reducing Foot Complications for People with Diabetes* (RNAO, 2004), the following elements should be included in basic foot care programs:

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

(ADA, 2001; Apelqvist, Bakker, van Houtum, Nabuurs-Franssen & Schaper, 2000; CDA, 1998; Diabetes Education Study Group of the European Association for the Study of Diabetes, 2001; Institute for Clinical Systems Improvement, 2000; NZGG, 2000; Pinzur, Slovenkai & Trepman, 1999).

See Appendix C for the University of Texas Foot Classification System – Categories 0-3: Risk Factors for Ulceration.

See Appendix D for the University of Texas Foot Classification System – Categories 4-6: Risk Factors for Amputation

See Appendix E for the University of Texas Health Science Center San Antonio Diabetic Wound Classification System.

See Appendix F for patient handout on diabetic foot care.

## 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)

The holistic assessment of patients with diabetes and foot ulceration should include:

- History of presenting illness (Level of Evidence = IV)
  - Initiating event (trauma, shoe wear, etc.)
  - Duration of ulceration
  - Treatments prescribed
  - Outcome of the treatments
- Past medical history (Level of Evidence = III)
- Medications (Level of Evidence = IV)
- Current diabetes management (Level of Evidence = Ib)
- Allergies (Level of Evidence = IV)
- Family history (Level of Evidence = III)
- Activities of Daily Living (ADL)/Instrumental Activities of Daily Living (IADL) or functional assessments (*Level of Evidence = III*)
- **Quality of life** (Level of Evidence = III)

## **Discussion of Evidence:**

A comprehensive assessment is required for all patients who present with diabetic foot ulceration. This assessment must include the etiology, factors that influence healing and the patient's biopsychosocial status.

#### History of Presenting Illness (Level of Evidence = IV)

- Initiating event
- Duration of ulceration
- Treatments prescribed
- Outcome of the treatments

The evaluation of the patient with a diabetic foot ulcer requires a detailed history and physical examination, appropriate diagnostic tests, and identification of risk factors for ulceration. People with diabetic foot ulcers should be identified as high risk for amputation (Australian Centre for Diabetes Strategies, 2001; Falanga & Sabolinski, 2000).

### Past Medical/Surgical History (Level of Evidence = III)

A careful history is required to determine general health, diabetes control and complications. This should include:

- All other medical conditions (co-morbidities) and complications associated with diabetes
- Any surgeries and/or previous amputation related to diabetes
- History of previous ulcers related to diabetes

### Co-morbidities and complications associated with Diabetes:

#### Renal impairment

Eggers et al. (1999), identified that patients with diabetes mellitus and end stage renal disease (ESRD), accounted for 50% of amputations within this patient population. Those with ESRD only, without diabetes mellitus had one-fifth the rate of amputations. Those with ESRD from other causes but had diabetes mellitus as a risk factor accounted for approximately 25% of the amputations. In the ESRD post amputation population, the survival rate at two years was 33%.

#### Hypertension

Results of the Hypertension Optimal Treatment and United Kingdom Prospective Diabetes Study (UKPDS) trials report clinically important reductions in microvascular and macrovascular complications and diabetes related death (CDA, 2003). Individuals with co-exisitng hypertension have a five-fold increased risk of developing peripheral vascular disease (PVD) and therefore are at increased risk for amputation, compared to normotensive individuals with diabetes (Royal Melbourne Hospital, 2002). Adler, Stratton, Neil, Yudkin, Matthews, Cull et al. (2000) demonstrated that macro and microvascular (retinopathy, nephropathy) complications are linked to elevated blood pressure.

#### Retinopathy

Reiber, Vileikyte, Boyko, Del Aguila, Smith, Lavery et al. (1999) reviewed seven studies indicating that retinopathy is an independent predictor of amputation, possibly due to microvascular disease.

#### Hospital admissions and previous surgeries

A history of previous amputation is a strong predictor of future amputations. Up to 34% of patients develop another ulcer within one year after healing while the 5 year rate of re-ulceration has been shown to be 70% (Frykberg et al., 2000).

#### Medications (Level of Evidence = IV)

Medication records will provide the health practitioner with information regarding diabetes management, as well as potential drug interactions, and those that may impair wound healing.

## Current Diabetes Management (Level of Evidence = Ib)

#### Gylcemic Control

The complications from diabetes are strongly related to high blood glucose levels. Improved glycemic control reduces complications. The United Kingdom Prospective Diabetes Study (UKPDS) showed that intensive control of blood glucose resulted in a substantial reduction of the risk of complications of type 2 diabetes. Each 1% reduction in A1C produced significant decreases in complications. A1C values in the normal range (<6%) comprised the lowest risk (Stratton, Adler, Neil, Matthews, Manley, Cull et al., 2000). The DCCT Research Group (1993) concluded that intensive therapy to maintain blood glucose levels close to the

normal range effectively delayed the onset and slowed the progression of diabetic retinopathy, nephropathy and neuropathy in patients with insulin dependent diabetes (IDDM), now identified as type 1.

A Japanese study examining glycemic control and microvascular complications concluded that intensive glycemic control can delay onset and progression of diabetic retinopathy, nephropathy and neuropathy in Japanese patients with NIDDM (type 2 diabetes)(Ohkubo, Kishikawa, Araki, Miyata, Isami, Motoyoshi et al., 1995). The Wisconsin Epidemiologic Study of diabetes retinopathy showed a consistent exponential relationship between worsening glycemic control and complications (Moss, Klein & Klein, 1996). The CDA Clinical Practice Guidelines (2003) recommends the following targets for glycemic control for most patients with type 1 and type 2 diabetes:

- $A_1C \le 7.0\%$  to reduce the risk of microvascular and macrovascular complications.
- Fasting plasma glucose of 4.0 to 7.0 mmol/L and 2-hour postprandial plasma glucose targets of 5.0 to 10.0 mmol/L.

The CDA (2003) advises that treatment goals and strategies must be individualized according to risk factors such as complications and co-morbidities.

#### Allergies (Level of Evidence = IV)

Any allergies should be recorded in the medical history. Particular notes should be made of medications.

#### Family History (Level of Evidence = III)

Persons who have close relatives with certain diseases (e.g., heart disease, diabetes, and osteoporosis) are more likely to develop those diseases themselves (Bennett, 1999). Family health history is an important risk factor that reflects inherited genetic susceptibility, shared environment and common behaviours (Centres for Disease Control and Prevention, 2004).

### Activities of Daily Living (ADL) (Level of Evidence = III)

It is important to determine how the patient is able to function within the environment that they are living in and how this impacts the patient's quality of life. Ribu & Wahl (2004) conducted a qualitative study with seven patients having type 1 or type 2 diabetes and foot ulcers to determine the patients' perspective of living with lower extremity ulcers and diabetes. The result indicates that patients experienced changes in their feet, pain and insomnia, fatigue and limited mobility, social isolation and loneliness, a restricted life, loss of control and fear for the future. When treating a patient's foot ulcer, clinicians need to consider patients' subjective feelings toward the various aspects of their life situations and the impact of their situation on their quality of life.

# Vascular Status:

### **Recommendation 2.1:**

Clinically assess bilateral lower extremities for vascular supply and facilitate appropriate diagnostic testing. (*Level of Evidence* = IIb - IV)

The assessment of vascular supply can be achieved through history, physical examination and diagnostic tests.

History and Physical Examination	
of the Lower Extremities	Diagnostic Tests*
Peripheral pulses	<ul> <li>Ankle brachial pressure index (ABPI)</li> </ul>
Intermittent claudication	<ul> <li>Arterial duplex scan</li> </ul>
<ul> <li>Colour (pallor on limb elevation, rubor</li> </ul>	Toe and ankle pressures
on limb dependency, mottling)	Transcutaneous oxygen
Temperature	
<ul> <li>Capillary refill</li> </ul>	
Edema	
Pain	
Dry gangrene	

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RNAO Guideline Development Panel, 2005
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\*Accesibility of these diagnostic tests may be limited to centres with specialty in vascular surgery and wound care.

## **Discussion of Evidence:**

The affected foot must have adequate blood flow to support healing (Birke et al., 2000; Reiber et al., 1999). The literature supports the notion that peripheral arterial disease (PAD), also known as peripheral vascular disease (PVD), is not the cause of skin breakdown alone, but can prolong wound healing and increase the risk of subsequent amputation (Apelqvist, 1998; Birke et al., 2000; Crane & Branch, 1998; Sinacore & Mueller, 2000). In persons with diabetes seen at a younger age, PAD is often bilateral. Moreover, risk of PAD increases with the duration of the disease (Calhoun, Overgaard, Stevens, Dowling & Mader, 2002). Furthermore the risk of PAD increases by ten-fold in those with diabetes and concurrent renal failure (Apelqvist, 1998; Eggers et al., 1999).

The presence of peripheral pedal pulses represents a minimum systolic pressure of 80 mmHg (Lavery & Gazewood, 2000). The National Evidence Based Guidelines for the Management of Type 2 Diabetes Mellitus (Australian Centre for Diabetes Strategies, 2001) states that the absence of peripheral pulses has prognostic significance for future amputation in people with or without foot ulceration. With the distal nature of the disease process, persons with diabetes may have ischemia in the presence of dorsalis pedis pulses (Boulton et al., 1999).

One of the first classical symptoms of vascular insufficiency is claudication (calf pain). However, in patients with diabetes, this classic symptom can be masked by the presence of neuropathy (Calhoun et al., 2002). A cohort study by Eneroth, Apelqvist & Stenstrom (1997), found that claudication was an insignificant predictor or symptom of vascular disease. A positive history of lower limb intermittent claudication combined with non-palpable pedal pulses bilaterally increases the probability of vascular insufficiency in diabetes (Boyko, Ahroni, Davignon, Stensel, Prigeon & Smith, 1997).

Capillary refill is defined as abnormal if it takes longer than 5 seconds for the tissue to return to its normal colour after applying pressure and releasing it.

The colour of the foot should be assessed for rubor on dependency, pallor on elevation, mottling and dry gangrene, all of which are signs of ischemia (Bowker & Pfeifer, 2001). A vascular surgery referral is recommended for patients with signs of arterial insufficiency in order that a comprehensive vascular assessment can be completed.

See Appendix G for further details about diagnostics to determine vascular supply.

## 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*)

# **Discussion of Evidence:**

Persons with diabetic foot ulcers may not be able to mount an inflammatory response due to impaired immunodefense, decreased peripheral circulation and metabolic control (Armstrong, Lavery, Sariaya & Ashry, 1996; Eneroth et al., 1997). In addition, increased co-morbidities associated with aging places the person with diabetes at a higher risk for infection.

Identifying infection in a chronic wound can be a challenge since the clinical assessment for infection in chronic wounds differs from acute wounds. Gardner, Frantz & Doebbling (2001) validated the work by Cutting & Harding (1994) and provided a checklist to aid the clinician in identifying the clinical signs of infection in chronic wounds. Gardner et al. (2001), in a cross-sectional design study, identified the following signs and symptoms:

- Increased pain (100% specificity)
- Wound breakdown (100% specificity)
- Friable granulation tissue (76% specificity)
- Foul odour (88% specificity)

Deep infection will often cause erythema and warmth extending 2 cm or more beyond the wound margin. This increased inflammatory response is painful and will cause the wound to increase in size or lead to satellite areas of tissue breakdown which cause adjacent ulceration. Deep infections, especially in ulcers of long duration can often lead to osteomyelitis. Probing to bone is a simple, non-invasive technique for rapid identification of osteomyelitis and should be included in the initial assessment of all patients with infected pedal ulcers (Grayson, Balaugh, Levin & Karchmer, 1995). When combined with clinical evaluation and radiographic interpretation, probing to bone is a cost-effective and specific assessment tool (Caputo, Cavanagh, Ulbrecht, Gibbons & Karchmer, 1994).

With infection, the wound may change in odour, colour, tissue quality and exudates. A healthy wound has a faint but not unpleasant odour, infections usually result in a distinctive and slightly unpleasant smell (Cutting & Harding, 1994).

Based on the utilization of the signs and symptoms listed below, the timely diagnosis and treatment of infection is vital to the healing of diabetic foot ulcers. Deep foot infections are serious, potentially limb threatening and have been identified as the immediate cause of 25-51% of amputations in persons with diabetes (Tennvall, Apelqvist & Eneroth, 2000).

Table 1: Clinical signs and symptoms of impaired bacterial balance in persons with a diabetic foot ulcer



SIGNS OF DEEP WOUND AND SYSTEMIC SIGNS OF INFECTION ARE POTENTIALLY LIMB AND/OR LIFE THREATENING. THESE CLINICAL SIGNS AND SYMPTOMS REQUIRE URGENT MEDICAL ATTENTION.

Non limb threatening infection	Limb threatening infection			
Superficial infection	Deep wound infection	Systemic infection		
<ul> <li>Non-healing</li> </ul>	Pain (in a previously insensate foot) In addition to deep wound inference of the previously insensate foot)			
<ul> <li>Bright red granulation tissue</li> </ul>	<ul> <li>Swelling, induration</li> </ul>	Ever		
<ul> <li>Friable and exuberant granulation</li> </ul>	Erythema (> 2 cm)	Rigours		
<ul> <li>New areas of breakdown or necrosis</li> </ul>	Wound breakdown	Chills		
Increased exudate	Increased size or satellite areas	<ul> <li>Hypotension</li> </ul>		
<ul> <li>Bridging of soft tissue</li> </ul>	<ul> <li>Undermining or tunnelling</li> </ul>	<ul> <li>Multi-organ failure</li> </ul>		
and the epithelium	Probing to bone			
Foul odour	Flu-like symptoms			
	Anorexia			
	<ul> <li>Erratic glucose control</li> </ul>			

RNAO Guideline Development Panel, 2005

Infection occurs when bacteria in a wound overcomes the natural defences of the host's immune system. The likelihood of a wound becoming infected is related to microbial load and the type of micro-organism. However, equally important factors are the characteristics of the wound (type, site, size and depth), the level of blood perfusion and the ability of the host to resist infection:

### Infection = <u>Number of organisms</u> x <u>Virulence of organisms</u> Host resistance

*This equation represents a balance between increasing number of organisms and virulence that can eventually overcome the host's ability to contain infection* (Dow, Browne & Sibbald, 1999; Peacock & Van Winkle, 1976).

While emphasis is frequently placed on bacterial burden, <u>the host resistance</u> (the patient with diabetes) is often the critical factor in determining whether infection will develop. Persons with diabetes have compromised immunity which leads to a reduced resistance to infection. Most chronic wounds contain more than three species of micro-organisms, which increases the risk of infection as they may develop synergies with one another. In wounds that are infected with a number of species it is not possible to distinguish which is the causative organism (Table 2).

### Changes in microbial flora over time

The microbial flora in a chronic wound changes over time in a predictable fashion as seen in Table 2.

Time	Type of micro-organism	Clinical and laboratory findings	
First few days	Cutaneous flora		
1 to 4 weeks	Cutaneous flora accompanied by Gram-positive aerobic cocci, often beta-haemolytic <i>Streptococci,</i> <i>S. aureus</i> .	Purulent discharge Gram-positive Single species	
4 weeks onwards	Cutaneous flora accompanied by Gram-negative facultative anaerobic bacteria, particularly coliforms followed by anaerobic bacteria and <i>Pseudomonas</i>	Tissue necrosis Undermining Deep involvement Poly-microbial mixture of aerobic and anaerobic pathogens	

Table 2: Microb	hial flora	in a	chronic	wound	over time
	Jidi liula	1 III d	CHIONIC	wound	over time

Used with permission. Dow, G., Browne, A. & Sibbald, R. G. (1999). Infection in chronic wounds: Controversies in diagnosis and treatment. *Ostomy/Wound Management, 45*(8), 23-27, 29-40.

Diagnostic tests and imaging are other procedures that are used to determine infection.

For diagnostic tests and imaging to determine infection, see Appendix H.

For description of swabbing technique, see Appendix I.



## **Neuropathy:**

**Recommendation 2.3:** 

Identify peripheral neuropathy by assessing for sensory, autonomic and motor (S.A.M.) changes. (Level of Evidence = II - IV)

## **Discussion of Evidence:**

Lavery, Armstrong, Vela, Quebedeau & Fleishchli (1998) noted that patients with only peripheral neuropathy and no other risk factors were 1.7 times more likely to develop ulceration. Patients with both neuropathy and foot deformity were 12.1 times more likely to have an ulcer. Patients with neuropathy, deformity and a history of amputation were 36.4 times likely to develop a foot ulcer.

There are three components to peripheral neuropathy. Listed below are the effects of each form of neuropathy that the patient with diabetes may present with that will increase the risk of ulcer development:

Component	Pathophysiology	Assessment	Outcome
Sensory	<ul> <li>Myelin sheath is disrupted by hyperglycemia</li> <li>Disruption leads to segmental demyelinization process accompanied by a slowing of motor nerve conduction and an impairment of sensory perception (Zangaro &amp; Hull, 1999)</li> </ul>	<ul> <li>4 site testing including the great toe, first, third and fifth metatarsal heads, using a 10-gram (5.07) monofilament* is recommended as an appropriate screening process to determine the presence of protective sensation in the persons with diabetes (ADA, 2001; Campbell, Graham, Kidd, Molly, O'Rourke &amp; Coagiuri, 2000; Frykberg et al., 2000; Hunt, 2001; Hutchinson et al., 2000; Institute for Clinical Systems Improvement, 2000; Lavery &amp; Gazewood, 2000; McCabe, Stevenson &amp; Dolan, 1998; NZGG, 2000; RNAO, 2004; Smieja, Hunt, Edelman, Etchells, Cornuz &amp; Simel, 1999; Zangaro &amp; Hull, 1999).</li> <li>Gait analysis</li> </ul>	<ul> <li>Loss of protective sensation</li> <li>Sensory ataxia</li> <li>Falls (15-fold increase compared to those without diabetes)</li> </ul>
Autonomic	Sympathetic Denervation Loss of vasomotor control Peripheral blood flow Arteriovenous shunting Bone blood flow hyperemia Glycosylation of collagen	<ul> <li>Dry scaly skin caused by lack of hydration</li> <li>Inspect between the toes especially between the fourth and fifth toes for fissures</li> <li>Maceration</li> <li>Loss of hair growth and thickened toenails</li> </ul>	<ul> <li>Anhydrosis</li> <li>Callus</li> <li>Fissure cracks</li> <li>Onychomycosis (fungal nails)</li> <li>Peripheral edema</li> <li>Waxy skin = altered joint mobility</li> </ul>
Motor	<ul> <li>Non-enzymatic glycosylation</li> <li>Atrophy of intrinsic muscles of the foot (toe plantar flexors)</li> <li>Subluxation of metatarso- phalangeal joints</li> </ul>	<ul> <li>Increased peak pressure</li> <li>Range of motion</li> <li>Absent deep tendon reflexes</li> <li>Diminished vibratory sense</li> </ul>	<ul> <li>Claw toes</li> <li>Hammer toes</li> <li>Charcot arthropathy</li> <li>Muscle weakness</li> <li>Ankle equinus</li> <li>Pes cavus</li> <li>Pes planus</li> <li>Contracture of Achilles Tendon</li> </ul>

\*(Apelqvist,1998; Boyko, Ahroni, Stensel, Forsberg, Davignon & Smith, 1999; Bureau of Primary Health Care, 2005; Frykberg, Lavery, Pham, Harvey, Harkless & Veves, 1998; Lavery, Armstrong, Wunderlich, Tredwell & Boulton; 2003; Shaw & Boulton, 1997).

See Appendix J for description and use of monofilament.

# Foot Deformity and Pressure:

#### **Recommendation 2.4:**

Assess for foot pressure, deformity, gait, footwear and devices. Facilitate appropriate referrals. (Level of Evidence = Ia - IV)

### **Discussion of Evidence:**

Studies have demonstrated that while trauma to a neuropathic foot may be related to a single event, ulcers frequently occur as a result of repeated minor trauma such as from footwear or elevated pressure on the bottom of the foot. Foot deformities such as prominent metatarsal heads, clawing of the toes and limited joint mobility alters the gait or mechanics of walking resulting in abnormal forces on the foot, poor shock absorption, and shearing and stress to soft tissues (RNAO, 2004; Shaw & Boulton, 1997). People with diabetes should be assessed regularly to detect foot deformities and should have interventions to reduce foot pressure and ulcer risk (Australian Centre for Diabetes Strategies, 2001; Royal Melbourne Hospital, 2002).

#### Assess for Pressure

Elevated foot pressure is an important risk factor for foot complications (Lavery et al., 2003). The plantar surface of the forefoot is found to be the most common location for the development of an ulcer (ADA, 1999). Forefoot and rear foot pressure ratios are increased in the severe diabetic neuropathic foot indicating an imbalance in pressure distribution. Equinus deformity with severe peripheral neuropathy may be an important factor in ulcer etiology (Caselli, Pham, Giurini, Armstrong & Veves, 2002). Reduced plantar soft tissue thickness at the metatarsal heads is associated with increased foot pressure and may predict development of diabetic foot ulcer (Abouaesha, van Schie, Griffiths, Young & Boulton, 2001).

Pressure over bony prominences can lead to callus formation and in the absence of protective sensation may predispose the area to breakdown (Australian Centre for Diabetes Strategies, 2001; Boyko et al., 1999; Frykberg et al., 1998; Hutchinson et al., 2000). Callus may act as a foreign body elevating plantar pressures and there is significant reduction in pressure when the callus is removed (Boulton et al., 1999; Murray, Young, Hollis & Boulton, 1996; Pataky, Golay, Faravel, Da Silva, Makoundou, Peter-Riesch et al., 2002; Young, Cavanagh, Thomas, Johnson, Murray & Boulton, 1992).

### **Identify Structural Deformities**

The physical examination of a person with diabetes should include assessment and intervention for foot deformity (Australian Centre for Diabetes Strategies, 2001; Royal Melbourne Hospital, 2002). There is significant evidence that with increased number of deformities, there is an increased risk and magnitude of plantar pressure (Lavery et al., 2003).

Deformities may include, but are not limited to, hammer toe, claw toe, hallux deformity, pes planus, pes cavus and Charcot arthropathy.

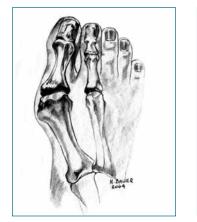
#### Deformity



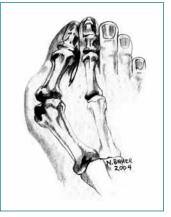
\*Hammer Toe – bent middle joint



\*Claw Toe – joint at base of toe is bent up and middle joint is bent down



\*Halgus Valgus or Small Bunion (Mild/Moderate) – joint at the base of big toe is pushed to the side

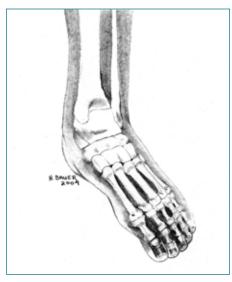


\*Hallus Valgus or Large Bunion (Severe) – big toe may move under second toe

#### **Description and Evidence**

With atrophy of the intrinsic muscles of the foot, especially the toe plantarflexors, the flexor/extensor balance at the metatarso-phalangeal joints is altered. This causes clawing at the toe and possible subluxation of the metatarso-phalangeal joints. As a result, the submetatarsal fat pads are displaced and there is reduced pressure absorbing subcutaneous tissue at the metatarsal heads. In addition, glycosalation of collagen from hyperglycemia results in thickened, waxy skin which affects joint mobility. All these factors contribute to foot deformity and ulcer risk (Bennett, Stocks & Whittam, 1996; Shaw & Boulton, 1997).

#### Deformity



Pes Planus

#### Description and Evidence

Pes planus produces flattening of the foot. Pes planus feet have increased lateral talometatarsal angle and increased second metatarsal length (Ledoux, Shofer, Ahroni, Smith, Sangeorzan & Boyko, 2003). There are many reasons for this condition, the first of which is heredity. Many have this condition and never have any problems of any kind.

However, others will have this condition created through years in soft, unsupportive shoes on hard surfaces, injury, pregnancy, or other factors. This often leads to other problems.

The arch in the foot is caused by a broad band of fibrous connective tissue, called the longitudinal ligament. A ligament is nothing more than connective tissue that connects bone to bone. The longitudinal ligament connects the metatarsal phalangeal joints to the os calcis or heel bone. Like a string on a bow, they hold the two ends together and create an arch. This arch is a shock absorption structure and it also helps to maintain all the tarsals in proper erect anatomic position. As this arch decreases, impact from the concrete becomes worse.

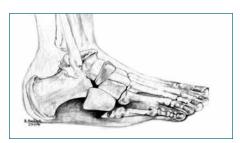
When the arch ligament stretches or tears, the arch falls. If it falls far enough, the tarsals may begin to shift to the inside or create pronation or a valgus (greater than 90 degree erect) position at the ankle. This can cause problems in the origin area, (the metatarsals) or in the heel. It also may cause pressure on the medial (inner) knee and perhaps the hip and back. It is like pulling the string on a marionette too tight, the result is a kinked mass on one side. The human body is much the same, put too much tension on major muscle groups and the joints kink and yell back.

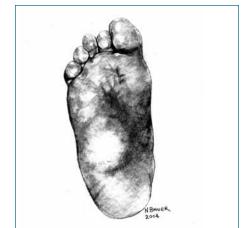
In pes cavus, the arch is abnormally high on weight bearing. The heel is often tilted inwards at the ankle (but not always). In many, the toes will appear clawed. When not standing the front half of the foot (forefoot) will appear to be dropped below the level of the rear foot. Ledoux et al. (2003) identified biomechanical differences among pes planus and pes cavus feet in persons with diabetes. They found pes cavus feet had more prominent metatarsal heads, bony prominences, hammer/claw toes, increased hallux dorsiflexion and decreased hallux plantarflexion.



Pes Cavus

Deformity





\*Charcot Arthropathy

Limited Joint Mobility

Description and Evidence

Charcot joint is a form of neuroarthropathy that occurs most often in the foot. Nerve damage from diabetes causes decreased sensation, muscle and ligamental atrophy and subsequent joint instability. Walking on this insensitive and weakened joint can cause even more damage to the foot structure. In the acute stage there is inflammation and bone reabsorption which destroys the bone. In later stages, the arch falls and the foot may develop a rocker bottom appearance. Weight distribution of the sole is altered causing deformities leading to pressure points that enhances ulcer development. Signs to assess for are: hot on the onset, pain, discomfort, erythema, swelling, rigid deformities, limited joint mobility, callus formation (ADA, 2001; Bowker & Pfeifer, 2001). One in 680 people with diabetes develop Charcot joint with an incidence of 9-12% individuals with documented diabetic peripheral neuropathy (Royal Melbourne Hospital, 2002). It is important that the Charcot foot is recognized early so that appropriate treatment of the foot can be provided to prevent further injury and promote a stable foot (Lavery et al., 1998). For patient information on Charcot arthropathy, visit www.rnao.org/bestpractices.

Progressive stiffening of collagen-containing tissues leads to thickening of the skin, loss of joint mobility, and potential fixed flexor deformity. Up to 30% of patients with diabetes may have limited joint mobility. Reduction in mobility of the ankle joint may cause increased plantar pressure when walking and be a major risk factor in the pathogenesis of diabetic foot ulcers (Fernando, Masson, Veves & Boulton, 1991; Zimny, Schatz & Pfohl, 2004). Achilles tendon contracture is a common cause of limited joint mobility causing increased pressure on the forefoot during ambulation (Armstrong, Lavery & Bushman, 1998; Mueller, Sinacore, Hastings, Strube & Johnson, 2004).

Above illustrations provided by Nancy A. Bauer, BA, Bus Admin, RN, ET.

\* Reference:

Diabetes Nursing Interest Group & Registered Nurses' Association of Ontario (2004). Diabetes foot: Risk assessment education program. Images of the diabetic foot. Registered Nurses' Association of Ontario [Electronic version]. Available: www.rnao.org/bestpractices/PDF/BPG Foot Diabetes Workshop slides.pdf

#### **Gait Abnormality**

Gait is the manner or style of walking. The neurodegenerative process is accelerated in diabetes and this results in a decline in motor control and a pathology-related decline in postural stability/foot posture, and abnormal weight bearing (Mason O'Keefee, McIntosh, Hutchinson, Booth & Young, 1999b; Meier, Desrosiers, Bourassa & Blaszczyk, 2001). Alterations in gait, balance and mobility are caused by sensory ataxia, poor vision, debilitation and/or neuropathy in the patient with diabetes (Sinacore & Mueller, 2000). Assessment of gait is important because patients with diabetes and neuropathy have a 15 times greater risk of experiencing a fall compared to those without neuropathy (Sinacore & Mueller, 2000).

Some gait patterns that may be observed in a patient with diabetes are: ataxic (unsteady, uncoordinated, employing a wide base of support), steppage (lift the foot higher to accommodate for foot drop and/or poor ankle-joint mobility) and antalgic (a limp, usually signifying discomfort).

#### Footwear and Devices

Examination and use of existing footwear and devices should be assessed for areas of pressure and adherence with wearing. Appropriate education should be provided. See Appendix K for suggestions in assessing and selecting shoes and socks.

#### Shoes

It is imperative that patients with diabetes see a foot or healthcare specialist regularly for the assessment of their feet as well as their shoes and other devices associated with ambulation as a preventative measure to reduce the occurrence and re-occurrence of ulcers (ADA, 2001; Campbell et al., 2000; Frykberg et al., 2000; Hunt, 2001; Hutchinson et al., 2000; Institute for Clinical Systems Improvement, 2000; Lavery & Gazewood, 2000; McCabe et al., 1998; NZGG, 2000; Smieja et al., 1999; Zangaro & Hull, 1999).

Foot ulceration has been associated with constant or repetitive pressure from tight shoes over bony prominences on the dorsum of the lesser toes, at the medial aspect of the first metatarsal head, or the lateral aspect of the fifth metatarsal (Lavery et al., 1998). In a large prospective study, Abbott, Carrington, Ashe, Bath, Every, Griffiths et al. (2002) found that the main cause (55%) of ulceration was pressure from footwear.

In a systematic review of interventions to prevent diabetic foot ulcers, two randomized controlled trials on patient footwear were reviewed. One study found that type of shoe may be independently important, and that providing patients with normal well-fitting shoes that distribute abnormal pressures may also reduce ulcer risk (Mason et al., 1999a). The second study reported that evidence does not support widespread dispensing of therapeutic shoes and inserts for patients with diabetes and foot deformities. Patient education may be a more important intervention. However, for those patients unable to be closely monitored or who have severe deformities, specialized footwear may be beneficial (Reiber, Smith, Wallace, Sullivan, Hayes, Vath et al. 2002). Maciejewski, Reiber, Smith, Wallace, Hayes & Boyko (2004) reported results consistent with the second study.

#### Orthotics

Orthotics are custom-made shoe inserts which serve to correct or relieve misalignment and or pressure areas of the foot. A systematic review was conducted to assess the effectiveness of pressure relieving interventions in prevention and treatment of diabetic foot ulcers. Spencer (2004) reviewed four randomized controlled trials of pressure relieving interventions and concluded that in-shoe orthotics are of benefit.

#### **Diagnostic Tests**

Accessability of these tests may be limited to specialty centres.

X-ray

X-rays are useful primarily as imaging tools to identify possible osteomyelitis, foreign bodies, tissue gas, or bony abnormalities (Royal Melbourne Hospital, 2002).

#### Pressure Map

Pressure mapping measures foot pressures in standing and walking positions. Lavery et al. (1998) identified high plantar pressure (65 N/cm2) as a significant factor associated with the presence of foot ulceration. Pham, Armstrong, Harvey, Harkless, Giurini & Veves (2000) using an F-Scan mat system, found that foot pressures  $\geq 6$ kg/cm put patients at risk for foot ulcerations.

#### Foot Ulcer Assessment:

**Recommendation 3.0:** 

**Describe and document the ulcer characteristics.** (*Level of Evidence = IV*)

## **Discussion of Evidence:**

Good record keeping using common language and objective descriptors such as wound measurements and ulcer grading can increase clarity and may improve outcomes. Careful monitoring of wound healing is as important as initial assessment and treatment in influencing outcome (Krasner, 1998). At present, there is a lack of clearly established standards for assessing and documenting wound progress.

#### **Recommendation 3.1:**

Identify the location, length, width, depth and classify the ulcer(s). (Level of Evidence = Ia - IV)

## **Discussion of Evidence:**

#### Identification of Ulcer on the Lower Extremity (*Level of Evidence = IIa*)

Location of a foot ulcer is determined by the site of trauma. In three large prospective studies, 53% of ulcers involved the toes and 22% involved the first metatarsal area (Apelqvist et al., 2000; Armstrong, Lavery & Harkless, 1998a; Reiber et al., 1999).

### Measuring the Length and Width (Level of Evidence = Ia)

A systematic review evaluated treatments for diabetic foot ulcers by calculating length and width (Margolis, Kantor & Berlin, 1999). As length and width decreased, the wound was classified as healing. It is important when measuring a wound that the measurements are done using a consistent method such as tracings (Krasner & Sibbald, 2001). This will greatly increase reliability in determining progress towards closure. Clinical studies have shown that a reduction in ulcer area (approximately 20 to 40%) after 2 to 4 weeks of treatment is a good predictor of healing (Margolis et al., 1999; Tallman, Muscare, Carson, Eaglstein & Falanga, 1997; van Rijswijk & Polansky, 1994).

#### Measuring the Depth (Level of Evidence = IV)

Wound depth is most commonly measured and quantified by gently inserting a sterile swab stick or probe into the wound. Find the deepest point and put a gloved forefinger on the swab stick at the skin level. Place next to a measuring guide. The presence or absence of undermining, a space between the surrounding skin and wound bed, and tunneling can also be determined in this manner. If tunneling or undermining is present, use the "clock" system to document location (e.g., area of the wound closest to the head is the 12 o'clock position.

Standardizing the procedure for measurement is crucial in order to evaluate whether the wound is moving in the direction of the goal of care. The University of Texas Health Science Center San Antonio Diabetic Wound Classification System (see Appendix E) is an example of a grading system to stage the depth of the wound.

#### **Recommendation 3.2:**

Assess ulcer bed, exudate, odour and peri-ulcer skin. (*Level of Evidence = IV*)

## **Discussion of Evidence:**

The aim of wound bed assessment is to identify and plan the management of factors that will promote an optimal healing environment (Vowden & Vowden, 2002). The condition of the periwound area provides important information about the status of the wound and can influence choice of treatment. Surrounding skin assessment includes evaluating colour, callus formation, induration, moisture and edema. Redness can be indicative of unrelieved pressure or prolonged inflammation (Boulton, 1991). When the surrounding skin has been exposed to moisture for a prolonged period of time, signs of maceration (pale, white or grey tissue) may be observed. Callus formation is indicative of ongoing pressure to the affected area.

Debridement of callus is generally performed to facilitate accurate assessment of the wound. Induration (an abnormal firmness of the tissue) and edema are assessed by gently pressing the skin within 4 cm of the wound.

Wound exudate characteristics, e.g., type and amount of drainage, provide important information about the status of the wound. Rating the amount of drainage is useful only if a description of each rating is provided.

Wound is dry = no exudate Moist wound = scant or small Wet/saturated = heavy

In addition to amount, the type of exudate should be described. Serous = clear yellow fluid without blood, pus or debris Serosanguinous = thin, watery, pale red to pink fluid Sanguinous = bloody, bright red Purulent = thick, cloudy, mustard yellow or tan

All wounds, especially those treated with moisture retentive dressings, can emit an odour. Necrotic wounds tend to have more offensive odour than clean wounds, while wounds infected with anaerobes tend to produce a distinct acrid or putrid odour. A descriptive odour assessment can provide important information, as a change in odour may be indicative of an alteration in bacterial balance.

# 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 healthcare professionals.** (*Level of Evidence = IV*)

## **Discussion of Evidence:**

The perceived value of treating foot ulcers varies from the point of view of the patients and healthcare professionals. The role of the nurse in the management of patients with a diabetic foot ulcer is to advocate, collaborate and facilitate the process of goal directed care. The healing potential of a wound must be taken into consideration. See Figure 2 for factors affecting healing potential.

Local <	-> Host -	→ Environment	
<ul> <li>Necrosis</li> </ul>	<ul> <li>Co-morbidities</li> </ul>	Access to care	
<ul> <li>Infection</li> </ul>	• ESRD	<ul> <li>Access to appropriate offloading</li> </ul>	
<ul> <li>Offloading</li> </ul>	Renal transplant	<ul> <li>Family support</li> </ul>	
<ul> <li>Microvascular supply</li> </ul>	<ul> <li>Inflammatory condition</li> </ul>	<ul> <li>Healthcare sector</li> </ul>	
<ul> <li>Foreign body</li> </ul>	<ul> <li>Visual impairments</li> </ul>	<ul> <li>Geographic</li> </ul>	
<ul> <li>Iatrogenic</li> </ul>	Glycemic control	<ul> <li>Socioeconomic status</li> </ul>	
Cytotoxic agents	<ul> <li>Nutrition</li> </ul>		
	• PVD		
• CAD (Coronary Artery Disease)			
<ul> <li>Adherence to plan of care</li> </ul>			
Cultural/personal beliefs			

# Figure 2: Healing Potential

RNAO Guideline Development Panel, 2005

The primary goal in the treatment of diabetic foot ulcers is to obtain wound closure as expeditiously as possible. The resolution of foot ulcers and decreasing the rate of re-ocurrence can lower the probability of lower extremity amputation in patients with diabetes.

According to the American Diabetes Association (1999) Consensus Development Conference of Diabetic Foot Wound Care, foot wounds in patients with diabetes should be treated for several reasons – improve function and quality of life; control infection; maintain health status; prevent amputation; and reduce costs.

Healing of foot wounds improves the appearance of the foot and may allow the patient to return to ambulation in appropriate footwear. Improving function and return to well-being are important goals of therapy (ADA, 1999). With impaired mobility, foot wounds often lead to general deconditioning and psychosocial dysfunction.

Frequent re-evaluation with response-directed treatment is essential. Once the ulcer is closed, the management of PWDFU should include strategies to decrease the probability of re-ocurrence. Patient involvement is an essential component of diabetic foot ulcer care, particularly when the encouragement of adherence, with chronic or complex treatment regimens, is imperative. The care of the patient should be based on a patient or client centred care approach (See the RNAO guideline [2002a] on *Client Centred Care*). Patient-focused care involves a collaborative care planning and interdisciplinary team approach to assessing, planning, implementing, monitoring and evaluating the care with the patient (Carter, 1995). Diabetic foot ulcer management in a patient-focused model of care is a holistic approach that offers an integrated care pathway, identifying the nursing, medical and paramedical activities that must be synchronized to ensure the patient receives the appropriate treatment from experts of each discipline (Carter, 1995). Carter (1995) also states that fragmentation of care may lead to conflicting advice for the patient, and the potential for wastage of time and effort which may lead to protracted wound healing. In a consumer focus group session led by the development panel, patients who were interviewed consistently expressed dissatisfaction with limited healthcare expertise and access to specialized services, fragmented care and long wait times.

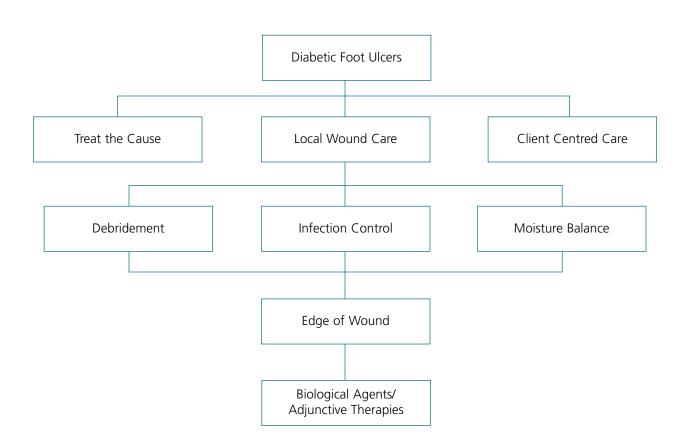
# Management:

This section will discuss the management of diabetic foot ulcers based on a holistic assessment as discussed in the previous section. The **Principles of Management should include:** 

- Vascular management of ischemia and existing co-morbidities
- Infection control and removal of necrotic tissue
- Plantar pressure offloading intrinsic and extrinsic

The following model assists the clinician in providing a practice framework for treatment of persons with diabetic foot ulcers (PWDFU).

#### Figure 3: Framework for Practice



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#### **Recommendation 5.0:**

Identify and optimize systemic, local and extrinsic factors that can influence wound healing. (*Level of Evidence = IV*)

## **Discussion of Evidence:**

Patients with diabetes often have a combination of complicating factors. These factors maybe categorized as systemic, local and extrinsic (see Appendix L). Morris, Jones & Harding (2001) indicate that there is no strong evidence to support that correcting all these factors will necessarily improve wound healing. However, addressing factors that can be controlled or optimized may increase the potential for healing and quality of life.

# Systemic Factors:

**Recommendation 5.1:** 

Modify systemic factors and co-factors that may interfere with or impact on healing. (*Level of Evidence = IV*)

# **Discussion of the Evidence:**

Healing diabetic foot ulcers is a complex process. One cannot expect healing to occur just by simply dressing the wound. Early identification of the co-factors for impaired healing allows the clinician to initiate appropriate referrals and develop a comprehensive interdisciplinary plan of care. By utilizing a systematic approach in the management of each patient with a diabetic foot ulcer, the wound care clinician increases the probability of achieving wound closure. According to McGuckin, Goldman, Bolton, & Salcido (2003) and Seaman (2000), the team directing the patient care must perform a thorough history and physical examination and order relevant investigative studies.

#### Local Factors:

#### **Recommendation 5.2:**

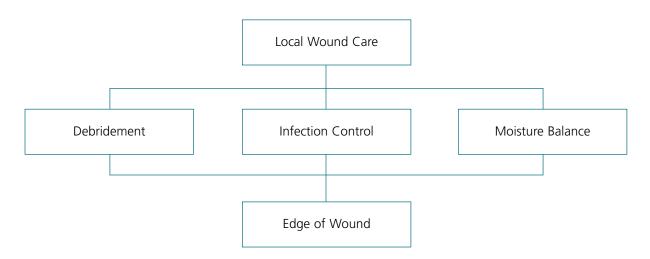
Provide local wound care considering debridement, infection control and a moist wound environment. (Level of Evidence = Ia - III)

## **Discussion of Evidence:**

If healing potential is not established, aggressive debridement and moist interactive healing is not recommended. Wounds that have the greatest potential for healing at an optimal rate require care that includes:

- Debridement
- Infection control
- Moisture balance

# Figure 4: Local Wound Care Model



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## Debridement

Although debridement methods vary, common methods of debridement for diabetic foot ulcers include:

- Mechanical irrigation with saline solution
- Use of autolytic agents (e.g., hydrogels)
- Sharp, using a scalpel or scissors (method of choice in an infected wound)
- Surgical (occurs in the operating room with anesthesia and surgical instruments)

The frequency of debridement is scheduled at the discretion of the clinician (Inlow et al., 2000).

## Callus Reduction

Debridement of callus can significantly reduce pressure at the callus site by approximately 30% (Pitei, Foster & Edmonds, 1999; Young et al., 1992). Debridement of callus is within the nurse's scope of practice, assuming that the nurse has the knowledge, skill and judgement to perform this procedure.

#### Tissue Debridement

The removal of nonviable, contaminated and infected tissue from the wound area has been shown to increase the rate of healing of diabetic foot ulcers (Inlow et al., 2000; Rodeheaver, 2001). In a post-hoc analysis conducted by Steed, Donohoe, Webster & Lindsley (1996), lower rates of healing were correlated with less frequent debridement practices. These observations were confirmed in a prospective trial where sharp debridement may be associated with better outcomes in patients with diabetic foot ulcers (Saap & Falanga, 2002).

Smith (2004) conducted a systematic review to determine the effectiveness of debridement methods for diabetic foot ulcers. Five randomized controlled trials (RCTs) were identified: three involved the use of hydrogels and two involved the use of sharp debridement. The results suggest that hydrogels were significantly more effective than gauze or standard care in healing diabetic foot ulcers. However, sharp

debridement has not been shown to be of significant benefit in promoting wound healing. It should be noted that the clinical trials on sharp debridment are inadequately powered. There is a need for more research to evaluate the effects of a range of widely used debridement methods and of debridement per se.

Sharp debridement is a high-risk procedure. Debridement with a scalpel should be undertaken with caution and performed by specially trained and experienced healthcare professionals.

Subcutaneous debridement with a scalpel is a controlled act that must be carried out by a physician or the delegate. Nurses should be aware of the policies and procedures of their facility.

# Infection Control

STOP

Infections in a diabetic patient must be treated urgently. Diabetic foot infections can rapidly progress to limb- or life-threatening situations. The amputation rate in diabetic populations with foot infections has been reported to range from 12-92% (Tennvall et al., 2000).

Management of diabetic foot ulcer infections should focus on four integrated parameters of care:

- Controlling bacterial balance;
- Host response/defence;
- Complete pressure offloading; and
- Local wound care.

According to Peacock and Van Winkle (1976), infection occurs when the number of organisms exceeds the ability of local tissue defenses to handle them. Maximizing the host ability to fight the infections should be a major consideration. This includes correction of hyperglycemia, stabilization of other co-morbidities, good nutrition and rest. Local wound care should include wound cleansing and debridement to remove devitalized tissue and reduce bacterial load in the wound (Saap & Falanga, 2002; Steed et al., 1996).

Antimicrobial management of diabetic foot infection should be based on the Ontario Anti-infective Guidelines for Community Acquired Infections (Ontario Anti-infective Review Panel, 2001). The prescribed antibiotic(s) should be based on the results of the culture and sensitivity of the organism(s) in conjunction with the physician's clinical judgement.

Once a treatment plan is developed and initiated, an evaluation period should be established to determine the patient's response to treatment.



Application of moisture retentive dressings in the context of ischemia and or dry gangrene can result in a serious life- or limb-threating infection.

See Table 3 for Treatment of Infection.

Non-limb-threatening infection	Limb-threatening infection		
Superficial infection	Deep wound infection	Systemic infection	
<ul> <li>Support host defences</li> </ul>	As in superficial infection	As in deep wound infection	
<ul> <li>Requires a team approach</li> </ul>	<ul> <li>Polymicrobial</li> </ul>	<ul> <li>Will require hospitalization</li> </ul>	
Cleanse and debride wound	<ul> <li>Will require oral/IV antibiotics</li> </ul>	<ul> <li>Will require IV antibiotics</li> </ul>	
<ul> <li>May be monomicrobial</li> </ul>	May require surgical debridement	Ongoing evaluation based	
<ul> <li>Topical antimicrobials</li> </ul>	Non weight bearing	on clinical findings	
■ <u>May</u> require oral/IV antibiotics	<ul> <li>Consider hospitalization</li> </ul>	Bedrest	
(based on host risk)	Consider Infectious Disease consultation		
<ul> <li>Offloading</li> </ul>	<ul> <li>Ongoing evaluation based</li> </ul>		
<ul> <li>Ongoing evaluation based</li> </ul>	on clinical findings		
on clinical findings			
Patient education			

### Table 3: Treatment of Wound Infection

RNAO Guideline Development Panel, 2005

# A. Non-Limb-Threatening Infections

Ulceration does not need to be present since non-limb-threatening infections can result from small puncture wounds, scratches, nail trauma or heel (fissure) cracks. Mild to moderate infection can usually be managed on an outpatient basis with close supervision by the medical practitioner. Topical antimicrobials can be used to reduce bacterial burden in superficial infections. There are several iodine and silver preparations now available that are safe, effective and economical (Sibbald et al., 2003). Systemic antibiotics may be prescribed by the physician or the Registered Nurse/Extended Class (RN/EC) in the community. See Appendix M for a list of Topical Antimicrobial Agents.

If the wound still fails to heal and there is evidence of increased superficial bacterial burden or delayed healing with no evidence of deep infection, use local antimicrobials with debridement and moisture balance. If there is evidence of deep infection, or if the wound fails to demonstrate signs of healing within two weeks with topical antimicrobials, systemic antibiotics may be considered.

## B. Limb-Threatening Infections

Diabetic foot infections in this category may have cellulitis that extends greater than 2 cm beyond the wound border including cardinal signs of infections such as fever, edema, lymphangitis, hyperglycemia, leukocytosis, and/or ischemia (Frykberg et al., 2000). An ulcer that probes to the bone or joint is highly predictive of osteomyelitis (Grayson et al., 1995). Since the patient with diabetes with a relatively severe infection may not necessarily present with these signs and symptoms, it is important to review the entire clinical assessment to guide the clinician to the proper course of treatment. A patient presenting with wet gangrene, deep abscesses, and advancing cellulitis must be transferred to a medical facility for urgent care. Hospitalization is required in order to treat the infection as well as the systemic sequelae. Patients with poor vascular status and deep infections may require vascular surgery and infectious disease consultation. Urgent surgical intervention may be required. Although many wound drainage procedures can be done at the bedside for patients with diabetic ulcers, most will require thorough debridement in the operating room (Frykberg et al., 2000). Even the sickest of patients should be considered for emergent incision, drainage,

and debridement procedures since their illness is directly attributable to the severity of their infection. Lifethreatening infections necessitate immediate surgical attention and such procedures should not be delayed while waiting for radiologic or medical workup of other co-morbid conditions (Frykberg et al., 2000).

Polymicrobial infection should be anticipated in patients with a diabetic foot ulcer, with a variety of grampositive cocci, gram-negative rods, and anaerobic organisms predominating. Empirical antibiotic therapy typically includes broad-spectrum coverage for more common isolates from each of these three categories (Frykberg et al., 2000). Once wound culture results have been obtained, the initial antimicrobial therapy may require adjustment to provide more specific coverage or to provide therapy against resistant organisms. If there is persistent infection while on antibiotic therapy, surgical assessment and wound culture should be revisited. Methicillin-resistant staphylococci aureus (MRSA) has been emerging as an important pathogen in chronic diabetic foot ulcers (Frykberg et al., 2000).

## C. Osteomyelitis

Osteomyelitis and joint infection will require excision of bone for microbiological and histopathological evaluation (Frykberg et al., 2000). If the affected bone has been completely resected or amputated, the infection may be treated as a soft-tissue infection. However, if residual bone is present in the wound, the patient will likely require 4-8 weeks of antibiotic therapy based on the culture results (Frykberg et al., 2000). Intravenous or oral agents may be used, depending on the microbial isolates and the infection severity.

#### Moisture Balance

Dressing selection should promote a moist wound environment that minimizes trauma and risk of infection. Selection should be based on the wound to provide local moisture balance. Modern, moist interactive dressings used for diabetic foot ulcers include foams (high absorbency), calcium alginates (absorbent, hemostasis), hydrogels (moisture balance), hydrocolloids (occlusion), and adhesive membranes (protection) (Inlow et al., 2000). Consideration should be given to the following when choosing a moist wound dressing for a diabetic foot ulcer (Sibbald, Williamson, Orsted, Campbell, Keast, Krasner et al., 2000):

- Assess the wound bed for bacterial balance, exudate level and the need for debridement.
- Select a dressing or combination of dressings that can manage and or control the above wound environment.
- Use a dressing that will keep the wound bed continuously moist and the peri-wound skin dry.
- Choose a dressing that controls exudate but does not dry the ulcer bed.
- Consider the caregiver time when selecting a dressing.
- Eliminate wound dead space by loosely filling all cavities with dressing material.
- Assure that the patient is aware that there is to be reduced pressure to the affected area.
- Evaluate the wound frequently to determine efficacy of treatment plan.

Systematic reviews in the past have shown no differences in chronic wound healing outcomes (Hutchinson et al., 2000; Ovington, 1999). However, in a recent systematic review by Smith (2004), hydrogels were shown to be of some benefit in improving diabetic foot ulcers. Consideration of caregiver time is essential to cost efficency (Ovington, 1999). For information on dressing selection see Appendix N.

# **Extrinsic Factors**

**Recommendation 5.3:** 

Provide pressure redistribution. (Level of Evidence = IIa)

# **Discussion of Evidence:**

Ninety four percent of diabetic foot ulcers occur at areas of increased pressure (Fleischli, Lavery, Vela, Ashry & Lavery, 1997). Elevated plantar pressures coupled with neuropathy (lack of sensation) can lead to callus formation. The callus build-up (hyperkeratosis) is a normal response to the stress of elevated pressures on the foot and if untreated leads to ulcer formation. For a diabetic foot ulcer to heal the repetitive pressure must be reduced. This can be accomplished by the application of a number of external devices. It is important that there is a member of the team skilled in the fabrication and modification of offloading devices, such as a foot care specialist. See Appendix O for examples and considerations in selecting offloading devices.

One randomized controlled trial showed that total contact casting (TCC) was effective in treating well vascularized non-infected plantar forefoot diabetic foot wounds. Healing rates range from 72% to 100% over a course of five to seven weeks (Armstrong, Nguyen, Lavery, van Schie, Boulton & Harkless, 2001). Spencer (2004) conducted a systematic review evaluating the effectiveness of various offloading modalities to treat diabetic foot ulcers. One randomized controlled trial on total contact casting was identified showing weak evidence on its effectiveness in the treatment of diabetic foot ulcers.

It is important that the patient with a diabetic foot ulcer recognizes that pressure is the cause of their foot ulcer and the offloading is required whenever they are on their feet. In a study by Armstrong, Lavery, Kimbriel, Nixon and Boulton (2003) describing adherence to offloading devices, subjects were found to be only 25% compliant with their prescribed device.

# Non-healing diabetic foot wounds

# **Recommendation 5.4:**

Evaluate and implement treatment options for non-healable wounds. (*Level of Evidence = IV*)

# **Discussion of Evidence:**

While complete wound closure is widely accepted to be an objective endpoint in wound healing, this may not always be appropriate in assessing outcomes in chronic wounds (Enoch & Price, 2004). There are various factors that can contribute to the chronicity of such wounds.

Examples of factors contributing to poor healing outcomes include:

- Inadequate blood supply;
- Poor glycemic control;
- Non-adherence with treatment plan;
- End-stage renal disease;
- Transplant recipients;
- Differing individual goals;
- Malnutrition;
- Connective tissue disorders;
- Systemic conditions such as sickle cell disease;
- Osteomyelitis;
- Immobility;
- Heart disease;
- Dementia;
- Cancer; and
- Advancing age.

Goals of care must be mutually agreed upon by the individual and the healthcare team, reflecting a realistic outcome based on quality of life. The significance of managing exudate, controlling infection, relieving pain, and minimizing odour in a non-healing wound must be established and accepted as legitimate outcome measures (Enoch & Price, 2004).

- When healing is not the goal, wound management should incorporate:
  - A palliative wound management model that includes pain control, infection control, exudate management and odour control.
  - Keep wound bed dry, moist wound care is <u>not recommended</u>:
  - If the patient cannot fight infection the moist wound will be a breeding ground for infection.
  - Use dry dressing.
  - Using a topical, cost effective and potentially cytotoxic antiseptic such as povidine iodine can be considered when the risk of infection outweighs the healing potential.

# Evaluation:

# **Recommendation 6.0:**

Evaluate the impact and effectiveness of the treatment plan. (*Level of Evidence = IV*)

# **Discussion of Evidence:**

Assuming that all systemic and local factors have been addressed, Sheehan, Jones, Caselli, Giurini & Veves (2003) have shown that a 50% reduction in wound surface area at four weeks is a good predictor of wound healing at 12 weeks. Furthermore, Flanagan (2003) has shown that a 20% – 40% reduction of wound area in two and four weeks is likely to be a reliable predictive indicator of healing.

Assessment of the *edge of the wound* will determine if cell migration has begun. According to Schultz, Barillo, Mozingo, Chin & The Wound Bed Advisory Board Members (2004), wound proliferation occurs when keratinocytes and responsive wound cells migrate; thus advancing the edge of the wound. Healthy wounds have a pink wound bed and an advancing wound margin while unhealthy wounds have a dark, friable wound bed and an undermined wound margin.

## **Reassess:**

It should not be expected that all diabetic foot ulcers will have closure of the wound as a primary outcome. Wounds that are unlikely to heal need to have alternative outcome expectations such as wound stabilization, reduced pain, reduced bacterial load and decreased dressing changes (Enoch & Price, 2004).

Ongoing wound assessment should be comprehensive and support the rationale for care. The guideline development panel suggests these questions below as an approach to evaluating outcomes of care.

- 1. Is the treatment plan effective?
- 2. How is wound healing evaluated?
- 3. Is wound closure the only successful wound care outcome?

#### **Recommendation 6.1:**

Reassess for additional correctable factors if healing does not occur at the expected rate. (Level of Evidence = III - IV)

# **Discussion of Evidence:**

Reassessment of the entire treatment program is the first step to establishing a new directed approach.

The most common reason for delayed healing in PWDFU is inadequate pressure offloading. If appropriate offloading is not prescribed, the patient should be referred to a centre specializing in diabetic foot ulcer care. Revisiting adherence to prescribed offloading devices may uncover the reason why the wound is not healing (Armstrong et al., 2003).

Infection should always be considered as a possible cause of non-healing in combination with glycemic control. Revisiting the health history, co-morbidities and overall diabetes management may maximize the desired outcome.

If patient and wound are optimized and edge is still not migrating, consider tissue culture, biopsy and other diagnostic tests to rule out other conditions.

If delayed healing occurs, continuously evaluate. Vascular, infection and pressure parameters can change quickly; frequent monitoring for change in status or parameters is required. See Table 3 for treatment of wound infection in Recommendation 5.2.

If healing is still delayed, adjunctive approaches should be considered. See Recommendation 6.2.

# 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 = 1a - IV)

# **Discussion of Evidence:**

Care for diabetic foot ulcers that have not healed at the expected rate may include the use of:

- Biological agents
- Adjunctive therapies
- Surgery (e.g., skin graft, Achilles tendon lengthening, bony reconstruction)

Type of Adjunctive Therapy	Description and Evidence
Electrical Stimulation	<ul> <li>This procedure involves applying a low level electrical current to the base of the wound or the peri-wound using conductive electrodes.</li> <li>It must be performed by trained healthcare professionals.</li> <li>Evidence:         <ul> <li>A meta analysis (Foster, Smith, Taylor, Zinkie &amp; Houghton, 2004) of 17 RCTs showed that electrical stimulation was effective in treating chronic wounds (p&lt; 0.0001), included in this analysis were 3 RCTs with patients with diabetic foot ulcers (Baker, Chambers, DeMuth &amp; Villar, 1997; Lundeberg, Eriksson &amp; Malm, 1992; Peters, Lavery, Armstrong &amp; Fleischli, 2001).</li> <li>(Level of Evidence = 1a)</li> </ul> </li> </ul>
Hyperbaric Oxygen Therapy (HBOT)	<ul> <li>In this procedure, systemic (inhaled) subatmospheric oxygen is delivered via hyperbaric chamber.</li> <li>It increases oxygen tension in the tissues.</li> <li>Evidence: The routine management of diabetic foot ulcers with HBOT is not justified by the evidence found in the systematic review conducted by Kranke, Bennett &amp; Roeckl-Wiedmann (2004). Although HBOT significantly reduced the risk of major amputation and may improve the chance of healing at one year, economic evaluations should be undertaken. With methodological shortcomings and poor reporting of the studies that were reviewed, Kranke et al. (2004) cautions that any benefit from HBOT will need to be examined further using rigorous randomized trials. (Level of Evidence = III)</li> </ul>

Type of Adjunctive Therapy	Description and Evidence
Topical Negative Pressure (TNP) Therapy	<ul> <li>It is a subatmospheric pressure device delivered to the wound by an open cell foam dressing covered with a clear membrane over the wound.</li> <li>The dressing is attached to a pump that delivers equalized intermittent or continuous suction within a prescribed range of settings.</li> <li>Vacuum Assisted Closure (VAC<sup>®</sup>) Therapy is a commercial brand of topical negative pressure.</li> </ul>
	Evidence: The two small trials that evaluated the effectiveness of TNP on chronic wound healing provide weak evidence suggesting that TNP may be superior to saline gauze dressings in healing chronic human wounds. Findings: Due to the small sample sizes and methodological limitations of these trials, there is weak evidence to date.
	The effect of TNP on cost, quality of life, pain and comfort was not reported. It was not possible to determine which was the optimum TNP regimen (Armstrong, Lavery, Abu-Rumman, Espensen, Vazquez, Nixon et al., 2002; Ballard & McGregor, 2001; Clare, Fitzgibbons, McMullen, Stice, Hayes & Henkel, 2002; McCallon, Knight, Valiulus, Cunningham, McCulloch & Farinas, 2000; Sibbald, Mahoney & VAC Therapy Canadian Consensus Group, 2003).
	A case series of 31 patients with diabetic foot ulcers showed a statistical reduction in wound size at four weeks on the continuous setting at ~100 mm Hg (Teague, Newbatt, Zschape, Daniels, Rankine, Hoeflock et al., 2004). (Level of Evidence = 1b)
Biological Agents	Description and Evidence
Growth Factors	<ul> <li>Wound bed vascularization can be achieved by applying recombinant human platelet derived growth factor BB(PDGF)</li> <li>Becaplermin gel, also known as Regranex®, is an example of a growth factor.</li> <li>The biological activity of becaplermin is similar to that of naturally occurring PDGF and includes promoting chemotaxic requirement and proliferation of cells involved in the wound repair process (Smiell, 1998).</li> </ul>
	Evidence: Four multicentre, randomized paralled group studies found that once-daily topical administration of becaplermin gel in conjuction with good ulcer care was effective and well tolerated in patients with full-thickness, lower extremity diabetic ulcers (Smiell, Wieman, Steed, Perry, Sampson & Schwab, 1999). (Level of Evidence = 1b

Biological Agents	Description and Evidence
Bioactive Agents	<ul> <li>Bioactive agents can be acellular or cellular and have the potential to stimulate, through topical activation the normal or enhanced activity of mechanisms involved in tissue repair.</li> <li>Dermagraft* is an example of living tissue equivalents.</li> <li>Dermagraft* is a cultured human dermis. It consists of human neonatal and dermal fibroblasts cultured in vitro onto a bioabsorbable mesh to produce a living metabolically active tissue containing normal matrix proteins and cytokines (Gentzkow, Iwasaki, Hershon, Mengel, Prendergast, Ricotta et al., 1996; Gentzkow, Jensen, Pollak, Kroeker, Lerner, Lerner et al., 1999; Marston, Hanft, Norwood &amp; Pollak, 2003) (<i>Level of Evidence = 1b</i>)</li> <li>Oasis*, Promogran* and Hyalofil* are examples of acellular bioactive agents.</li> <li>Oasis* is a freeze dried wound matrix derived from porcine (pig) small intestinal submucousa (Brown-Etris, Cutshall &amp; Hiles, 2002).</li> <li>Xenograft: Oasis*, a relatively new product, is a xenogeneic, acellular, collagen matrix derived from porcine small intestinal submucousa in a way that allows extracellular matrix and natural growth factors to remain intact. This provides a scaffold for inducing wound healing.</li> <li>Evidence:</li> <li>In a small multicentre clinical study evaluating the efficacy of Oasis* compared to Regranex*, Niezgoda (2004) found similar wound healing outcomes in both treatment groups. (Level of Evidence = Ila)</li> <li>Promogran* is a freeze dried sponge prepared from bovine collagen and oxidized regenerated cellulose prepared in acetic acid. It reduces protease MMPs known to promote inflammation in chronic wounds and protect endogenous growth factors.</li> <li>Evidence:</li> <li>One RCT comparing Promogran* to moistened gauze dressings shoued</li> </ul>
	One RCT comparing Promogran <sup>®</sup> to moistened gauze dressings showed that at 12 weeks, no statistical differences were found in the healing rates between the two groups (Veves, Sheehan & Pham, 2002). Ghatnekar, Willis & Persson (2002) suggest that Promogran <sup>®</sup> may be cost effective as a result of reduced dressing frequency. (Level of Evidence = Ib)
	<ul> <li>Hyalofil<sup>®</sup> is a hyaluronic acid ester which is thought to provide structural support, developmental regulation and assists with receptor mediated gene expression as a major molecule in the extra cellullar matrix. It affects inflammation, regulation, angiogenesis, granulation formation and re-epithelialization. To date, only anecdotal results are available. <i>(Level of Evidence = IV)</i></li> </ul>

Surgery	Description and Evidence
Surgical (Skin Graft – Autologous)	<ul> <li>This procedure requires surgical transplant of epidermis and dermis from the same patient's donor site.</li> <li>(Level of Evidence = IV)</li> </ul>
Surgical (Achilles tendon lengthening)	<ul> <li>Lengthening the tendon or an attached calf muscle increases ankle dorsiflexion, thus reducing wound healing time and ulcer re-occurrence (<i>Level of Evidence = 1b</i>)</li> </ul>
	Evidence: Mueller et al. (2004) compared the effect of Achilles tendon lengthening to treatment with total contact casting. The outcomes measured were healing rates and ulcer re-occurrence at seven-months follow up and two-year follow up. Although the initial wound healing outcomes were similar, statistical reduction in ulcer re-occurrence was noted at seven- months and at two-years follow up.
Other surgical procedures	<ul> <li>Surgery for foot deformities can be beneficial in preventing the development and re-ocurrence of ulcers.</li> <li>Careful patient selection is critical, primarily with regard to an intact vascular supply.</li> <li>In appropriate cases, arthroplasty, digital amputation, bunionectomy, metatarsal osteotomy or ray resection, may be indicated (Muha, 1999).</li> <li>To date, only anecdotal results are available. <i>(Level of Evidence = IV)</i></li> </ul>

# **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 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*)

# **Discussion of Evidence:**

Nurses play a vital role in the early detection and ongoing assessment of diabetic foot ulcers. They are also in a pivotal position to facilitate an evidence-based, team approach to treatment (Mason et al., 1999a; Whittemore, 2000). If nurses are to fulfill these roles, they must utilize the nursing process and evidence to support patient care decisions. Nurses need to avail themselves of recognized, accredited continuing educational opportunities that support the interdisciplinary team approach to diabetic foot ulcer care. In order to improve health outcomes for persons with diabetic foot ulcers and increase job satisfaction for nurses, agencies need to provide a full scope of support (financial, education, and human resources) for nurses seeking professional education (Best & Thurston., 2004; Gottrup, 2004).

Refer to Appendix P for a list of resources for diabetic foot ulcer information.

# **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 a 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*)

# **Discussion of Evidence:**

In order to achieve optimal outcomes for individuals with diabetic foot ulcers, diabetes ulcer care should be platformed around an interdisciplinary healthcare team that can establish and sustain a communication network between the person with diabetes and the necessary healthcare and community systems. Frykberg (1998), through a retrospective review of the literature reported a reduction in non-traumatic amputation rates ranging from 58% to 100% after the implementation of a multidisciplinary approach to foot care. The team should be dedicated to both maintaining the overall well-being of the patient with diabetes and to preserving the integrity of their lower extremities (Inlow et al., 2000). Key players on the team, along with patients and families, may include diabetologists/endocrinologists, vascular surgeons, plastic surgeons, dermatologists, chiropodists/podiatrists, infectious disease specialists, family physicians, nurses specializing in diabetes and wound care, occupational therapists, physiotherapists, and dietitians. Teams can work without walls (not necessarily on the same site, but accessible to each other). However, coordination takes more effort to ensure the goal(s) remain consistent (Inlow et al., 2000). Both the organization and the delivery of diabetes foot care should be comprehensive, supported by evidence-based clinical practice guidelines, and equitable in access throughout the person's lifetime. Diabetes foot ulcer care should be community based and respectful of age, gender, cultural beliefs and socioeconomic dispositions. Organizations have a role to play in advocating and facilitating access to diabetes care and foot ulcer care services.

Graham, Harrison, Bouwers, Davies & Dunn (2002) indicate that in order for guidelines to be implemented successfully, a critical initial step must be the formal adoption of the guideline recommendations into the policy and procedure structure. This key step provides direction regarding the expectations of the organization, and facilitates integration of the guideline into such systems as the quality management process.

New initiatives such as the implementation of a best practice guideline require strong leadership from nurses who understand concepts of planned change, program planning and evaluation and research utilization. This knowledge will empower the nurse to effectively transform organizations in changing practice. This can be achieved by developing a program plan. Pollack (1994) developed a four-step planning process called "pre-start plan". The process includes mission statement clarification, stakeholder analysis, problem identification, and strength, weakness, opportunities and threats (SWOT) analysis.

Further, it is suggested that the RNAO *Toolkit* (2002b) be considered to assist organizations develop the leadership required for successful implementation. Refer to Appendix Q for a description of the RNAO *Toolkit: Implementation of Clinical Practice Guidelines.* 

# **Research Gaps & Future Implications**

The guideline development panel found that there is little research to support:

- Establishment of a standardized assessment and documentation tools for diabetic foot ulcers.
- Dressing choices for local wound care.
- Effectiveness of adjunctive therapies to promote wound healing.
- Effectiveness of various devices utilized for pressure redistribution/offloading.
- Health delivery issues (government support and funding of programs and treatment for diabetic foot ulcer management, cultural beliefs, high risk patient populations).
- Impact of sharp/surgical debridement on wound healing.
- Impact of education on healthcare provider and specific patient outcomes (ulcer healing/re-occurrence).
- Pharmacoeconomics of secondary and tertiary prevention strategies.

The above list, although in no way exhaustive, is an attempt to identify and prioritize the enormous amount of research that is needed in this area. Some of the recommendations in the guideline are based on evidence gained from quantitative and qualitative research. Other recommendations are based on consensus or expert opinion. Further substantive research is required to validate the expert opinion. Increasing the research can impact knowledge that will lead to improved practice and outcomes for patients who experience diabetic foot ulcers.

# **Evaluation & Monitoring of Guideline**

**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. The following table, based on a framework outlined in the RNAO *Toolkit: Implementation of Clinical Practice Guidelines* (2002b), illustrates some indicators for monitoring and evaluation:

Level of Indicator	Structure	Process	Outcome
Objectives	To evaluate the supports available in the organization that allow for nurses and the interdisciplinary team to integrate in their practice the assessment and management of diabetic foot ulcers.	To evaluate the changes in practice that lead towards assessment and management of diabetic foot ulcers.	To evaluate the impact of implementation of the recommendations.
Organization/ Unit	<ul> <li>Review of best practice recommendations by organizational committee(s) responsible for policies and procedures.</li> <li>Availability of patient education resources that are consistent with best practice recommendations.</li> <li>Provision of accessible resource people for nurses and the interdisciplinary team to consult for ongoing support during and after initial implementation period.</li> </ul>	<ul> <li>Development of forms or documentation systems that encourage documentation of assessment and management of diabetic foot ulcers.</li> <li>Concrete procedures for making referrals to internal and external resources and services.</li> </ul>	<ul> <li>Incorporation of assessment and management of diabetic foot ulcers in staff orientation program.</li> <li>Referrals internally and externally.</li> </ul>
Provider	<ul> <li>Percentage of healthcare providers attending the best practice guideline education sessions on assessment and management of diabetic foot ulcers.</li> </ul>	<ul> <li>Self-assessed knowledge of assessment and management of diabetic foot ulcers.</li> <li>Average self-reported awareness levels of community referral sources for patients with diabetic foot ulcers.</li> </ul>	<ul> <li>Evidence of documentation in the patient's record consistent with the guideline recommendations.</li> <li>Referral to the following services or resources within the community or within the organization as necessary – Chiropodist/ Podiatrist, Wound Care Clinic, Diabetes Education Centre, Nurses specializing in wound and diabetes care, Dermatologist, Infectious Disease Specialist, Vascular Surgeon, Plastic Surgeon, Family Physician, Endocrinologist/Diabetologist, Dietitian, Occupational Therapist, Physiotherapist.</li> <li>Provision of education and support to patient and family members.</li> <li>Patient/family satisfaction.</li> </ul>

Level of Indicator	Structure	Process	Outcome
Patient (new or recurrent diabetic foot ulcer)	<ul> <li>Percentage of patients admitted to unit/facility or seen at the clinic with diabetic foot ulcers.</li> </ul>	<ul> <li>Percentage of patients who were assessed and treated using the VI.P. (vascular supply, infection, and pressure redistribution/ offloading) principle.</li> </ul>	<ul> <li>Improvement in quality of life and satisfaction.</li> <li>Percentage of patients adhering to treatment plan at three months post-discharge.</li> <li>Percentage of patients with ulcers partially or fully healed at three months post-discharge.</li> <li>Percentage of patients who regularly examine their feet.</li> <li>Percentage of patients accessing referral sources in community.</li> <li>Percentage of patients seen or to be seen for referral.</li> </ul>
Financial Costs	Provision of adequate financial resources for the level of staffing necessary to implement guideline recommendations.	<ul> <li>Cost related to implementing guideline:</li> <li>Education and access to on the job supports.</li> <li>New documentation systems.</li> <li>Support systems.</li> <li>Cost related to diagnostic services, equipment, devices and products (e.g., monofilaments, patient resource materials, biological agents, surgical interventions; adjunctive therapies, pressure redistribution/offloading).</li> </ul>	<ul> <li>Cost efficiency and effectiveness of treatment.</li> <li>Overall resource utilization.</li> <li>Length of stay in health system.</li> <li>Hospital readmission rates.</li> <li>Reintegration into community.</li> </ul>

# **Implementation Strategies**

**The Registered Nurses' Association of Ontario** and the guideline development panel have compiled a list of implementation strategies to assist healthcare organizations or healthcare disciplines who are interested in implementing this guideline. A summary of these strategies follows:

- Have at least one dedicated person such as an advanced practice nurse or a clinical resource nurse who will provide support, clinical expertise and leadership. The individual should also have good interpersonal, facilitation and project management skills.
- Conduct an organizational needs assessment related to diabetic foot ulcer management to identify current knowledge base and further educational requirements.
- Initial needs assessment may include an analysis approach, survey and questionnaire, group format approaches (e.g., focus groups), and critical incidents.
- Establish a steering committee comprised of key stakeholders and interdisciplinary members committed to lead the change initiative. Identify short term and long term goals. Keep a work plan to track activities, responsibilities and timelines.
- Create a vision to help direct the change effort and develop strategies for achieving and sustaining the vision.
- Program design should include:
  - Target population;
  - Goals and objectives;
  - Outcome measures;
  - Required resources (human resources, facilities, equipment); and
  - Evaluation activities.
- Design educational sessions and ongoing support for implementation. The education sessions may consist of presentations, faciltator's guide, handouts, and case studies. Binders, posters and pocket cards may be used as ongoing reminders of the training. Plan education sessions that are interactive, include problem solving, address issues of immediate concern and offer opportunities to practice new skills (Davies & Edwards, 2004).

- Provide organizational support such as having the structures in place to facilitate the implementation. For example, hiring replacement staff so participants will not be distracted by concerns about work and having an organizational philosophy that reflects the value of best practices through policies and procedures. Develop new assessment and documentation tools (Davies & Edwards, 2004).
- Identify and support designated best practice champions on each unit to promote and support implementation. Celebrate milestones and achievements, acknowledging work well done (Davies & Edwards, 2004).
- Organizations implementing this guideline should adopt a range of self-learning, group learning, mentorship and reinforcement strategies that will, over time, build the knowledge and confidence of nurses in implementing this guideline.
- Beyond skilled nurses, the infrastructure required to implement this guideline includes access to specialized equipment and treatment materials. Orientation of the staff to the use of specific products and technologies must be provided and regular refresher training planned.
- Teamwork, collaborative assessment and treatment planning with the patient and family and interdisciplinary team are beneficial in implementing guidelines successfully. Referral should be made as necessary to the following services or resources in the community or within the organization: Chiropodist, Wound Care Clinic, Diabetes Education Centre, Nurses specializing in wound and diabetes care; Dermatologist, Infectious Disease Specialist, Vascular Surgeon, Plastic Surgeon, and other healthcare professionals who provide care to patients with diabetic foot ulcers such as Family Physician, Dietitian, Occupational Therapist and Physiotherapist.
- The RNAO's Advanced/Clinical Practice Fellowships (ACPF) Project is another resource that registered nurses in Ontario may apply for a fellowship and have an opportunity to work with a mentor who has expertise in diabetic foot ulcer management. With the ACPF, the nurse fellow will have the opportunity to hone their skills in assessing and managing diabetic foot ulcers.

In addition to the strategies mentioned above, the RNAO has developed resources that are available on their website. A *Toolkit* for implementing guidelines can be helpful if used appropriately. A brief description about this *Toolkit* can be found in Appendix R. A full version of the document in pdf format is also available at the RNAO website, <u>www.rnao.org/bestpractices</u>.

# **Process for Update/Review of Guideline**

The Registered Nurses' Association of Ontario proposes to update this best practice guideline as follows:

- 1. Each nursing best practice guideline will be reviewed by a team of specialists (Review Team) in the topic area every three years following the last set of revisions.
- 2. During the three-year period between development and revision, RNAO Nursing Best Practice Guidelines program staff will regularly monitor for relevant new literature in the subject area.
- 3. Based on the results of the monitor, program staff will recommend an earlier revision period. Appropriate consultation with a team of members comprised of original panel members and other specialists in the field will help inform the decision to review and revise the guideline earlier than the three-year milestone.
- 4. Three months prior to the three year review milestone, the program staff will commence the planning of the review process by:
  - a. Inviting specialists in the field to participate in the Review team. The Review Team will be comprised of members from the original panel as well as other recommended specialists.
  - b. Compiling feedback received, questions encountered during the dissemination phase as well as other comments and experiences of implementation sites.
  - c. Compiling new clinical practice guidelines in the field, systematic reviews, meta-analysis papers, technical reviews, randomized controlled trial research, and other relevant literature.
  - d. Developing a detailed work plan with target dates and deliverables.

The revised guideline will undergo dissemination based on established structures and processes.

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# Appendix A: Search Strategy for Existing Evidence

#### STEP 1 – DATABASE Search

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".

#### STEP 2 – Structured Website Search

One individual searched an established list of websites 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 websites, 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 websites at times did not house a guideline but directed to another website or source for guideline retrieval. Guidelines were either downloaded if full versions were available or were ordered by phone/e-mail.

- Agency for Healthcare Research and Quality: <u>http://www.ahcpr.gov</u>
- Alberta Heritage Foundation for Medical Research Health Technology Assessment: http://www.ahfmr.ab.ca//hta
- Alberta Medical Association Clinical Practice Guidelines: <u>http://www.albertadoctors.org</u>
- American College of Chest Physicians: <u>http://www.chestnet.org/guidelines</u>
- American Medical Association: <u>http://www.ama-assn.org</u>
- British Medical Journal Clinical Evidence: <u>http://www.clinicalevidence.com</u>
- Canadian Coordinating Office for Health Technology Assessment: <u>http://www.ccohta.ca</u>
- Canadian Task Force on Preventive Healthcare: <u>http://www.ctfphc.org</u>
- Centers for Disease Control and Prevention: <u>http://www.cdc.gov</u>
- Centre for Evidence-Based Mental Health: <u>http://www.cebmh.com</u>
- Centre for Evidence-Based Pharmacotherapy: <u>http://www.aston.ac.uk/lhs/teaching/pharmacy/cebp</u>
- Centre for Health Evidence: <u>http://www.cche.net/che/home.asp</u>
- Centre for Health Services and Policy Research: <u>http://www.chspr.ubc.ca</u>
- Clinical Resource Efficiency Support Team (CREST): <u>http://www.crestni.org.uk</u>
- CMA Infobase: Clinical Practice Guidelines: <u>http://mdm.ca/cpgsnew/cpgs/index.asp</u>
- Cochrane Database of Systematic Reviews: <u>http://www.update-software.com/cochrane</u>
- Database of Abstracts of Reviews of Effectiveness: <u>http://nhscrd.york.ac.uk/darehp.htm</u>
- Evidence-Based On-Call: <u>http://www.eboncall.org</u>
- Government of British Columbia Ministry of Health Services: http://www.hlth.gov.bc.ca/msp/protoguides/index.html
- Institute for Clinical Systems Improvement: <u>http://www.icsi.org/index.asp</u>
- Institute of Child Health: <u>http://www.ich.ucl.ac.uk/ich</u>
- Joanna Briggs Institute: <u>http://www.joannabriggs.edu.au/about/home.php</u>

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- Medic8.com: <u>http://www.medic8.com/ClinicalGuidelines.htm</u>
- Medscape Women's Health: <u>http://www.medscape.com/womenshealthhome</u>
- Monash University Centre for Clinical Effectiveness: <u>http://www.med.monash.edu.au/healthservices/cce/evidence</u>
- National Guideline Clearinghouse: <u>http://www.guidelines.gov</u>
- National Institute for Clinical Excellence: <u>http://www.nice.org.uk</u>
- National Library of Medicine Health Services/Technology Assessment: <u>http://hstat.nlm.nih.gov/hq/Hquest/screen/HquestHome/s/64139</u>
- Netting the Evidence: A ScHARR Introduction to Evidence-Based Practice on the Internet: <u>http://www.shef.ac.uk/scharr/ir/netting</u>
- New Zealand Guidelines Group (NZGG): <u>http://www.nzgg.org.nz</u>
- NHS Centre for Reviews and Dissemination: <u>http://www.york.ac.uk/inst/crd</u>
- NHS Nursing & Midwifery Practice Development Unit: <u>http://www.nmpdu.org</u>
- NHS R & D Health Technology Assessment Programme: <u>http://www.hta.nhsweb.nhs.uk/htapubs.htm</u>
- PEDro: The Physiotherapy Evidence Database: http://www.pedro.fhs.usyd.edu.au/index.html
- Queen's University at Kingston: <u>http://post.queensu.ca/~bhc/gim/cpgs.html</u>
- Royal College of General Practitioners: <u>http://www.rcgp.org.uk</u>
- Royal College of Nursing: <u>http://www.rcn.org.uk/index.php</u>
- Royal College of Physicians: <u>http://www.rcplondon.ac.uk</u>
- Sarah Cole Hirsch Institute: <u>http://fpb.cwru.edu/HirshInstitute</u>
- Scottish Intercollegiate Guidelines Network (SIGN): <u>http://www.sign.ac.uk</u>
- Society of Obstetricians and Gynecologists of Canada Clinical Practice Guidelines: http://www.sogc.medical.org/sogcnet/index\_e.shtml
- The Canadian Cochrane Network and Centre: <u>http://cochrane.mcmaster.ca</u>
- The Qualitative Report: <u>http://www.nova.edu/ssss/QR</u>
- Trent Research Information Access Gateway: <u>http://www.shef.ac.uk/scharr/triage/TRIAGEindex.htm</u>
- TRIP Database: <u>http://www.tripdatabase.com</u>
- U.S. Preventive Service Task Force: http://www.ahrq.gov/clinic/uspstfix.htm
- University of California, San Francisco: <u>http://medicine.ucsf.edu/resources/guidelines/index.html</u>
- University of Laval Directory of Clinical Information Websites: <u>http://132.203.128.28/medecine</u>
- University of York Centre for Evidence-Based Nursing: <u>http://www.york.ac.uk/health-sciences/centres/evidence/cebn.htm</u>

#### STEP 3 – Search Engine Web Search

A website 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 websites 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.

#### STEP 4 – Hand Search/Panel Contributions

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.

#### STEP 5 – Core Screening Criteria

This above search method revealed eight guidelines, several systematic reviews and numerous articles related to diabetic foot ulcers.

The final step in determining whether the clinical practice guideline would be critically appraised was to have two individuals screen the guidelines based on the following criteria. These criteria were determined by panel consensus:

- Guideline was in English, international in scope.
- Guideline 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.

#### **RESULTS OF THE SEARCH STRATEGY**

The results of the search strategy and the decision to critically appraise identified guidelines are detailed below. Seven guidelines met the screening criteria and were critically appraised using the *Appraisal of Guidelines for Research and Evaluation* (AGREE Collaboration, 2001) instrument.

#### TITLE OF THE PRACTICE GUIDELINES CRITICALLY APPRAISED

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]. Available: <a href="http://www.diabetes.net.au/PDF/evidence\_based\_healtcare/FootProblems.pdf">http://www.diabetes.net.au/PDF/evidence\_based\_healtcare/FootProblems.pdf</a>

CREST – Clinical Resource Efficiency and Support Team (1998). Guidelines for the management of the diabetic foot: Recommendations for practice. Clinical Resource Efficiency and Support Team [Electronic version]. Available: <u>http://www.crestni.org.uk/publications/diabetic\_foot.pdf</u>

Frykberg, R. G., Armstrong, D. G., Giurini, J., Edwards, A., Kravette, M., Kravitz, S. et al. (2000). Diabetic foot disorders: A clinical practice guideline. American College of Foot and Ankle Surgeons [Electronic version]. Available: <u>http://www.acfas.org/diabeticcpg.html</u>

Hutchinson, A., McIntosh, A., Feder, R. G., Home, P. D., Mason, J., O'Keefee, C. et al. (2000). Clinical guidelines and evidence review for type 2 diabetes: Prevention and management of foot problems. Royal College of General Practitioners [Electronic version]. Available:

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# Appendix B: Glossary of Terms

**A1C (formerly referred to as Glycosylated Hemoglobin or HBA1C):** The A1C test measures the average glycemia over the preceding 2-3 months and, thus, assesses glycemic control. When the A1C is done every three months, it can detect whether glycemic control has been reached and maintained within the target range and also reflects departures from the target range.

**Abscess:** A circumscribed collection of pus that forms in tissue as a result of acute or chronic localized infection. It is associated with tissue destruction and frequently swelling.

**Anhydrosis:** Failure of the sweat glands to produce sweat, resulting in dryness in the skin, often a result of damaged nerves or neuropathy.

**Ankle Brachial Pressure Index (ABPI):** A comparison between the brachial systolic pressure and ankle systolic pressure. It gives an indication of arterial perfusion. The normal resting pressure is 1.0.

Antibiotic: An agent that is synthesized from a living organism (e.g., penicillin from mold) and can kill or halt the growth of microbes or bacteria.

**Antimicrobial:** An agent that is used to kill bacteria or microbes, that is not synthesized from a living organism (e.g., iodine or silver).

Antiseptic (Topical): Product with antimicrobial activity designed for use on skin or other superficial tissues; may damage cells.

**Callus:** An area of skin that is abnormally thick or hard, usually from continual pressure or friction, sometimes over a bony prominence.

**Cellulitis:** An infection of the skin characterized most commonly by local heat, redness (erythema), pain and swelling.

Claw Toes: Same as hammer toes.

**Culture (Swab):** Techniques involving the use of a swab to remove bacteria from a wound and place them in a growth medium for propagation and identification.

**Diabetic Neuropathy:** Peripheral, somatic or autonomic nerve damage attributable solely to diabetes mellitus.

**Edge of Wound:** It is an important part of the algorithm for wound management in diabetic foot ulcers. It provides an outcome statement (goal of care), provides structure for care (enabler), and it supports the use of a common language to determine healing (links practitioners). It determines if cell migration has begun.

**Exuberant Granulation Tissue:** New granulation tissue that is proliferating above the normal rate.

Fissures: A long, narrow opening or gap that can extend into other cavities or areas of the body.

**Friable Tissue:** Granulation tissue that bleeds easily with minimal stimulation. Normal healthy tissue is not friable.

**F-Scan mat:** Measures dynamic plantar pressures (foot pressure in standing and walking positions). This device measures peak pressures under the forefoot and the rear foot and is used to assist healthcare providers in reducing pressure areas to the foot.

Hallux Deformity: A deformity of the great toe.

**Hammer Toes:** A hammer toe is a toe that is contracted at the middle joint, which may cause severe pressure and pain. The ligaments and tendons that have tightened cause the toe's joints to curl downwards and may occur in any toe except the great toe.

**Infection:** The presence of bacteria or other micro-organisms in sufficient quantity to damage tissue or impair healing. Clinical experience has indicated that wounds can be classified as infected when the wound tissue contains 10<sup>5</sup> or greater micro-organisms per gram of tissue. Clinical signs of infection may not be present, especially in the immuno-compromised patient or the patient with a chronic wound.

Local Clinical Infection. A clinical infection that is confined to the wound and within a few millimeters of its margins – e.g., purulent exudate, odour, erythema, warmth, tenderness, edema, pain, fever, and elevated white cell count.

Systemic Clinical Infection. A clinical infection that extends beyond the margins of the wound. Some systemic infectious complications of pressure ulcers include cellulitis, advancing cellulitis, osteomyelitis, meningitis, endocarditis, septic arthritis, bacteremia, and sepsis.

**Insensate:** A word that describes a region of the body where the person cannot feel a stimulus. An example is when a monofilament is applied using proper technique, if the person does not feel the filament, that area of the foot is described as insensate.

**Malnutrition:** State of nutritional insufficiency due to either inadequate dietary intake or defective assimilation or utilization of food ingested.

**Metatarsal Heads:** The "metatarsal region" of the foot is the area on the bottom of a foot just before the toes, more commonly referred to as the ball-of-the-foot.

**MRSA:** Methicillin-resistant staphylococcus aureus (MRSA) is a strain of the staphylococcus bacterium which is resistant to the main groups of antibiotics.

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**Onychomycosis:** Fungal infection in the toe nails. Nails may appear dry, thickened, white or yellow and flaky.

**Pallor:** White, pale, blanched colour of a limb when in the upright position.

**Pes Cavus:** A foot characterized by an abnormally high arch. Hyperextension of the toes may be present which can give the foot the appearance of a claw.

**Pes Planus:** A foot that has a fallen arch and appears abnormally flat or spread out.

**Photoplethysmography:** Photoplethysmography uses infra-red light to assess changes in the blood volume in the micro-circulation.

**Rubor:** Dark purple to bright red colour of a limb when in a dependent position.

**Sensory Ataxia:** Is an impairment of one's sense of body position. It may be characterized by striking the ground forcibly with the bottom of the foot as well as a stiff fling of the leg with walking.

**Specificity:** The chance of having a negative test result given that one does not have a disease.

**Sensitivity:** The chance of having positive test result given that one does have a disease.

Toe Pressure: See photoplethysmography.







## Appendix C: University of Texas Foot Classification System – Categories 0-3: Risk Factors for Ulceration

#### Category 0: No Pathology

- Patient diagnosed with Diabetes Mellitus
- Protective sensation intact
- Ankle Brachial Pressure Index (ABPI) > 0.80 and toe systolic pressure >45 mmHg
- Foot deformity may be present
- No history of ulceration

#### POSSIBLE TREATMENT FOR CATEGORY 0

- Two to three visits a year to assess neurovascular status, dermal thermometry, and foci of stress
- Possible shoe accommodations
- Patient education

#### Category 1: Neuropathy, No Deformity

- Protective sensation absent
- Ankle Brachial Pressure Index (ABPI) > 0.80 and toe systolic pressure >45 mmHg
- No history of ulceration
- No history of diabetic neuropathic osteoarthropathy (Charcot's joint)
- No foot deformity

#### POSSIBLE TREATMENT FOR CATEGORY 1

Same as Category 0 plus:

- Possible shoe gear accommodation (pedorthic/orthotist consultation)
- Quarterly visits to assess shoe gear and monitor for signs of irritation

#### Category 2: Neuropathy with Deformity

- Protective sensation absent
- Ankle Brachial Pressure Index (ABPI) >0.80 and toe systolic pressure >45 mmHg
- No history of neuropathic ulceration
- No history of Charcot's joint
- Foot deformity present (focus of stress)

#### POSSIBLE TREATMENT FOR CATEGORY 2

Same as Category 1 plus:

- Pedorthic/orthotist consultation for possible custom molded/extra depth shoe accommodation
- Possible prophylactic surgery to alleviate focus of stress (e.g., correction of hammer toe or bunion deformity)

#### Category 3: History of Pathology

- Protective sensation absent
- Ankle Brachial Pressure Index (ABPI) >0.80 and toe systolic pressure >45 mmHg
- History of neuropathic ulceration
- History of Charcot's joint
- Foot deformity present (focus of stress)

#### POSSIBLE TREATMENT OF CATEGORY 3

Same as Category 2 plus:

- Pedorthic/orthotist consultation for custom molded/extra depth shoe accommodation
- Possible prophylactic surgery to alleviate the focus of stress (e.g., correction of bunion or hammer toe)
- More frequent visits may be indicated for monitoring

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Assessment and Management of Foot Ulcers for People with Diabetes

# Appendix D: University of Texas Foot Classification System – Categories 4-6: Risk Factors for Amputation

#### Category 4A: Neuropathic Wound

- Protective sensation absent
- Ankle Brachial Pressure Index (ABPI) > 0.80 and toe systolic pressure >45 mmHg
- Foot deformity normally present
- Non-infected neuropathic ulceration (ALL UT\* STAGE A wounds)
- No <u>acute</u> diabetic neuropathic osteoarthorpathy (Charcot's joint) present

#### POSSIBLE TREATMENT FOR CATEGORY 4A

Same as Category 3 plus:

- Pressure reduction program instituted
- Wound care program instituted

#### Category 4B: Acute Charcot's Joint

- Protective sensation absent
- Ankle Brachial Pressure Index (ABPI) > 0.80 and toe systolic pressure >45 mmHg
- Non-infected neuropathic ulceration may be present
- Diabetic neuropathic osteoarthropathy (Charcot's joint) present

#### POSSIBLE TREATMENT FOR CATEGORY 4B

- Pressure reduction program instituted
- Thermometric and radiographic monitoring
- If ulcer is present, treatment same as Category 4A

#### Category 5: The Infected Diabetic Foot

- Protective sensation may or may not be present
- Infected wound
- Charcot's Joint may be present
- ALL UT\* STAGE B wounds

#### POSSIBLE TREATMENT FOR CATEGORY 5

- Debridement of infected, necrotic tissue and/or bone, as indicated
- Possible hospitalization, antibiotic treatment regimen
- Medical management

#### Category 6: The Ischemic Limb

- Protective sensation may or may not be present
- Ankle Brachial Pressure Index (ABPI) <0.80 and toe systolic pressure <45 mmHg or Pedal Transcutaneous Oxygen Tension < 40 mmHg</li>
- Ulceration may be present
- ALL UT\* STAGE C AND D wounds

#### POSSIBLE TREATMENT OF CATEGORY 6

- Vascular consult, possible revascularization
- If infection present, treatment same as for Category 5. Vascular consultation concomitant with control of sepsis.

Legend: \*UT = University of Texas

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# Appendix E: University of Texas Health Science Center San Antonio Diabetic Wound Classification System

		GRADE	S	
	0	L	II	Ш
A	Pre-or post- ulcerative lesion	Superficial wound, not involving tendon, capsule, or bone	Wound penetrating to tendon or capsule	Wound penetrating to bone or joint
В	Pre- or post-ulcerative lesion, completely epithelialized with infection	Superficial wound, not involving tendon, capsule, or bone with infection	Wound penetrating to tendon or capsule with infection	Wound penetrating to bone or joint with infection
C	Pre- or post-ulcerative lesion, completely epithelialized with ischemia	Superficial wound, not involving tendon, capsule, or bone with ischemia	Wound penetrating to tendon or capsule with ischemia	Wound penetrating to bone or joint with ischemia
D	Pre- or post-ulcerative lesion, completely epithelialized with infection and ischemia	Superficial wound, not involving tendon, capsule, or bone with infection and ischemia	Wound penetrating to tendon or capsule with infection and ischemia	Wound penetrating to bone or joint with infection and ischemia

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Armstrong, D., Lavery, L. A. & Harkless, L. B. (1998b). Validation of a diabetic wound classification system: The contribution of depth, infection and ischemia to risk of amputation. *Diabetes Care*, *21*(5), 855-859. Copyright© 1998 American Diabetes Association.



# Appendix F: Diabetic Foot Care – Patient Handout

Any healthcare team member can assess the patient and/or caregiver's knowledge regarding their foot care. This patient handout was designed to assist team members in reviewing basic foot care strategies. Each item is explained in details on p.84 while p.85 is an easy to use checklist that encourages the patient to check each important aspect of care, using a simple check mark in each box. The "make notes" section is intended to remind patients to discuss any changes or questions with their healthcare provider.

#### As a person with diabetes, you and your feet are special!



#### Keep your feet clean

- · Check temperature of water using your elbow
- · Wash feet daily using lukewarm water and mild soap
- · Dry feet gently, especially between your toes



Check your feet daily between and under all toes

- as well as top and bottom of both feet · Use good lighting and wear your glasses
- · Use a mirror to see the bottom of your foot
- · Get help if you cannot see your feet well
- · Check for: dry skin, hard areas, blisters, breaks in the skin
- · Feel for changes in temperature and look for changes in colour or size
- · Any changes you should get help right away



#### Keep your feet soft to prevent problems

- · Use a lotion daily after your bath (eg. Uremol, Lac-Hydrin or Lubriderm)
- · Do not put lotion between your toes or on open sores



#### Nail care is best done after a bath or shower-nails are soft then

- · Shape nails even with the end of your toes using an emery board
- · Never use a sharp pointed instrument
- · Use a soft nail brush daily
- · If you have hard areas of skin, thick or curled toenails, or have trouble seeing, you should see your doctor or a foot care specialist that your doctor suggests



#### Good footwear is very important to prevent breaks in the skin

- · Shop for shoes in the afternoon when your feet are a little larger
- · Shop at a shoe store suggested by your doctor and tell them that you have diabetes-use the same shoe store regularly
- · Never go barefoot or wear sandals because your feet can get injured easily then, which can lead to infection
- · Wear cotton socks in your shoes to allow your feet to breathe
- · Shake out your shoes before you put them on to make sure there is nothing inside



#### Record and report any changes in your feet

Remember you and your feet are special! Take the time to visit your doctor and diabetes education centre to keep your diabetes and health well managed. Record and report any changes in your feet.

Information from: Love Your Feet, Convatec and Foot Care for Diabetics, Diabetes Education Centre, Credit Valley Hospital

Reprinted with permission: Laurie Goodman, RN, BA, IIWCC, Nurse Clinician, Skin & Wound Care, Credit Valley Hospital.

Foot Care Record	Mon	Tues	Wed	Thur	Fri	Sat	Sun
Wash							
Look							
Use Lotion							
HO							
Trim Nails							
Check Shoes							
Make Notes							

Reprinted with permission: Laurie Goodman, RN, BA, IIWCC, Nurse Clinician, Skin & Wound Care, Credit Valley Hospital.

# Appendix G: Diagnostic Tests to Determine Vascular Supply

Diagnostic Test	Description
Arterial Duplex Scan	<ul> <li>Non-invasive ultrasound test that can identify macro- and microvascular changes in the arterial tree.</li> <li>Used to diagnose aneurysm for large vessel stenosis &gt;50%.</li> <li>Patients with suspected superficial artery stenosis and claudication may undergo duplex scanning to identify a lesion that is amenable to angioplasty, before subjected to angiogram (Sales, Goldsmith &amp; Veith 1994).</li> <li>Non-invasive arterial duplex scan as having sensitivity and specificity rates greater than 90% (Kravitz, McGuire &amp; Shanahan, 2003).</li> </ul>
Transcutaneous Oxygen (T <sub>c</sub> pO <sub>2</sub> )	<ul> <li>Measures absolute oxygen partial pressure in the dermis. According to Goldman and Salcido (2002), T<sub>c</sub>pO<sub>2</sub> less than 20 mmHg gives a guarded prognosis for healing.</li> <li>40 mmHg is a good indication for healing (Goldman &amp; Salcido, 2002).</li> <li>T<sub>c</sub>pO<sub>2</sub> should be measured on upper leg and dorsum of the foot for best results.</li> <li>Areas of callus, edema or bony prominences produce inaccurate results.</li> <li>Valuable for evaluating perfusion and is a good predictor of amputation in the lower limbs (Adler, Boyko, Ahroni &amp; Smith, 1999; Ballard, Eke, Bunt &amp; Killeen, 1995; Lehto, Ronnemaa, Pyorala &amp; Laakso, 1996; Mayfield, Reiber, Sanders, Janisse &amp; Pogach, 1998; Pecoraro, Ahroni, Boyko &amp; Stensel, 1991; Reiber et al., 1992).</li> <li>T<sub>c</sub>pO<sub>2</sub> &lt; 30 mmHg was an independent predictor of diabetic foot ulceration (McNeely, Boyko, Ahroni, Stensel, Reiber, Smith et al., 1995).</li> </ul>
Toe and Ankle Pressures	<ul> <li>Systolic toe and ankle pressures are measured with a fitted occluding cuff placed most often around the base of the first toe and around both ankles.</li> <li>Toe pressure of &gt;45 mmHg is necessary for optimal healing (Apelqvist, Castenfors, Larsson, Stenström &amp; Agardh, 1989; Frykberg et al., 2000).</li> <li>Most patients with toe blood pressures &gt;30mmHg healed with conservative management (Apelqvist et al., 1989; Kalani, Brismar, Fagrell, Ostergren &amp; Jorneskog, 1999; Royal Melbourne Hospital, 2002).</li> <li>With ankle pressures &gt; 80 mmHg, most patients had an amputation or died before healing occurred (Apelqvis et al., 1989).</li> <li>Kalani et al. (1999) suggests a cut-off of 25mmHg for T<sub>c</sub>pO<sub>2</sub> and 30mmHg for toe blood pressure as predictors of wound healing, with T<sub>c</sub>pO<sub>2</sub> being the better predictor in patients with diabetes and chronic foot ulcers. Toe pressures, however, may be more technically and economically feasible.</li> </ul>
Ankle-Brachial Pressure Index (ABPI)	<ul> <li>ABPI or ratio of systolic blood pressure in the lower extremity to blood pressure in the arm is a common clinical measure of reduced circulation (Boyko et al., 1999).</li> <li><i>Caution:</i></li> <li>This should not be the sole diagnostic test performed.</li> <li>In patients with diabetes, ABPI results can be unreliable (falsely negative) due to calcification of the arterial vessels (Apelqvist et al., 1989).</li> </ul>

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# Appendix H: Diagnostic Tests and Imaging to Determine Infection

#### **Diagnostic tests**

Accessability and interpretation of these tests may be limited to certain areas of specialty. Diagnostic tests are performed in conjunction with the clinical assessment. Utilizing isolated test results in isolation may lead the clinician to a misdiagnosis (RNAO Guideline Development Panel, 2005).

#### Wound cultures

Cultures of the wound should be obtained to guide antibiotic therapy effectively and accurately. Bacterial swabs can provide information on the predominant flora within a non-progressing, deteriorating or heavily exudating wound. See Appendix I for swab techniques. Blood cultures are useful if sepsis is suspected (Perry, Pearson & Miller, 1991). Bacterial swabs or wound cultures do not diagnose infection but they can be used as guidance for antimicrobial therapy. The diagnosis of infection is based on clinical symptoms and signs.

#### C-reactive protein

The sensitivity and specificity of serological markers of infection, e.g., C-reactive protein, tends to increase with more severe infection (Royal Melbourne Hospital, 2002).

#### • White Blood Cell Count (WBC) and Erythrocyte Sedimentation Rate (ESR)

Elevated lab values should alert the clinician to the possibility of sepsis; however, normal values should not be used to rule out infection (Armstrong et al., 1996). These lab tests are helpful but must be considered in conjunction with the clinical assessments of infection.

#### Imaging

Imaging presentation will vary and should only be conducted to establish or confirm a suspected diagnosis and/or direct patient management. Accessability and interpretation may be limited to certain areas of specialty:

X-Ray

Plain X-rays are a useful primary imaging tool as they may reveal changes consistent with osteomyelitis, the presence of foreign bodies, tissue gas or bony abnormalities (Bonham, 2001). Bone destruction and periosteal changes are not usually evident for 10-21 days following infection (Royal Melbourne Hospital, 2002).

#### Bone / Gallium scans

Gallium 67citrate is a nuclear medicine technique that is not used as frequently today due to more accurate alternative imaging studies (Frykberg et al., 2000; Johnson, Kennedy, Shereff, Patel & Collier, 1996; Keenan, Tindel & Alavi, 1989; Longmaid III & Kruskal, 1995). Edelson, Armstrong, Lavery & Caicco (1996) established that the technetium bone scan is an expensive, non-specific test for evaluating bony pathology (e.g., osteomyelitis).

#### CT scan

CT scans may be indicated in the assessment of suspected bone and joint pathology not evident on plain radiographs (Frykberg et al., 2000; Lipsky, 1997).

#### Magnetic Resonance Imaging (MRI)

MRI has superior sensitivity and specificity (approximately 90-95% for each) for diagnosing osteomyelitis. If plain X-ray is not sufficient MRI may be subsequently ordered to confirm the diagnosis and to determine the extent of osteomyelitis.

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# Appendix I: Wound Swabbing Technique

Obtain a wound culture when clinical signs and symptoms of infection are present. NB: In Ontario, the Ontario Laboratories Act requires a physician's order to process the culture.

#### Semi-quantitative Swab Sample Technique:

Semi-quantitative swab results are equally effective with quantitative biopsy results if the wound is properly prepared (Dow et al., 1999).

- Use sterile cotton tipped swab and culture medium in a pre-packaged collection and transport system available from the hospital or Gamma, MDS or CML laboratories. Community nurses should not allow transport medium to freeze or become overheated in the car before using it.
- Thoroughly rinse wound with normal saline (non-bacteristatic).
- Don't swab pus, exudate, hard eschar or necrotic tissue.
- Rotate the swab tip in a 1 cm square area of clean granulation tissue using enough pressure to release tissue exudate for a period of 5 seconds. *This may be painful so warn the patient of the possibility of pain and pre-medicate with analgesic if possible.*
- Remove protective cap from culture medium and insert cotton tipped applicator into the culture medium without contaminating the applicator.
- Transport to the laboratory at room temperature within 24 hours.

#### Interpretation of semi-quantitative results:

Many labs that service the community do not provide quantitative results or report gram stains. The following chart can be used to compare semi-quantitative results with a quantitative report.

Surface Cultures Grow	rth at 24 – 48 hours			Rx
Quantitative Growth (Colony Forming Units/ Gm)	Gram Stain Results	Sector (1+ to 4+)	Semi-quantitative result (terms will vary with each lab)	Suggested Antibiotic Treatment
$<10$ to the $3^{rd}$	No growth	No growth	No growth	None
$>= 10$ to the $3^{rd}$	No growth	Ι	Scant or light	None
>=10 to the 4 <sup>th</sup>	No growth	I, II	Small to moderate	None
>=10 to the 5 <sup>th</sup>	No growth	I, II, III	Moderate to heavy	Treat if localized signs of infection present
>=10 to the 6 <sup>th</sup>	Bacteria observed	I, II, III, IV	Large or heavy	Treat – considered infected

Prepared by and reprinted with permission of Connie Harris, RN, ET, IIWCC 2000.

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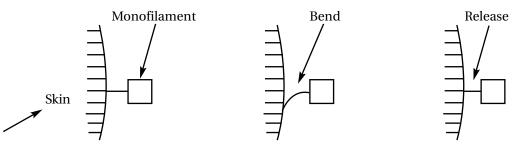
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# Appendix J: Use of the Semmes-Weinstein Monofilament

#### Directions for use of Semmes- Weinstein Monofilament

- 1. Assess integrity of monofilament (no bends/breaks).
- 2. Show the monofilament to the patient. Place the end of the monofilament on his/her hand or arm to show that the testing procedure will not hurt.
- 3. Ask the patient to turn his/her head and close his/her eyes or look at the ceiling.
- 4. Hold the monofilament perpendicular to the skin.



- 5. Place the end of the monofilament on the sole of the foot. Ask the patient to say 'yes' when he/she feels you touching his/her foot with the monofilament. DO NOT ASK THE PATIENT "did you feel that?" If the patient does not say "yes" when you touch a given testing site, continue on to another site. When you have completed the sequence RETEST the area(s) where the patient did not feel monofilament.
- 6. Push the monofilament until it bends, then hold for 1-3 seconds.
- 7. Lift the monofilament from the skin. Do not brush or slide along the skin.
- 8. Repeat the sequence randomly at each testing site on the foot (see pictures below).

#### Sites on the sole of the foot for monofilament testing

Loss of protective sensation = absent sensation at one or more sites



#### Notes

Apply only to intact skin. Avoid calluses, ulcerated or scarred areas. DO NOT use a rapid or tapping movement.

- If the monofilament accidentally slides along the skin, retest that area later in the testing sequence.
- Store the monofilament according to the manufacturer's instructions.
- Clean the monofilament according to agency infection control protocols.

Reference: Registered Nurses' Association of Ontario (2004). *Reducing Foot Complications for People with Diabetes.* Toronto, Canada: Registered Nurses' Association of Ontario.

# Appendix K: Suggestions for Assessing and Selecting Shoes and Socks

#### **Shoes**

- Shoes should be comfortable and well-fitting.
- Have both feet measured each time shoes are bought.
- Buy new shoes late in the day since feet often swell or enlarge during the day. Buy shoes to fit the larger foot if there is a difference.
- Choose shoes with a wide and deep toe box (test depth with a looney put in sideways, test width by outlining your foot on a piece of paper and placing the shoe over the drawing).
- When buying shoes, wear the type of socks that you will be wearing with those shoes.
- Choose shoes made of calfskin or soft leather, if possible.
- Buy shoes with laces. These provide more support, distribute pressure around the sides and top and allow adjustment for swelling.
- Shoes should have good, non-skid soles, closed toes and heels, with no ridges, wrinkles or seams in the linings (good running shoes or walking shoes are recommended).
- Avoid slip-on shoes, shoes with pointed toes and sandals, especially sandals with thongs between the toes.
- Do not wear shoes with heels higher than 1 inch (2.5cm) as they increase pressure on the metatarsal heads.
- Break new shoes in gradually, adding one hour of wearing time each day. Frequently inspect the feet, looking for areas of redness that indicate potential problems.
- Do not wear any shoes longer than six hours without removing. Each pair of shoes fits differently and distributes pressure differently.
- Check shoes before wearing for small stones or puckered or bunched up areas.

#### Socks

- Wear clean socks everyday. Cotton or wool is best to absorb perspiration.
- Socks should fit well. Avoid tight elastic at the top.
- If wearing knee-high hosiery, make sure it has a wide band at the top.
- Check socks for irritation or bunching. Avoid seams if possible.
- Do not wear mended socks; they may cause an area of pressure.
- Do not wear socks with holes; they may cause an area of friction.

Adapted from: Zangaro, G. A. & Hull, M. M. (1999). Diabetic neuropathy: Pathophysiology and prevention of foot ulcers. *Clinical Nurse Specialist*, 13(2) 57-65

#### Nursing Best Practice Guideline

# Appendix L: Factors Affecting Wound Healing

Systemic Factors	Local Factors	Extrinsic Factors
Affecting Wound Healing	Affecting Wound Healing	Affecting Wound Healing
<ul> <li>Age</li> <li>Anemia</li> <li>Anti-inflammatory drugs</li> <li>Auto-immune disorders</li> <li>Blood supply</li> <li>Cytotoxic drugs</li> <li>Fever</li> <li>Hypotension</li> <li>Jaundice</li> <li>Malignant disease</li> <li>Malnutrition</li> <li>Obesity</li> <li>Renal Failure</li> <li>Systemic infection</li> <li>Trauma</li> <li>Smoking</li> <li>Vasculopathy</li> <li>Vitamin deficiency</li> <li>Zinc deficiency</li> </ul>	<ul> <li>Blood supply</li> <li>Denervation</li> <li>Edema</li> <li>Hematoma</li> <li>Iatrogenic causes <ul> <li>psychosocial/cognitive impairment</li> <li>poor surgical</li> <li>use of cytotoxic agents</li> </ul> </li> <li>Local infection</li> <li>Mechanical stress</li> <li>Radiation</li> <li>Suture material</li> <li>Type of tissue</li> </ul>	<ul> <li>Cultural beliefs</li> <li>Footwear <ul> <li>shoes</li> <li>orthotics</li> </ul> </li> <li>Offloading devices</li> </ul>

RNAO Guideline Development Panel, 2005







# Appendix M: Topical Antimicrobial Agents

#### TOPICAL ANTIMICROBIAL AGENTS

	Agent	<b>C A</b>	14064		Spect		A 1.		Comments		
		SA	MRSA	Strep	PS	F	Anaerobic	VRE	Broad spectrum.		
Safe & Effective	Cadexomer Iodine	~	r	V	~	~	V	٢	Broad spectrum. Effective for fungi & virus. Widely available. Sheet requires wound contact. Caution if on thyroid medication		
	Ionized Silver	~	~	•	~	~	~	~	Broad Spectrum. Effective for fungi & virus. Sheet requires wound contact.		
	Silver Sulphadiazine	~	~	•	~		~		Limited potential for resistance Available in paste or ointment. Do not use if sulfa sensitive.		
	Polymyxin B Sulphate – Bacitracin Zinc	~	~	~	~		~		Sheet requires wound contact.		
Selective Use	Metronidazole gel/cream						~		Reserve for anaerobes & odour control.		
	Benzyl/ Peroxide	~		~	~		~		Reserve for MRSA & other resistant gram positive.		
	Acetic Acid				~				Used in 0.25% (e.g. 1/4 of 1.0% maximum concentration).		
	Mupuricin Bactroban	~	~	~					Should be reserved for MRSA colonization.		
	Povidone iodine	~	~	~	~	~	~	~	Use with caution. This agent is cytotoxic.		
	Chlorhexidine	•	r	•	~	~	~	~	Use during inflammatory phas Cytotoxic during proliferative phase.		
Caution	Gentamycin	~		~	~				Reserve for oral/IV use.		
	Fucidic Acid	~	~	~					Sensitizer.		
	Polymixin B Sulphate Bacitracin Zinc Neomycin	~	~	•	~		~		Potent Sensitizer.		
Not Recommended	Alcohol Hydrogen peroxide Hypochlorite solution (Dakens)								Cytotoxic. No antimicrobial properties. Cytotoxic.		

Candida Glabrata, & Saccharomyces), (VRE = Vancomycin-Resistant Enterococci)

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Wounds
Dressing Foot Wound.
uide to Dress
A Guida
Appendix N

time, necessitating a change in dressing type. Influencing factors include wound type, wound depth, presence and volume of exudates, presence of infection, surrounding skin condition, likelihood of re-injury and cost. Dressings should never be commenced in isolation and should be a part of the treatment package of debridement, dressings, pressure offloading and when clinically indicated, antibiotics. This list is not exhaustive. These are There is limited evidence that any specific dressing type enhances the speed of healing of diabetic foot ulcers. It is clear, however, that a moist wound environment results in more rapid wound healing. Many factors need to be considered when selecting a dressing and these factors may change over common products used in Ontario. Please check with local suppliers to see what specific dressings are used in your region.

*Note:* Read the product monographs for specific details.

	Considerations	Levels of toxicity vary among commercial wound cleansers. Some contain antimicrohial agents which may be toxic to new tissue	Read literature and product monograph to determine safety.	Cleansers contain mild preservatives, which stabilize the product but may cause irritation and increase toxicity.		Ease of use facilitates patient independence.	Risk of contamination is reduced in unclean situations.	Caution – Wound cleansers are for wounds. Skin cleansers are for intact skin only.		
	Indications	Cleanses wound debris with minimal trauma								
S	Description	Normal saline preferred.	Physiologic.	Not harmful to tissue.	Commercial wound cleansers.	May contain surfactants to assist	with removal of debris.	Adjustable spray nozzle provides variable pressures for cleansing (from gentle flush to 15 psi).		
Wound Care Products	Examples	CLEANSERS Normal Saline	Shur-Clens	Dermagran cleanser Restore	Other				Ranked according to toxicity AHCPR (1994)	

# . . . . . .

Examples	Description	Indications	Considerations
TRANSPARENT ADHESIVE DRESSINGS	Semi- permeable adhesive sheets.	Wounds at risk for contamination.	Can be cut to accommodate difficult areas or used as adhesive strips to waterproof dressing edges.
Bioclusive MeFilm	Impermeable to water molecules and bacteria.	Protects intact skin from friction or irritants.	Moisture resistance allows for bathing.
Opsite FlexiFix Opsite Terradorm	Incapable of absorbing moisture.	Secondary cover dressing to enhance moisture and odour	Use with caution on fragile peri-wound skin.
1¢garci III	Transparency permits wound visualization.	containment.	For removal, stretch product to break adhesive bond and prevent skin stripping.
	Some are shaped to fit problem	A flexible outer dressing for uneven areas.	Decrease wound pain by protecting superficial nerve endings.
	areas.	Superficial wounds, skin breaks	Use of liquid skin barriers on peri-wound skin increases adhesion.
	Non-sterue rou is intended for use on intact skin or as a	with minimal drainage.	Not suitable if skin is evidencing yeast infection.
	secondary cover dressing.	Supports autolytic debridement.	Removal by stretching the edges will minimize superficial tears.
Moisture Retentive: Non-Adhere	ve: Non-Adherents		
NON-IMPREGNATED Alldress FTF	Varied densities, sizes and shapes of woven mesh.	Wound contact layer to: Protect fragile tissue Maintain comanued	Some mesh dressings can remain in place up to 7 days. Outer absorbent dressings can be replaced as needed.
Melolite Mepitel	Some have plastic coating to create semi-occlusion.	hydration Pydration Protect post-operative	Plastic coated products may macerate peri-wound skin. Protect skin with suitable barrier.
Primapore Release	Minimal absorption capability.	Incision     Prevent painful dressing	Layering tulle dressings increases semi-occlusion.
regapore Telfa Others	Mepitel is a silicone mesh.	aunerence	Slight overlap onto peri-wound skin stabilizes dressing and decreases pain.
IMPREGNATED/	Tulle dressings contain either		Most require secondary cover dressing to absorb drainage and enhance stability. Some are self-adhesive.
Adaptic	perotatum, anusepucs or antibiotics.		Products containing antiseptics and antibiotics reported
bacugras Fucidin Jelonet Sofratulla	Some tulle dressings contain minimal amounts of antibiotic.		to assist with local pacterial control in a containinated would. Long term use increases risk of local sensitization and the development of resistant bacteria.
CONTACUTO	*see Topical Antimicrobial Agents, Annendix M		Infection requires appropriate systemic management.
			Consider alternative nroduct if dressing adheres

Consider alternative product if dressing adheres.

#### Assessment and Management of Foot Ulcers for People with Diabetes

	Considerations	al drainage. Sheets can be customized to fit difficult areas. Size must always extend 2.5-5 cm beyond wound margins to ensure	tolytic adherence and wear time.	Use of additional tapes or transparent film dressings to edges may	n and improve stability in areas of high stress.	Caution with use of adhesive dressings on fragile peri-wound skin.	nination. Dressings create an occlusive harrier	-	May remain in place for 3-7 days. Frequency of change is determined secondary by amount of drainage and before leakage occurs.		Can be used over absorbent alginates or hydrofibers to contain drainage. kin from Change by 3-4 days.		Not advised for copiously draining wounds.	ention. If signs and symptoms of clinical infection should develop.	appropriate medical treatment should be initiated.	Use is not appropriate if infection suspected.	Use liquid skin barriers on peri-wound skin to decrease risk	of maceration and to increase adherence.				
	Indications	Wounds with minimal drainage.	Wounds requiring autolytic		Promotes granulation and	epithelialization.	Protects from contamination.	An aesthetic cover dressing.	A moisture retentive secondary	dressing.	Protects underlving skin from	tape injury.		May be used for prevention.								
nyarocollolas	Description	Available as adhesive sheets, powders or pastes.	Mav contain gelatin, sodium	carboxymethylcellulose, and	pectin.	Sheet dressings have an	occlusive or semi-occlusive		Thickness, size, absorption capability, and transparency	varies.	Minimal to moderate absorbency.	Some have tapered or adhesive	borders to increase stability.	interactive dressings.	Do not confuse characteristic	odour with infection.	Comes in thick and thin versions.					
иоции пуагацоп. пуагосопоная	Examples	HYDROCOLLOIDS Comfeel	Comfeel Plus	Cuunova nyuro DuoDERM CGF	RepliCare	Restore SignaDress	Tegasorb	Others														

# Wound Hydration: Hydrocolloids

	Considerations	Monitor closely for infection during autolysis.	Protect peri-wound skin from maceration with suitable barrier.	Cross-hatch eschar to promote penetration of gel.	Gel can be applied to gauze ribbon packing to fill deep areas and nromote autolyric debridement.	Constraints in the section of the section and section of the secti	becomenty these is required to retain moisture, absolut excess drainage and to stabilize gels over wounds.	Can be used in combination with transparent films, foams, hydrocolloids or other non-adherent cover dressing.	Not advised for copiously draining wounds.	Wear time varies from 1 to 3 days according to amount of drainage (read product monograph).	Sheet gels can be cut to slightly larger than wound.	Prevent contamination of opened product. Handle and discard according to the product monograph.			
	Indications	Granulating wounds.	Prevents dressing adherence, bleading or nain	Wound or punt.	wounds requiring autorytic debridement.	Minimally exudating wounds.	Maintains wound moisture,	uecreasing neeu ior irequent changes.							
Hydrogels	Description	Polymers with high water	Content. Moisture donating	Monotario aomanib.	Noti-toxic. Non-adherent.	Como controla mucorractivos	outre currant preservatives.	Avanable as inquit gets, in solid sheets or imbedded into gauze dressings.							
Wound Hydration: Hydrogels	Examples	HYDROGELS	DuoDERM Gel	Normgel	Nu-Gel Puriclens	Tegagel	woun Dres Others								

Considerations	Remove residue by flushing with saline.	If dressing dries and adheres due to decreased moisture, review product choices. Select alternative or extend wear time of alginate.	Maximum wear time is 5 days.	Requires moisture retentive cover dressing to avoid drying by evaporation.	Occlusive cover dressings can enhance absorptive capabilities.	Maintains wound cleansing in gel state.	Low tensile strength. Do not use in a wound without a visible base.					
Indications	Wounds with visible depth requiring soft filler.	Exudating wounds during autolytic debridement.	Bleeding wounds.	Post sharp debridement.	Reduces the need for bulky dressings.							
Description	Absorbs moderate to large amounts.	Sheets or fibrous ropes of calcium sodium alginate.	Seaweed derivative.	Applied in dry state.	As drainage is absorbed, it converts to a gelatinous mass.	Hemostatic capabilities.	Calcium and sodium interact to promote clotting.	Non-adhesive.	Fibracol contains collagen.	Tegagen offers a choice of a high gelling or a high integrity product. Review product monograph and wound needs.		
Examples Description	ALGINATES Algisite	Calcicare Curasorb Fibracol	Kaltostat Melgisorb	Seasorb Tegagen								

# Absorbent Dressings: Alginates

Absorbent Dressing Examples HYDROFIRRF	Absorbent Dressings: Hydrofibre, Hypertonic Gauze Examples Description Indications HYDROFIBRE Soft, non-woven fibrous sheet or Pack wounds wit	onic Gauze Indications Pack wounds with a visible base.	Considerations Concentrates drainage.
Aquacel	packing strip of sodium carboxymethylcellulose. Highly absorbent.	Supports debridement of exudating wounds.	Dressing can extend beyond wound margin onto peri-skin. Flush to remove all residue.
	Apply dry. Converts to a solid gel when activated by moisture.	Prevents trauma to fragile wound tissue. Manages large amounts of	Product may slightly increase in size with absorbing action. Vertical absorption prevents maceration of peri-wound skin.
	Fibres maintain integrity in gel- state, facilitating intact removal. Non-adhesive. Vertically absorbs, contains	drainage. Prevents leakage and peri-skin breakdown.	Layering dressing increases absorption capability. Wear time is 1-4 days depending on volume of drainage.
	drainage.	Promotes comfort.	Tensile strength decreases when over-saturated.
		Decreases dressing bulk.	Not compatible with ointments or creams.
			Do not use in a wound without a visible base.
HYPERTONIC SALINE DRESSING Curasalt Mesalt	Sheet, ribbon gauze, or gel impregnated with salt concentrate Product absorbs drainage.	Copiously draining wounds. Debridement of slough. Infected wounds.	Apply in a dry state to wound. May damage granulation tissue if drainage is minimal. Adequate wound drainage is essential to prevent dressing adherence or damage from concentrated salts.
The Ber	becoming an isotonic normal saline dressing.	Consider gel for dry necrosis	Evaluate for alternative product choice when drainage decreases or wound base becomes clean.

Consider risk of loose fibres if cutting products.

May be painful for sensitive patient.

Moisture-retentive cover dressing is advised.

#### Assessment and Management of Foot Ulcers for People with Diabetes

		ption.
		despite copious disclarate to enhance abso ainage is minimal. a moist wound base, g. ducts. a protective barrier* ate odour containmen <b>pressure relief.</b>
	Considerations	Product integrity is maintained despite copious discharge. Secure dressing with slight pressure to enhance absorption. May not support autolysis if drainage is minimal. Porous foams may not maintain moist wound base, requiring suitable cover dressing. <b>Do not overpack the cavity products.</b> Assure product has contact with wound base. Extend wear time as volume of drainage decreases to a maximum of 4 to 7 days. Maintain peri-wound skin with a protective barrier <sup>*</sup> if drainage is excessive. Some occlusive products facilitate odour containment. Foam dressings do not provide pressure relief. *See: Skin Barriers
	Consi	Produce Secure May no Porous requiri requiri requiri tequiri fean to a m Mainté to a m to a m to a m Some o Some o
	Indications	Absorbs small, moderate to copious amounts of drainage. Aesthetic cover dressing. Reduces dressing bulk. Protects peri-wound skin from irritation and maceration.
js: Foams	Description	Non-adherent polyurethane foam. Various thickness. Some are semi-occlusive and only for use as cover dressings. Others may be used to fill wound defect. Read product monograph. Bordered adhesive products may provide occlusion. Flexibility and moldability varies.
Absorbent Dressings: Foams	Examples	FOAMS Allevyn Cutinova Hydrasorb Lyofoam Extra Mepilex Polymem 3M Foam Tielle Biotain

Absorbent Dressings: Composites,	gs. composites, odour	Daour specific	
Examples	Description	Indications	Considerations
Antimicrobial Silver Agents: Acticoat Aquacel AG Contreet Actisorb	See Appendix M Please refer to manufacturer's product monograph.	Critically colonized or infected wounds.	May be used in conjunction with systemic antibiotic. Expect to see discolouration in wound bed (graying)
lodine Agents: Iodosorb	Superficial broad spectrum coverage, gram ±, fungi, MRSA, & VRE. Cadexomer iodine in paste or ointment 0.9% slow-release. Changes from brown to yellow colour.	Critically colonized or infected wounds	Maximum dose of iodosorb is 150 mg/week. Flush iodosorb to remove residue.
COMPOSITES CombiDERM CombiDERM ACD Tielle Exudry Versiva	Highly absorbent multi-layered island dressings. Inner layers absorb and retain drainage, preventing pooling at wound base. Combination of several products prevents lateral migration of drainage.	Copiously draining wounds. Maintains a moist wound environment. Aesthetic cover. Reduces dressing bulk. Improves integrity of macerated skin.	Non adherent to wound base. Wear time determined by volume of drainage (2-7 days). Patient independence is enhanced by ease of application. Some products are self-adhesive to skin. Adhesive styles may facilitate odour containment.

# Absorbent Dressings: Composites, Odour Specific

Considerations	Ensure underlying infection has been evaluated and treated, prior to use. Choose highly absorptive products when drainage is copious. Some products can be applied directly to the wound base. Other products become inactivated when wet. Ensure that dressing edges are sealed for maximum odour containment.	Products containing alcohol can cause transient burning or stinging if skin is broken. Products without alcohol increases comfort and may be used on intact or broken skin. Allow product to dry before cover dressing is applied. Not for use on open wounds.
Indications	Actisorb adsorbs endotoxins. Any odorous wound during autolytic debridement.	Protects peri-wound skin from maceration, irritation or tape injury. Enhances adhesion of some cover dressings. Provide increased protection of peri-wound skin for scant to copious exudate.
Description	Activated charcoal in some products works by adsorption. Products containing odour absorbent charcoal layered within product. Ability to absorb odour varies. Some contain silver to enhance antibacterial capability. CarboFlex contains alginate and hydrofibre in the contact layer to also absorb drainage.	Quickly drying liquid to provide a thin layer of skin protection. Durability varies. Some contain alcohol of variable amounts. Available as moistened wipes, applicators or spray.
Examples	CHARCOAL Actisorb Plus CarborFLEX Carbonet Odour Absorbent Dressing	Skin Barriers LIQUID BARRIERS Coloplast ConvaCare No Sting Skin Prep Sween Others

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#### Assessment and Management of Foot Ulcers for People with Diabetes

# Appendix O: Offloading Devices

The selection of the appropriate device is based on the following considerations:

- 1. The ability to effectively remove all pressures from the ulcer site.
- 2. Cost effectiveness of the device.
- 3. Ease of use and/or skill required for the application of the device.
- 4. Characteristics of the diabetic ulceration.
- 5. The ability to encourage patient adherence.

Offloading Device	Advantages	Disadvantages
<b>Total Contact Cast (TCC)</b> <i>A well-molded minimally</i> <i>padded cast that maintains</i> <i>contact with the entire aspect</i> <i>of the foot and lower leg</i>	<ul> <li>Highest healing rates (gold standard)</li> <li>Distributes pressure over the entire plantar surface</li> <li>Completely offloads</li> <li>Protects foot from infection</li> <li>Controls edema</li> <li>Maintains patient adherence as non-removable</li> </ul>	<ul> <li>Requires trained technician</li> <li>Cannot assess foot on a daily basis</li> <li>Affects sleeping and bathing</li> <li>Exacerbate postural instability or cause poor balance</li> <li>Cannot use if wound infected</li> <li>Cannot be used in the neuro-ischemic limb</li> </ul>
<b>Scotchcast Boot</b> <i>A fibreglass boot that reduces</i> <i>pressure over the wound</i>	<ul> <li>Lighter with high integral strength</li> <li>Removable for examination</li> <li>Can be non-removable for poorly adherent patients</li> <li>Promotes continued ambulation</li> </ul>	<ul> <li>If removable – poor adherence</li> <li>Has not yet been compared in studies to other forms of offloading for efficacy</li> </ul>
<b>Removable walker</b> <i>A commercially available</i> <i>removable boot that reduces</i> <i>plantar pressures</i>	<ul> <li>Easily removable allowing wound inspection and treatment</li> <li>Allows more comfortable bathing and sleeping</li> <li>Can be used for infected wounds and superficial ulcers</li> </ul>	<ul> <li>Removable nature of cast reduces adherence</li> <li>No clinical data to support its efficacy compared to TCC</li> </ul>
Halfshoes Offer support only under the rear and mid-foot	<ul><li>Inexpensive</li><li>Easy to apply</li></ul>	<ul><li>Less effective than TCC</li><li>Hampers gait</li></ul>
Healing Sandals Application of a rigid rocker to the bottom of a shoe or sandal	<ul> <li>Limit dorsiflexion therefore distributes pressure of metatarsal heads</li> <li>Lightweight and stable</li> <li>Reusable</li> </ul>	<ul> <li>Requires significant amount of time and experience to produce therefore not easily accessible</li> <li>Not as efficient compared to other methods of offloading</li> </ul>
Mabal Shoe Cross between healing sandal and TCC	<ul> <li>Removable (inspection)</li> <li>Better contact with foot than healing sandal</li> <li>Comparative rates of healing with TCC</li> </ul>	<ul> <li>Removable (reduces adherence)</li> <li>Expertise required to make &amp; apply</li> </ul>
Felted Foam Bilayered felted foam over the plantar surface with opening for the wound	<ul><li>Inexpensive</li><li>Accessible</li></ul>	<ul> <li>Can produce pressure and shear at wound edges</li> <li>No studies to suggest its efficacy in offloading</li> </ul>
Crutches, Walkers, and Wheelchairs	<ul> <li>If used consistently will offload pressure</li> <li>Rentable</li> </ul>	<ul> <li>Requires upper body strength and endurance</li> <li>May not be used all the time</li> <li>Difficulty in navigating indoors</li> <li>Can increase pressures on contralateral side</li> </ul>
Therapeutic Footwear Depth inlay shoes	<ul> <li>Beneficial in <i>preventing</i> ulcerations</li> </ul>	<ul> <li>No proof of efficacy in healing ulcers</li> <li>Allow up to 900% more pressure in forefoot than TCC and removable walker</li> </ul>

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# Appendix P: Resources for Diabetic Foot Ulcer Information

The following websites provide information on diabetic foot ulcers. These are examples only and are not intended to be a comprehensive listing.

#### **Organizations**

- American Academy of Wound Management <u>www.AAWM.org</u>
- American Academy Wound. Net <u>www.Wound.net</u>
- American Physical Therapy Association <u>www. APTA.org</u>
- Association for the Advancement of Wound Care <u>www.AAWC1.com</u>
- Australian Wound Management Association <u>www.AWMA.com.au</u>
- Canadian Association of Enterostomal Therapy <u>www.CAET.ca</u>
- Canadian Association of Wound Care <u>www.CAWC.net</u>
- Centres for Disease Control <u>www.CDC.gov</u>
- IDF Consultative Section on the Diabetic Foot/IWGDF <u>www.diabetic-foot-consensus.com</u>
- Journal of Wound Care <u>www.journalofwoundcare.com</u>
- National Coalition of Wound Care linked to AAWC
- Tissue Viability Society <u>www.TVS.org.uk</u>
- Wound Care Information Network <u>www.medicaledu.com/wndguide.htm</u>
- Wound Healer <u>www.woundhealer.com</u>
- Wound Healing Society <u>www.woundheal.org</u>
- Wound, Ostomy & Continence Nurses Society <u>www.WOCN.org</u>

#### Corporations

- Carrington <u>www.carringtonlabs.com</u>
- Coloplast <u>www.us.coloplast.com</u>
- Convatec <u>www.convatec.com/en-ca</u>
- Hollister <u>www.hollister.com</u>
- ICN <u>www.icncanada.com</u>
- Johnson & Johnson <u>www.jnjgateway.com</u>
- Kendall <u>www.kendallhq.com</u>
- 3M <u>www.mmm.com</u> or <u>www.3m.com</u>
- Molnlycke <u>www.molnlycke.com</u>
- Smith & Nephew <u>www.wound.smith-nephew.com/ca-en/wound</u>

#### Nursing Best Practice Guideline

#### Essential Services for Pressure Offloading

- Orthotic fabrication custom-made, adjustments, braces, aircast or TCC
- Regular shoe fitting width fittings, comfort laced walking shoes
- Specialty shoe fitting deep toe box, post-op boots, custom made shoes
- Shoe modification rocker sole, sole widening
- Assistive devices canes and walkers, hosiery, heel protectors

#### **Service Providers**

- Pedorthists
  - orthotics, shoes, shoe mods
  - Canada: <u>www.pedorthic.ca</u>
  - U.S: <u>www.pedorthics.org</u>

#### Orthotists

- othotics, braces, TCC, shoe mods
- Canada: <u>www.pando.ca</u>
- U.S.: <u>www.oandp.org</u>

#### Chiropodists/Podiatrists

- orthothics, soft tissue management
- Ontario: <u>www.cocoo.on.ca</u>
- Canada: <u>www.podiatrycanada.org</u>

#### Occupational Therapists

- assistive devices, orthotics
- Canada: <u>www.caot.ca</u>
- U.S.: <u>www.aota.org</u>



# Appendix Q: Description of the Toolkit

#### **Toolkit: Implemention of Clinical Practice Guidelines**

**Best practice guidelines** can only be successfully implemented if there are: adequate planning, resources, organizational and administrative support as well as appropriate facilitation. 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 healthcare 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.

The *Toolkit* is available through the Registered Nurses' Association of Ontario. The document is available in a bound format for a nominal fee, and is also available free of charge from the RNAO website. For more information, an order form or to download the *Toolkit*, please visit the RNAO website at <u>www.rnao.org/bestpractices.</u>

Nursing Best Practice Guideline

Notes:			

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## Notes:


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# Nursing Best Practice Guideline

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This program is funded by the Government of Ontario

0-920166-68-7



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