

Best Practice Recommendations for the Prevention, Diagnosis and Treatment of Diabetic Foot Ulcers: Update 2006

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Abstract

The intent of this article is to update and incorporate the evidence identified by several Canadian guidelines into the Canadian Association of Wound Care (CAWC) Best Clinical Practices for the Prevention, Diagnosis and Treatment of Diabetic Foot Ulcers recommendations.¹ Guidelines included are as follows:

1. Registered Nurses' Association of Ontario (RNAO). *Nursing Best Practice Guideline: Reducing Foot Complications for People with Diabetes* (2004).²
2. Registered Nurses' Association of Ontario (RNAO). *Nursing Best Practice Guideline: Assessment and Management of Foot Ulcers for People with Diabetes* (2005).³
3. Anti-infective Guidelines for Community Acquired Infections (2005).⁴

The best practices in the document focus on the clinical aspects of care relating to the education of both clinician and patient. Care components include assessing for, and the removal of, factors that can affect healing, as well as the delivery of adequate vascular supply, infection control and pressure downloading and the provision of an

optimal local wound environment. The adequate delivery of care requires an interprofessional team approach to provide co-ordinated and integrated management.

This article is meant to provide a practical, easy-to-follow guide or bedside *enabler*, based on the best available evidence, to support the wound-care clinician and team in planning and delivering the best clinical practice related to diabetic foot ulcers.

This article is not meant to be comprehensive. The Registered Nurses' Association of Ontario (RNAO) *Nursing Best Practice Guideline: Reducing Foot Complications for People with Diabetes*² and *Nursing Best Practice Guideline: Assessment and Management of Foot Ulcers for People with Diabetes*³ should be consulted at www.rnao.org for more in-depth information relating to diabetic foot ulcer management. The RNAO guidelines offer the clinical directions for practice based on the level of evidence, as well as a challenge to "go one step further" and review what is required to implement the clinical aspect of practice by addressing educational and organizational recommendations to support best clinical practice.

Introduction

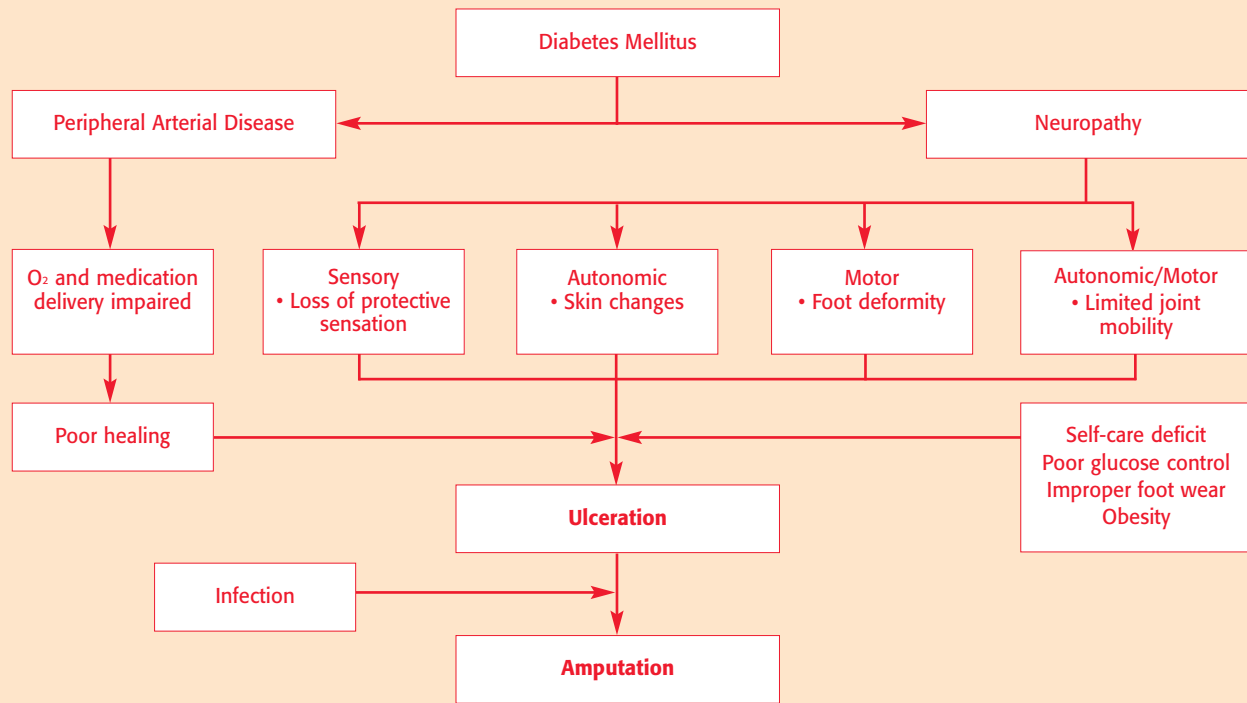
Diabetes mellitus is characterized by a lack of glycemic control that can cause damage to the body's small and large blood vessels and nerves, which can affect all organs in the body. These changes, along with others, can lead to a cascade of events resulting in changes to the foot itself. The structural changes, along with **V**ascular insufficiency, **I**nfection and

Pressure (VIP), predispose the person with diabetes (PWD) to develop foot ulceration (Figure 1).

In our original paper, Best Clinical Practices for the Prevention, Diagnosis and Treatment of Diabetic Foot Ulcers, we identified diabetes as a serious, complex, life-long condition that affects 4.2 per cent of the world's population and 1.5 million Canadians.¹ Since then it has

FIGURE 1

Pathway to Diabetic Foot Ulcers



Reprinted with permission from Registered Nurses' Association of Ontario.³

become known that the aboriginal population in Canada demonstrates a prevalence of type 2 diabetes that is at least three times the national average.³ And, even more frightening, a study to determine if there is a need for screening for type 2 diabetes in seventh graders raises serious concerns that really bring the severity of the issue home.⁵

In industrialized countries, diabetes is the leading cause of non-traumatic, lower extremity amputations. Approximately 15 per cent of all PWD will develop a foot ulcer at some time during the course of their disease. Eighty-five per cent of lower extremity amputations are preceded by foot ulcers. Of these, 14 per cent to 24 per cent will proceed to major amputation. Neuropathy is most commonly associated with the development of diabetic foot ulcers, but the presence or co-existence of peripheral arterial 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. Moreover, the risk of amputation increases 10-fold in patients with diabetes and concurrent end-stage renal disease (ESRD).³

Given the data on the burden of illness and the significant long-term impact on the health of people with diabetes, care of persons with diabetic foot ulcers demands a systematic team approach (Figure 2) from health-care professionals. A specialized interprofessional 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.

Recommendation 1: (Level of Evidence: Ib–IV)

Take a careful history to determine general health, diabetic control, complications and co-factors that may cause skin breakdown or affect the healing of an ulcer.

Discussion

A comprehensive assessment by an interprofessional team is required for all patients who present with diabetic foot ulceration. This assessment must include a detailed history, physical examination,

Levels of Evidence Employed by RNAO Guideline Development Panels (2005)

- Ia Evidence obtained from meta-analysis or systematic review of randomized controlled trials.
- Ib Evidence obtained from at least one randomized controlled trial.
- IIa Evidence obtained from at least one well-designed controlled study, without randomization.
- IIb Evidence obtained from at least one other type of well-designed quasi-experimental study, without randomization.
- III Evidence obtained from well-designed non-experimental descriptive studies such as comparative studies, correlation studies and case studies.
- IV Evidence obtained from expert committee reports or opinions and/or clinical experiences of respected authorities.

appropriate diagnostic tests and identification of risk factors related to ulcer development. Ulcer etiology, factors that influence healing and the patient's bio-psychosocial status need to be explored. When treating a person with a diabetic foot ulcer, clinicians need to consider the person's life situations (lifestyle: vocational, recreational) and the impact of their situation on their quality of life.

The RNAO *Nursing Best Practice Guideline: Assessment and Management of Foot Ulcers for People with Diabetes* 2005 (RNAO guideline recommendation 2.0³) discusses factors affecting wound healing that can be systemic, local, or extrinsic. Some systemic factors can't be modified, such as age, or are non-reversible, such as a malignancy. Other factors that have a profoundly negative impact on healing can be modified, such as smoking, nutritional deficiencies, recurrent trauma, glycemic control and adherence. Medication review can reveal anti-inflammatory and cytotoxic drugs that are known to interfere with wound healing. Some systemic factors that can affect healing include autoimmune disorders, decreased blood supply, jaundice, obesity, renal failure, and vasculopathy. Some local factors that affect wound healing include blood supply, denervation, edema, hematoma, local infection, mechanical stress, radiation and suture material, in addition to other causes such as psychosocial/cognitive impairment, use of cytotoxic agents, and poor surgical outcome. Extrinsic factors include various cultural beliefs, quality-of-life issues, inappropriate footwear (shoes, orthotics), and offloading devices.⁷

These lists are certainly not exhaustive and can vary from person to person.

Recommendation 2: (Level of Evidence: Ia-IV)

Complete a physical assessment that includes vascular status, bony/structural deformities (and footwear), and sensation.

Discussion

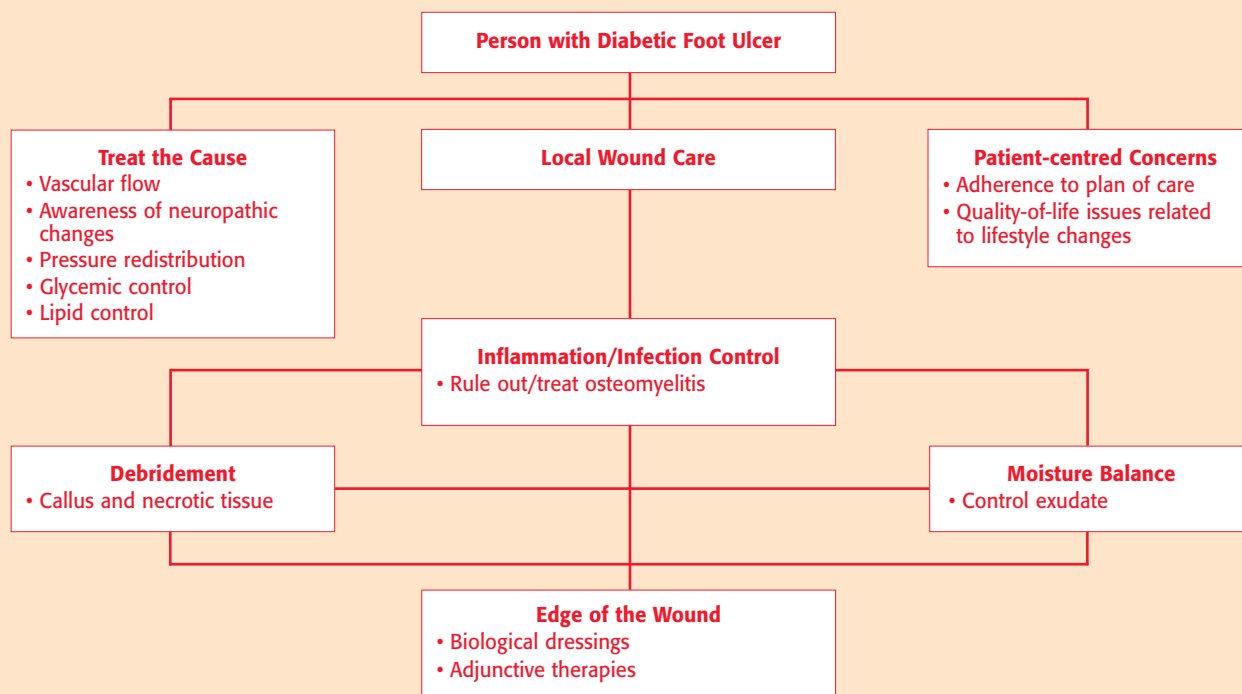
Vascular status: (Level of Evidence: IIb-IV)

Vascular assessment and a vascular consult are not only important to determine treatment but can also determine the probability of healing. Vascular assessment begins when the clinician obtains the patient's history. Pain or cramping of the calves or thighs indicates intermittent claudication (insufficient blood supply to the muscles locally if the patient is mobile). Patients experience night pain or pain at rest in more advanced cases. A physical examination also should help detect clinical signs of vascular compromise such as vascular dilation/flush (rubor) that blanches with elevation, hair loss, and thickened nails with decreased nail luster. On palpation, the foot is characteristically cold with a loss of pulses. Microcirculatory supply can be tested by pressing a finger on the dorsum of the dependent foot to produce a noticeable blanching. Normally, erythema should return within five seconds; if not, there is decreased local perfusion microcirculation time. Distal gangrene of the toes with a palpable pulse or adequate circulation may indicate microemboli from proximal atheromatous plaques.

Intermittent claudication and rest pain normally associated with vascular disease may be absent in the PWD with peripheral neuropathy. Palpable pulses are also a poor indicator of vascular status. Due to the

FIGURE 2

Pathway to Assessment/Treatment of Persons with Diabetic Foot Ulcers



Adapted from Sibbald RG, Orsted HL, Schultz GS, et al.⁶

TABLE 1

Quick Reference Guide

No.	Recommendations	RNAO Guidelines*	Level of Evidence
Identify and Treat the Cause			
1	Take a careful history to determine general health, diabetic control, complications and co-factors that may cause skin breakdown or affect the healing of an ulcer.	2.0	Ib–IV
2	Complete a physical assessment that includes vascular status, bony/structural deformities (and footwear), and sensation.	2.1, 2.3 and 2.4	Ia–IV
3	Classify persons with diabetes into a risk category to support co-ordination of care.	1.2	IV
4	Modify factors that cause skin breakdown and/or influence healing and make referral(s) to the team to ensure comprehensive care.	5.0 and 5.1	IV
5	Provide pressure downloading if there is loss of protective sensation.	5.3	Ila
Address Patient-centred Concerns			
6	Provide individualized education as indicated by patient need and by risk category.	1.2 and 4.2	IV
Provide Local Wound Care			
7	Assess diabetic foot ulceration(s).	3.0, 3.1 and 3.2	Ia–IV
8	Provide an optimum wound environment: debridement, moisture balance, infection control.	5.2	Ia–III
9	Determine the effectiveness of interventions; reassess if healing is not occurring at expected rate.	6.0 and 6.1	III–IV
10	Consider the use of biological agents and adjunctive therapies.	6.2	Ia–IV
Provide Organizational Support			
11	Establish, train and empower a team to work with patients with diabetes.	7.0, 9.0, 9.1, 9.2, 9.3 Prevention guideline - 9.0-13.0	IV

* Unless otherwise indicated, the guideline referred to is the RNAO guideline *Assessment and Management of Foot Ulcers for People with Diabetes*³

false high readings frequently encountered with ankle-brachial pressure index readings relating to vessel calcification, toe pressures and/or transcutaneous oxygen readings are required to determine the quality of arterial flow to the feet (RNAO guideline recommendation 2.1 and Appendix G and J³). Note: Specialized equipment and training are required to assess the vasculature of a PWD.

Bony/structural deformities: (Level of Evidence: Ia–IV)

Bony and structural deformities may be related to a combination of aging, recurrent trauma, systemic diseases, motor and sensation neuropathy (RNAO guideline recommendation 2.4³). Clinical expertise is required to assess for abnormal pressure over bony deformities that can lead to callus formation and ulceration in the absence of protective sensation. The most common sites for callus and ulcer formation are the first metatarsal head, the second metatarsal head, and the hallux. The body's weight and force is concentrated over these bony structures with every step. Obesity, hard-soled footwear, and excessive walking all increase the load and pressure through these structures.

In addition, biomechanical issues such as hallux limitus/rigidus, tight Achilles tendon/gastrocnemius muscle, dropped transverse arches/metatarsal heads, and digit deformities significantly contribute to excessive pressures. As a result, ulcers typically develop under these calluses.

X-rays and pressure mapping will help the clinician determine the extent of the deformity and its affecting forces on the foot. Long-standing bony deformities become a clinical issue in the presence of neuropathy.

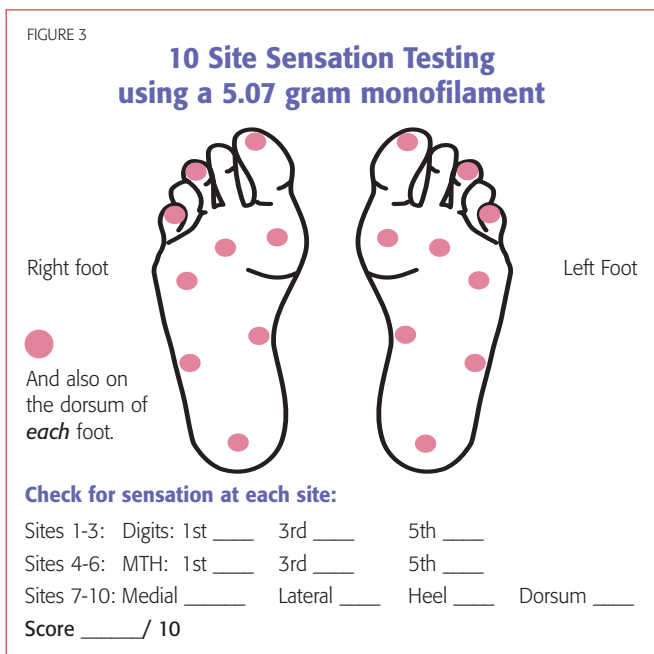
Bony reabsorption and multiple spontaneous fractures—i.e., acute neuroarthropathy (diabetic Charcot foot)—are results of autonomic-neuropathy-induced bone blood flow hyperemia. Hypervascularity of the midfoot osseous structures results in decreased structural integrity of the bone, significantly increasing risk of fracture. These fractures may result from activities of daily living and not obvious trauma. Clinical presentation includes dermal flush/redness, increased skin temperature, +/- deep bony pain, +/- local edema and bounding pulses. X-ray and bone scan are used to assess and reconfirm re-ossification.

Unlike typical osseous fractures, patients often do not experience

pain due to their sensory neuropathy. Charcot fractures frequently result in catastrophic osseous deformity often ignored by the patient because of lack of perceptible pain. The risk of pressure ulceration increases significantly due to the magnitude of the deformity and the absence of typical fat pads over weight-bearing structures. Vascularity of the skin is also compromised (RNAO guideline recommendation 2.4 and Appendix J³). Footwear assessment is mandatory and is required for all individuals with diabetes (RNAO guideline recommendation 2.4³). It is also important to ensure that footwear matches the person's function and activity level, both indoor and outdoor, and is not a source of pressure.

Sensation: (Level of Evidence: II–IV)

Peripheral neuropathy affects sensory, motor and autonomic nerves. Loss of protective sensation (LOPS) is the most significant predictor of diabetic foot ulceration. Assessment of LOPS is easily accomplished—by the clinician or patient/family member—by using a Semmes Weinstein 5.07 monofilament. The inability to perceive the 10 g of bending force applied by the monofilament is associated with clinically significant large-fibre neuropathy. While the diagram in the RNAO guideline Appendix J is complete, it advocates only four test sites on the foot, which will capture 90 per cent of patients with insensate feet.³ Ten test sites are preferable.⁸



Use only calibrated nylon monofilaments to ensure optimal accuracy. Purchased and hand-made monofilaments can vary widely in accuracy due to differences in monofilament length and diameter. Due to the memory properties inherent in nylon, monofilaments require a two-hour rest period after 100 applications. Given that a biped patient will be tested at 20 sites, after five such patients the monofilament will lose accuracy. In a busy clinic several monofilaments will be needed to ensure accuracy. Further studies will help determine when a nylon monofilament requires complete replace-

ment. It is important to avoid “leading” questions and cues when assessing with monofilaments (RNAO guideline recommendation 2.3³).

Assessment of LOPS, as well as hot and cold perception, can be a valuable teaching and biofeedback tool for patient safety. Monofilaments are available online at www.cawc.net.

Recommendation 3: (Level of Evidence: IV)

Classify PWD into a risk category to support co-ordination of care.

Discussion

Assessment for risk category should drive initial and ongoing therapy. The University of Texas Treatment-based Diabetic Foot Classification System identified in RNAO guideline Appendices C and D (Risk Factors for Ulceration and Risk Factors for Amputation, respectively) aid the clinician in identifying critical parameters of diabetic foot dysfunction.³ The categories are as follows:

- Category 0 — Protective sensation intact
- Category 1 — Loss of protective sensation (LOPS)
- Category 2 — LOPS with deformity
- Category 3 — LOPS with deformity and history of pathology
- Category 4A — Non-infected, non-ischemic wound
- Category 4B — Acute Charcot arthropathy
- Category 5 — Diabetic foot infection
- Category 6 — Critical ischemia

This validated system quickly and accurately classifies patients with diabetes and guides the clinician in selecting the most appropriate therapy both for prevention and for therapeutic interventions.⁸ There are several published risk category tools, and it is important that the team selects and uses the same tool.

Recommendation 4: (Level of Evidence: IV)

Modify factors that cause skin breakdown and/or influence healing and make referral(s) to the team to ensure comprehensive care.

Discussion

The healing of diabetic ulcers is a complex process that requires more than just a topical dressing. It is essential that the team directing care modifies patient-related factors that can influence wound healing, primarily glycemic control, vascular flow, infection and pressure. However, there may be other co-factors identified during the history and physical that can affect healing and need appropriate treatment. Consult RNAO guideline recommendation 5.0/5.1 and Appendix L.³ By using the University of Texas Treatment-based Diabetic Foot Classification System, clinicians are able to treat based on the factors identified in each individual category (RNAO guideline: Appendices C, D and L³). Clinicians need to facilitate a bridge between the patient and clinical expertise to establish early and aggressive treatment to achieve early wound closure.

Recommendation 5: (Level of Evidence: IIa)

Provide pressure downloading if there is loss of protective sensation.

Discussion

Pressure is a factor in 90 per cent of diabetic plantar ulcers, and the pressure must be modified or removed. Pressure-induced ischemia occurs in tissues over bony areas of weight-bearing during ambulation and standing. Neuropathy prevents the perception of protective pain, resulting in an increased potential for tissue breakdown. Diabetic plantar ulcerations require aggressive and effective downloading in order to achieve wound healing (RNAO guideline recommendation 5.3 and Appendix O³). Effective downloading is the ability to reduce pounds per square inch (PSI) of pressure forces over the wound site during weight-bearing using an external device. Without pressure relief, care is undermined and all of the patients' and caregivers' efforts to optimize the condition of the wound bed are lost.

Effectiveness of downloading is dependent on the patient's understanding of why it works and how it should be used, "with every step taken, day and night, indoors and outdoors."⁹ The resulting evidence of non-wound healing is an excellent feedback tool to achieve better patient adherence. The first choice of downloading devices should be limited to total contact casts (TCC) or removable walkers, and then to Darco healing sandals if gait and balance are issues. Katz et al. (2005) demonstrated in their study that a removable cast walker when rendered irremovable may be equally efficacious, faster to place, easier to use, and less expensive than a TCC in the treatment of diabetic neuropathic plantar foot ulcers.⁹ Removable walkers and Darco healing sandals require a soft, custom-made, total contact insert to be effective in distributing pressures over the entire plantar surface of the foot.⁹

Caution:

- The use of a wheelchair or crutches is an ineffective downloading strategy due to the functional needs of the patient relating to activities of daily living.

Management goals of the Charcot foot involve early intervention and immobilization of the midfoot. Immobilization must be maintained until the bone has re-fused together and is verified on bone scan. This process may take six to 24 months. A total contact cast or removable cast walker with total contact, custom-made orthosis is used for patients who are not highly active or weigh less than 68 kg. Risks are better managed as activity level and/or weight increases with the use of a bi-valved custom-made ankle-foot orthosis. It is rare that a foot with a Charcot deformity can be accommodated in off-the-shelf footwear. Typically, custom-made footwear or custom-made bi-valve ankle-foot orthoses are required to adequately manage pressure at the site of the deformity.

To prevent recurrence of ulceration, Birke et al. (2004) demonstrated in their study that a wedge shoe modified with relief was more effective than a wedge shoe alone and was more effective than a short leg walker in offloading pressure under the area of previous great toe ulceration in individuals with diabetes.¹⁰ Through their study they demonstrate that careful local pressure-relieving may enhance the effectiveness of appliances that provide a reduction in plantar pressures.

TABLE 2

Pressure Downloading According to Category

Category	0	1	2	3	4a + 4b	5 + 6
Assess Downloading	Screen yearly	Screen twice per year	Screen two to four times per year	Screen four times per year	See biweekly/weekly as required	See as needed for wound care
Non Surgical Downloading (Footwear)	<ul style="list-style-type: none"> • Suggest slippers with firm soles 	<ul style="list-style-type: none"> • Professionally fitted from now on • Extra depth/width footwear plus custom-made total contact orthotic (CMTCO) of shock-absorbing material 	<ul style="list-style-type: none"> • Extra-depth, modified or custom-made • Consider rocker plus CMTCO 	<ul style="list-style-type: none"> • Extra-depth, modified or custom-made • Rocker plus CMTCO 	<ul style="list-style-type: none"> • Footwear not appropriate: use offloading devices e.g., TCC, Walker, healing sandal, bivalve custom-made walking orthosis 	<ul style="list-style-type: none"> • As in 4
Surgical Pressure Downloading	Elective <ul style="list-style-type: none"> • Bunions or other deformities • Nail wedge resection • Ensure adequate blood flow 	Elective <ul style="list-style-type: none"> • Hammer toes • Bunions • Hallux limitus • Achilles tendon release • Nail wedge resection • Ensure adequate blood flow 	Elective <ul style="list-style-type: none"> • As in 1, plus other "deformities" causing plantar-pressure problems • Ensure adequate blood flow 	Elective and Urgent <ul style="list-style-type: none"> • As in 1, if re-occurrence of ulcer imminent and non-surgical attempts ineffective • Ensure adequate blood flow 	Urgent and Emergent <ul style="list-style-type: none"> • As in 1, when aggressive debriding of ulcers is required • Ensure adequate blood flow 	Urgent and Emergent <ul style="list-style-type: none"> • When bypass surgery needed • To reduce ulcer bioburden

Adapted from Inlow S, et al.¹

TABLE 3

Essential Offloading Devices

Offloading Device	Advantages	Disadvantages
Rocker Sole An additional device applied to the sole of an approved shoe	<ul style="list-style-type: none"> • Can be applied to most walking/running/extra-depth footwear • Downloads MT and hallux/digit pressures • Needs to be a rigid rocker to withstand toe-off forces • Needs to be used with CMTCO orthosis 	<ul style="list-style-type: none"> • Specialty skill to apply rocker may not be available everywhere • Can't be applied to all shoes • Not for patients with balance issues • Not effective for ulcer healing—only preventive
Darco™ Healing Sandal A Darco sandal with a customized footbed orthosis	<ul style="list-style-type: none"> • Its rocker sole downloads digit and heel pressure • Used for ambulation only if ambulation is unsafe in a removable walker/TCC • Lightweight and stable • Reusable and adaptable • Built to accommodate thick, soft CMTCO • Must be used with CMTCO to distribute pressure over entire plantar surface 	<ul style="list-style-type: none"> • Not as efficient compared with other methods of downloading • Second choice when TCC and removable walker are contraindicated due to gait and frailty issues • Not effective in extremely obese and very active patients
Removable Walker A commercially available removable boot that reduces plantar pressures	<ul style="list-style-type: none"> • Distributes pressure over the entire plantar surface • Easily removable, allowing wound inspection and treatment • Allows bathing and sleeping comfort • Can be used for infected wounds • Must be used with CMTCO to distribute pressure over entire plantar surface as in TCC • Lightweight, has rigid rocker sole, fits right or left • Reusable, can be kept on hand and used at the first sign of ulcer recurrence (with modified CMCTO) 	<ul style="list-style-type: none"> • Removable nature of cast reduces adherence • Requires education regarding activities of daily life use to improve patient adherence
Total Contact Cast (TCC) A well-moulded minimally padded cast that maintains contact with the entire aspect of the foot and lower leg	<ul style="list-style-type: none"> • Distributes pressure over the entire plantar surface • Protects foot from infection • Maintains patient adherence as non-removable 	<ul style="list-style-type: none"> • Requires trained technician • Cannot assess foot on a daily basis • Affects sleeping and bathing • Exacerbates postural instability or causes poor balance • Cannot be used if wound infected • Cannot be used in the neuro-ischemic limb • Recurrent cost to the patient • Takes time to apply and set • Heavy

Recommendation 6: (Level of Evidence: IV)

Provide individualized education as indicated by patient need and by risk category.

Discussion

Evidence supports educational intervention for improvement in foot-care knowledge and behaviour in the short term for people with diabetes. (RNAO guideline recommendations 1.2 and 4.2 Appendices C, D, E, F and K³). There is additional evidence to support the concept that people with diabetes who are at a higher risk for foot ulceration significantly benefit from education and regular reinforcement of that education (Table 4). A three-fold increased amputation risk was demonstrated for those people with diabetes who had not received formal diabetes education, suggesting significant prevention is possible with appropriate teaching strategies. Once wound closure is achieved, the focus of education needs to be on prevention of recurrence through diligent self-monitoring.

Diabetes education should be evidence-based, 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 patient-centred approach. The clinician should be sensitive to socioeconomic, cultural, psychosocial and other individual domains when planning all interventions with the patient.

Armstrong et al. (2004) suggest in their study on activity and the development of diabetic foot ulceration that instructing patients on the modulation of the “peaks and valleys” of activity may prove to reduce the risk for ulceration in the high-risk population.¹¹

Recommendation 7: (Level of Evidence: Ia-IV)

Assess diabetic foot ulceration(s).

Discussion

A healthy wound has a pink wound bed and an advancing wound margin, while an unhealthy wound has a dark, friable wound bed with undermined wound margins. All clinicians (team members) assessing

TABLE 4

Schedule of Practice Recommendations Based on Category¹

Category	Foot Education	Professional Follow-up	Professional Nail Care	Activity and Mobility
0	Yes	Yearly	No	Wear well-fitting shoes, exercise as you wish
1	Yes	Q 6 months	Yes or No	Avoid excessive walking if recurrent pressure points occur on feet
2	Yes	Q 3 months	Yes or No	Low-impact activities preferred, such as biking
3	Yes	Q 1–3 months	Yes or No	Walk only for activities of daily living, non-impact exercise, such as swimming or recumbent biking
4a + 4b	Yes	Daily–weekly	Yes or No	Pressure downloading devices, no weight-bearing exercises, reduce activity to self-care
5	Yes	Daily–weekly	Yes or No	Pressure downloading devices, minimal activity required until emergent issues dealt with
6	Yes	As required	Yes	As in 4

Recommendations may vary dependent on co-existing risk factors.

the diabetic foot ulcer need to use a common language. Objective descriptors such as wound measurements and ulcer grading increase the clarity in describing wound-care outcomes (RNAO guideline recommendations: 3.0, 3.1 and 3.2, Appendices E, H, I and Table 1).³

Measuring Length and Width: (Level of Evidence: Ia)

Clinical studies have shown that a reduction in ulcer area (approximately 20 per cent to 40 per cent after two to four weeks of treatment) is a good predictor of healing.¹² It is important when measuring the ulcer that the measurements are done using a consistent method such as tracings and/or measurement tools. This will greatly increase reliability in determining progress toward closure.

Measuring Depth: (Level of Evidence: IV)

Ulcer depth is most commonly measured and quantified by gently inserting a sterile swab stick or probe into the ulcer. The presence or absence of undermining, a space between the surrounding skin and ulcer bed, and tunneling can also be determined in this manner.

Increasingly, wound photography and digital imaging are becoming part of practice not only for chart records but for consulting with specialists and telehealth, yet few clinicians have a standard for this procedure. Buckley et al. (2005) developed a competency-based program to support photography skills and procedures that provides a framework for a practice that integrates wound photography as part of its method for assessment.¹³

Classification System: (Level of Evidence: IIa)

Standardizing the procedure for measurement is crucial in order to

evaluate whether the ulcer is moving in the direction of the goal of care. The University of Texas Health Center, San Antonio, Diabetic Wound Classification System in the RNAO guideline (Appendix E³) is an example of a grading system to stage the depth and severity relating to ischemia and infection of a diabetic foot ulcer that may assist in directing therapeutic decisions relating to care. This staging system positively correlates to the risk of amputation and other adverse outcomes.

Note: Subkeratotic hematoma and peri-ulcer callus formation may obscure the ability to accurately assess depth, width and length.

Assess for Infection

There is a high incidence of infection associated with the diabetic foot. Small erosions or fissures of the skin that go undetected may lead to a local cellulitis or lymphadenitis. With loss of protective sensation, a daily foot exam is important. All skin ulcers are contaminated with bacterial flora. When the bacteria multiply in microcolonies and attach to the surface tissue, colonization is established.

As many chronic wounds are colonized by multiple bacterial species, a swab culture will not be able to identify the causative organism. While acute wound infections traditionally present with pain, redness, swelling, loss of function and heat, Gardner, Frantz and Doebbling (2001) have validated the following signs and symptoms (Cutting and Harding 1994) indicative of a chronic wound infection:

- Increased pain (100 per cent specificity)
- Wound breakdown (100 per cent specificity)
- Foul odour (85 per cent specificity)
- Friable granulation tissue (76 per cent specificity)^{14,15}

Infection involving the deep tissue compartment will often cause erythema and warmth that extends 2 cm beyond the wound margin. Any wound that shows sinus tract formation or undermining must be probed. Any contact with bone or ligament structures indicates osteomyelitis.¹⁶ Signs of deep-wound and systemic infection are potentially limb- and/or life-threatening and require immediate attention. Unfortunately, swabbing the wound bed will not reliably identify the causative organism. The microbial flora in a chronic wound will change in a predictable fashion over time.

In persons with diabetes, some of these symptoms—both acute and chronic—may not be present or may be difficult to assess due to objective assessments varying from clinician to clinician.¹⁷ Lavery et al. (2004) observed the use of a hand-held infrared skin temperature device by persons with diabetes at home to identify early warning signs of inflammation and tissue injury. In their standard therapy group there was a 20 per cent foot complication, while in the group that used home infrared temperature monitoring there was a two per cent complication rate, indicating that the standard therapy group was 10.3 times more likely to develop a foot complication than the group using the home infrared temperature monitoring.¹⁸

Recommendation 8: (Level of Evidence: Ia-III)

Provide an optimum wound environment: debridement, moisture balance, infection control.

Discussion

Figure 2, the Pathway to Assessment/Treatment of Diabetic Foot Ulcers, provides a framework within local wound care that asks the clinician to assess and treat three specific pillars for practice (RNAO guideline recommendation 5.2, and Appendices M and N³).

Debridement:

A significant goal of preventative treatment is the removal and prevention of calluses through skin-care techniques, including paring and debridement of callus build-up, biomechanical assessment and medical/surgical management, shock-absorbing footwear, shock-absorbing orthotics, rocker soles/footwear adaptations and patient

education. Diabetic foot care must include removal of callus build-up, subkeratotic hematoma and peri-ulcer callus formation. Removal of plantar calluses can reduce peak plantar pressures by 26 per cent.¹⁹ It is important to seek out the correct health-care professional to assist your patient with these issues.

Tissue debridement of nonviable, infected and/or contaminated tissue from the wound bed has been shown to improve the rate of healing of diabetic foot ulcers, and lower rates of wound healing have been correlated with less frequent debridement practices.²⁰ While there are a variety of debridement methods available (see Table 5), the most common methods used for diabetic foot ulcers include

- Autolytic debridement using non-occlusive dressings
- Mechanical debridement through cleansing using normal saline solution or appropriate wound cleanser
- Sharp debridement using scissors or a scalpel
- Surgical debridement

Debridement of callus around a diabetic wound is important for healing as it can reduce pressure at the callus site by approximately 30 per cent (Pitei, Foster and Edmonds, 1999, cited in the RNAO guidelines³). Callus debridement falls within the scope of nursing practice provided the nurse has the skill, knowledge and judgement to safely and competently perform the procedure.

Caution:

- Sharp or surgical debridement is performed by physicians, their delegates, or specially trained and experienced health-care professionals. Nurses should be aware of the policies and procedures of their facility.
- Adequate vascular supply must be determined for healability. If healability of the wound is not established, moist interactive dressings and aggressive debridement are *not* recommended.

Infection Control: (Level of Evidence: IIa)

Chronic wounds that are colonized do not require any antimicrobials. The host is capable of managing the deleterious effects of the microbes, and wound healing can proceed (RNAO guideline recommendations 2.2, 5.2, Table 2, Table 3, Appendix M³).

If the superficial tissue compartment is critically colonized, the

TABLE 5

Key Factors in Deciding Method of Debridement

	Surgical	Enzymatic	Autolytic	Biologic	Mechanical
Speed	1	3	5	2	4
Tissue selectivity	3	1	4	2	5
Painful wound	5	2	1	3	4
Exudate	1	4	3	5	2
Infection	1	4	5	2	3
Cost	5	2	1	3	4

Where 1 is most desirable and 5 is least desirable. Adapted from Sibbald et al.⁶

TABLE 6

Mild³ to Moderate or Non-limb-threatening Infection in the Diabetic Foot

Cellulitis – Special Considerations: Diabetic Foot ^{1,2}					
Modifying Circumstances	Probable Organism(s)	Antibiotic Choice(s)		Usual Dosage	Cost per Day*
Mild ³ to Moderate or Non-limb-threatening	<i>S. aureus</i> Group A Strep. Group B Strep. Enterococci <i>P. aeruginosa</i> ³ Mixed aerobic and anaerobic	First Line	TMP/SMX ³	1-2 DS tabs BID	\$0.24–\$0.48
			or		
			Cephalexin		
		Second Line	plus	500 mg QID	\$1.19
			Metronidazole ¹	500 mg BID	\$0.11
			Amoxicillin / Clavulanate ^{3,4}	500 mg TID or 875 mg BID	\$2.52–\$2.80
Third Line	or	TMP/SMX	1-2 DS tabs BID	\$0.24–\$0.48	
	plus	Clindamycin ¹	300–450 mg QID	\$3.91–\$5.87	
	Cefazolin IV	1–2 g q8h	\$9.00–\$18.00		
	plus either one of	Metronidazole IV ¹	500 mg q12h	\$3.78	
		or			
		Clindamycin IV ¹	600 mg q8h	\$27.44	

Common oral dosage ranges are provided unless otherwise stated. Consult the drug monograph for details on age and condition-specific dosing.

* Approximate costs were derived from the ODB formulary (#38) or manufacturers' price lists and do not include professional fees or markups.

Adapted from Rosser WW, Pennie RA, Pilla NJ, and the Anti-infective Review Panel.⁴

1. Deep cultures should be done in diabetic patients if the cellulitis is recurrent or associated with a long-standing ulceration. Swabs of pus are useful; however, surface swabs are not. **If anaerobes are an issue ("presence of necrotic tissue" or "foul smell"), clindamycin or metronidazole should be added. This will depend on the location, spectrum of pathogens and severity of infection.** (Most non-limb threatening, or mild, infections are monomicrobial involving gram-positive bacteria only; therefore, it may not be necessary to cover for anaerobes; severe infections are usually polymicrobial, involving anaerobes.)
2. No evidence of systemic toxicity, deep tissue involvement, or spreading erythema. Non-limb threatening infections include superficial infections, < 2 cm cellulitis, no evidence of serious ischemia. Usually monomicrobial: *S. aureus*, *Streptococci*.
3. TMP/SMX or amoxicillin/clavulanate should not be used if *Pseudomonas* is present. Consider using ciprofloxacin instead.
4. Amoxicillin/clavulanate covers anaerobes and can be used alone.

wound may show signs of distress, and the wound will appear to be stalled on serial assessments. The first approach should be appropriate debridement of the wound bed. Eschar is an optimal environment for microbial growth, and removal will rapidly improve the microbial environment. If debridement is insufficient to control the critical colonization of the superficial tissue compartment, topical antimicrobials may have a role in controlling the wound environment, and rebalance host defences. Selection of the proper topical antimicrobial includes a low sensitization potential and an intention to use for only two weeks before reassessment. Failure to improve the wound environment at this time would indicate the need for systemic treatment. The spectrum of antimicrobial activity should target the most likely causative organism (RNAO guideline: Appendix M⁵).

Dow et al. (1999) have outlined the natural progression of microbial colonizers found in chronic wounds over time.²¹ Empirical selection of antimicrobials based on the predominant organism is a prudent and rational approach to an infected wound. Only if the wound fails to improve would quantitative cultures and blood cultures be effective.

Antimicrobial management of diabetic foot infection should be based on a rational selection of antimicrobial agents so that most, if not all, organisms are controlled, and no survival advantage is given to any one organism. Since chronic wounds are *polymicrobial*, prudent selection of broad spectrum antimicrobials is necessary. The 2005 *Anti-infective Guidelines for Community Acquired Infections*: Tables 3A and 3B⁴ (Tables 6 and 7 in this article) are an evidence-based approach to

rational antimicrobial selection and put forth recommendations for the treatment of mild to moderate or non-limb-threatening infections as well as severe, limb-threatening infections.

Moisture Balance:

Dressing selection should promote a local balance of moisture in diabetic ulcers that also minimizes trauma and risk of infection (RNAO guideline recommendation 5.2³). Clinicians need to have a good understanding of the dressing categories and their characteristics in order to match the dressing to the needs of the person with the diabetic foot ulcer (RNAO guideline: Appendix N²). Clinicians should

- Assess the wound bed for bacterial balance, exudate level and need

for debridement.

- Select a dressing or combination of dressings that can manage and/or control the assessed wound environment.
- Use a dressing that will keep the wound bed continuously moist and the peri-wound skin dry.
- Choose dressings based on cost-effectiveness rather than cost.
- Choose a dressing that controls the exudate but does not dry the ulcer bed.
- Consider the caregiver’s time when selecting the dressing.
- Eliminate wound dead space by loosely filling all cavities with dressing materials.
- Ensure that the patient is aware there is to be reduced pressure to the affected area.

TABLE 7

Severe³ or Limb-threatening Infections in the Diabetic Foot

Cellulitis – Special Considerations: Diabetic Foot ^{1,2}							
Modifying Circumstances	Probable Organism(s)	Antibiotic Choice(s)		Usual Dosage ±	Cost per Day*		
Severe ² or Limb-threatening	<i>S. aureus</i> <i>Group A Strep.</i> <i>Group B Strep.</i> <i>Enterococci</i> <i>P. aeruginosa</i> ³ <i>Mixed aerobic and anaerobic</i>	First Line	Ceftriaxone IM/IV	1–2 g q24h	\$34.00–\$67.00		
			or				
			Cefotaxime IV	1–2 g q8h	\$29.67–\$55.20		
				plus			
				Metronidazole ¹	500 mg BID	\$0.11	
				or			
				Clindamycin ¹	300-450 mg QID	\$3.91–\$5.87	
		Second Line		Ciprofloxacin PO/IV ⁵	PO: 750 mg BID IV: 400 mg q12h	\$9.45 \$69.64	
				plus Clindamycin PO/IV ¹	PO: 300–450 mg QID IV: 600 mg q8h	\$3.91–\$5.87 \$27.44	
Third Line ⁴		Imipenem / Cilastatin IV	500 mg q6h	\$98.68			
		Piperacillin / Tazobactam IV	3 g/0.375 g q6h	\$66.80			

Common oral dosage ranges are provided unless otherwise stated. Consult the drug monograph for details on age and condition-specific dosing.

* Approximate costs were derived from the ODB formulary (#38) or manufacturers’ price lists and do not include professional fees or markups.

Adapted from Rosser WW, Pennie RA, Pilla NJ, and the Anti-infective Review Panel.⁴

1. Cultures should be taken. Consider admission to hospital. **If anaerobes are an issue (“presence of necrotic tissue” or “foul smell”), clindamycin or metronidazole should be added. This will depend on the location, spectrum of pathogens and severity of infection.** (Most non-limb-threatening, or mild, infections are monomicrobial involving gram positive bacteria only; therefore, it may not be necessary to cover for anaerobes; severe infections are usually polymicrobial, involving anaerobes.)
2. Severe as evidenced by systemic toxicity, deep tissue involvement, or spreading erythema. Limb-threatening infections include full-thickness ulcer, > 2 cm cellulitis, serious ischemia. Usually polymicrobial.
3. Consider using ciprofloxacin if *Pseudomonas* is present.
4. Consideration can be given to using other agents including fluoroquinolones (gatifloxacin, evofloxacin, moxifloxacin), ceftazidime, piperacillin-tazobactam, imipenem, meropenem or ertapenem in people with multiple drug allergies or as part of a multi-drug regimen.

- Evaluate the wound frequently to determine efficacy of the treatment plan.

For information relating to dressing selection for diabetic foot ulcers, see Table 12 in the Preparing the Wound Bed article on page 27.

Caution:

- The superficial nature of bones and tendon structures of the foot can potentially make the use of occlusive dressings undesirable.
- Avoid over-packing plantar ulcers as this may increase pressure even with the use of a downloading device.

Recommendation 9: (Level of Evidence: III–IV).

Determine the effectiveness of interventions, reassess if skin breakdown occurs and/or if healing is not occurring at the expected rate.

Discussion

Examining the edge of the wound is an assessment step in the Pathway to Assessment/Treatment of Diabetic Foot Ulcers (Figure 2) to determine if epidermal cell migration has begun (RNAO guideline recommendation 6.0, 6.1³). Evaluation needs to be an ongoing step in the wound healing-process and the clinician needs to address three key issues:

1. How do you know if your treatment plan has been effective?
2. How do you currently evaluate wound healing?
3. Is wound closure the only successful wound-care outcome?

Sheehan et al. demonstrated that a 50 per cent reduction in wound surface area at four weeks is a good predictor of wound healing at 12 weeks.²² If the wound is healing, keratinocytes and responsive wound cells migrate, advancing from the edge of the wound. If the edge is not migrating, the wound will require a full reassessment of cause, and corrective therapies need to occur. The most common reason for delayed healing of diabetic foot ulcers is inadequate downloading. If both the patient and the wound are optimized and the edge is still not migrating, the wound may need advanced therapies to kick-start the healing process. If signs of healing still do not occur, a biopsy should be taken to rule out disease.

Change to the edge of the wound is only one outcome parameter, and wound closure is not always the expected outcome. Wounds that are unlikely to heal need to have an alternative outcome with expectations such as wound stabilization, reduced pain, reduced bacterial load and decreased frequency of dressing changes.²³

Recommendation 10: (Level of Evidence: Ia-IV)

Consider the use of biological agents and adjunctive therapies.

Discussion

As part of the ulcer management strategies, or if the wound is optimized and the edge is still not migrating, the clinician should consider adjunctive therapies such as electrical stimulation, hyperbaric oxygen therapy (HBOT), topical negative pressure therapy, growth factors and bioactive agents (RNAO guideline

recommendation 6.2³). Referral may be required for some therapies—and they may not be available in all centres. Cultural and religious barriers may prohibit the use of some therapies. Surgical referrals for interventions such as Achilles tendon lengthening, skin grafts, arthroplasty, amputation, debridement and bony/vascular reconstruction should also be considered.

Recommendation 11: (Level of Evidence: IV)

Establish, train, and empower a team to work with patients with diabetes.

Discussion

Best practice care delivery for persons with diabetic foot ulcers demands a systematic, team approach from health-care professionals that can establish and sustain a communication network between the PWD and the necessary health-care and community systems. A specialized interprofessional 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. Clinicians can facilitate and positively influence wound-healing outcomes by promoting, collaborating and participating in interprofessional care teams who follow best practice guidelines similar to those presented in this document. Primary team members should represent the patient/family/caregivers, medicine, podiatry/chiropractic, nursing, rehabilitation (occupational therapist/physical therapist), enterostomal therapist, orthotist and pedorthist. The team should be affiliated with members from medical specialties such as endocrinology, dermatology, vascular, orthopedics and infectious diseases, as well as social workers, dietitians, mental-health workers and diabetes nurse educators. The ideal model involves the team working together in one location, but that is not always possible. Teams can be created without walls; linkages and relationships need to be created to support the complex needs of the person with diabetes.

The development and implementation of a successful diabetic foot ulcer program not only involves collaboration with practice leaders, but, as the RNAO guideline demonstrates, there is also a need for collaboration with educators and administrators. Their support is required to ensure co-ordinated care with community and health-care agencies and the specialized, knowledgeable interdisciplinary team of health-care professionals striving for improved outcomes in diabetic foot (RNAO guideline recommendations 7.0 and 9.0 through 9.3. and recommendations 9.0–16.0³). The RNAO guideline 2004 stresses the same approach for preventative strategies.²

Conclusion

Initiatives such as the implementation of a best practice guideline require strong leadership from clinicians who understand the concepts of planned change, program planning, evaluation and research utilization.

Clinicians need to participate in recognized, accredited continuing educational opportunities that support the interprofessional team approach to diabetic foot-ulcer care and prevention.

In order to improve health outcomes for persons with diabetic foot ulcers and increase job satisfaction for clinicians, agencies need to

provide a full scope of support (financial, educational, and human resources) for clinicians seeking professional education.

Another critical initial step must be the formal adoption of the guideline recommendations into the policy and procedure structure of the clinical setting. 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 (RNAO guideline³).

Lasting impressions of this 2005 revision of the RNAO guideline are

1. Guideline development and maintenance is a complex and time-consuming process, with the Registered Nurses' Association of Ontario (RNAO) leading the way.

2. RNAO Best Practice Guidelines are living documents and receive revision as follows: q3 months, literature search; q6 months, full Internet search; q3 years, full review of the RNAO guideline document.
3. RNAO guidelines provide operational and educational recommendations that support and are the backbone to clinical practice recommendations.
4. The pivotal differences between the two types of documents are that the RNAO guidelines provide a thorough review of the evidence while the CAWC Best Practice Recommendations support a transfer of the evidence into a concise format to support change at the bedside.
5. The revised CAWC Best Practice Recommendations are now based on the evidence (which includes expert opinion) according to the RNAO Best Practice Guideline rather than expert opinion alone.
6. The RNAO Guideline, however interprofessional in nature, has a focus on nursing practice. The CAWC Best Practice Recommendations benefit from a more interprofessional approach to care. ☺

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