Health Quality Ontario: Supporting Better Wound Care

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On November 22, 2017, the Ontario Ministry of Health and Long-Term Care announced it would begin covering the costs of specialized casts for patients with diabetic foot ulcers.

In its announcement, the ministry acknowledged that wound care devices, which include removable, irremovable and total contact foot casts, can significantly improve quality of life for patients with diabetic foot ulcers by relieving or offloading pressure around the heel, ankle and toes, allowing the foot to heal properly. The ministry stated that the decision to fund the specialized casts was based on its acceptance of the Health Quality Ontario recommendation, made in September, to fund three types of offloading devices. The decision demonstrates the important role Health Quality Ontario, the provincial adviser on quality in health care, plays in enhancing wound care for patients in the province, both by developing quality standards to help guide care in clinical areas where wide variations in treatment and outcomes exist and by making recommendations on the funding of health-care services and medical devices.

In early December 2017, Health Quality Ontario released quality standards outlining what quality care looks like for people with diabetic foot ulcers, venous leg ulcers and pressure injuries.

Developing Quality Standards

Every quality standard is based on the best available evidence and developed in collaboration with clinical experts from across the province as well as patients and caregivers with lived experience of the condition being discussed. Each quality standard consists of a patient guide, a clinical guide, data detailing why a particular standard was developed and recommendations for its adoption at the system, regional and practice level to help health-care professionals and organizations.

The quality standard dealing with diabetic foot care begins by setting out the rationale for the standard by noting the negative impact of dia-

betic foot ulcers on quality of life for patients and the fact that such ulcers cause about a third of all non-traumatic below-the-knee amputations in Canada.

"Wound care represents a significant area of opportunity for quality improvement in Ontario," the document goes on to state. "There are important gaps and variations in access to services and in the quality of care received by people who have developed or are at risk of developing a diabetic foot ulcer. In 2014, the amputation rate in the local health integration network (LHIN) with the highest rate was almost eight times that of the LHIN with the lowest rate."

The clinical document for the standard outlines 12 quality statements detailing how foot care can be improved for people with diabetes. One of these deals specifically with offloading: "People with diabetic foot ulcer or foot complications are offered pressure redistribution devices as part of their individualized care plan."

The accompanying patient guide for the same condition tells patients and their families what they should do and what to expect if they have a diabetic foot ulcer or other foot problem: "As part of your care plan, you should be offered ways to take pressure off your foot so it can heal, and to prevent future ulcers, too." These methods could include total contact casts, removable cast walkers and irremovable cast walkers.

Data had indicated that such offloading devices were often recommended by clinicians but not widely available, and organizations such as Wounds Canada and the Registered Nurses' Association of Ontario had advocated for full funding of the devices.

As a result of these efforts, offloading devices for diabetic foot ulcers were prioritized as a topic warranting a health technology assessment by Health Quality Ontario. Health technology assessments use scientific methods to analyze the evidence for a wide range of health interventions, including diagnostic tests, medical devices and interventional and surgical procedures.

Which Technologies Are Evaluated?

As with quality standards, the decision regarding which technologies to evaluate is the result of an open process through which any person or organization in Ontario can submit a topic request. Selection of assessment topics is made through a prioritization process using explicit criteria that include in part the potential clinical benefits and harms of the technology and the potential need for the technology in Ontario.

Evidence is analyzed to determine clinical benefit, safety, value for the money, and patient preferences and values. The reports are prepared by a team of medical librarians, clinical epidemiologists, health economists, patient engagement program analysts and medical editors in consultation with health-service researchers, patients, families, caregivers, clinical experts and industry.

The Ontario Health Technology Advisory Committee (OHTAC), a group of health-care experts and individuals from across the province who can contribute the patient perspective, reviews the evidence and makes recommendations as to which health-care services and medical devices should be publicly funded. These recommendations are then posted on the Health Quality Ontario website and promoted through social media for public input prior to recommendations being approved by the Health Quality Ontario Board of Directors. The final recommendations are then shared with the Ministry of Health and Long-Term Care.

Comparing Offloading Devices

In the case of offloading devices to help patients with foot ulcers as a result of diabetes, the assessment noted that about one in 10 people in Ontario have diabetes, and 2% to 3% of them will develop a foot ulcer annually and are at risk for lower-limb amputation.

The assessment team identified 13 randomized controlled trials of offloading devices. The evidence suggests that fibreglass total contact casts and cast walkers (removable or irremovable) may be beneficial for treating neuropathic non-infected diabetic foot ulcers.

An economic analysis conducted as part of the assessment found total contact casts and irremovable cast walkers were less expensive and led to more health outcome gains than removable cast walkers and that irremovable cast walkers were as effective as total contact casts and associated with lower costs.

Patients who were interviewed as part of the assessment process said they felt that wound healing was improved with total contact casts more than with removable cast walkers, but that removable cast walkers were more convenient and cost less.

The assessment concluded that increased access to offloading devices could result in fewer amputations and therefore cost savings for the health system.

Offloading devices represent just one tool for improving care for patients with diabetic foot ulcers and play a role in improving wound care in general. By adopting health technology assessments and quality standards, Health Quality Ontario supports the use of evidence to enhance quality health care in the province—in this case specifically wound care.

An Advanced Breakthrough Therapy to Treat Foot Ulcer: EpiFix® – a skin substitute clinically proven for effective healing of DFUs and VLUs.

Don Fetterolf MD, MBA, FACP, Chief Medical Officer MiMedx Group, Inc.

Q1 Why is choosing an advanced therapy, like EpiFix, important to Ontarians?

Millions of people are living with diabetes in Canada. *Diabetes Canada* and *Wounds Canada* are leaders in highlighting key issues that affect Canadians living with diabetes and, more importantly, in guiding Canadians to important treatment remedies for insidious complications of diabetes like Diabetic Foot Ulcers (DFU).

In Ontario, for example, as a direct result of DFUs, there is one amputation every four hours, according to *Diabetes Canada*, and the majority of these amputations are the direct result of foot ulcers that do not heal. More importantly, diabetics are more likely to be hospitalized for limb amputation - almost 25 times more likely than non-diabetics. Furthermore, the complications from DFUs costs the system almost half a billion dollars annually.

Q2 Why EpiFix, a human allograft consisting of dehydrated Human Amnion/Chorion Membrane (dHACM), and how does it help as an advanced wound care therapy?

Human amniotic membrane has been noted in clinical literature for over a century. *In vivo* studies show that the barrier properties of amniotic membrane help reduce scar tissue formation and enhance wound healing, and physicians have been using amniotic membrane for wound repair for years.

Since 2006, MiMedx has optimized its PURION® Process, a proprietary processing methodology that employs aseptic processing techniques in addition to terminal sterilization to produce EpiFix, a skin substitute consisting of dehydrated Human Amnion/Chorion Membrane (dHACM) allograft.

Q3 Can EpiFix be used in Canada?

Since its introduction in the United States, MiMedx has processed and distributed in excess of 1 million tissue allografts for the treatment of wound care. MiMedx has had a license registration in Canada since 2011.

In several peer-reviewed publications MiMedx PURION® Processed dHACM allografts demonstrated recruitment of stem cells, promotion of cell migration, and modulation of stem cell activity *in vitro* and *in vivo* compared to appropriate controls. Numerous published randomized, controlled, clinical trials have demonstrated that the PURION Processed dHACM is an effective therapy for treatment of chronic wounds and to promote healing.

Q4 How does EpiFix compare from an economic standpoint?

According to *Diabetes Canada*, it has been demonstrated that the cost for chronic wound management to the health care system in Canada is high in terms of resource utilization and the negative impact to the quality of life of the patient.

In a complex Markov Model approach used in a recent Ontario study comparing the costs and outcomes of EpiFix with the costs and outcomes associated with standard of Care (SOC) and off-loading, the model found that EpiFix used in DFU treatments resulted in superior wound healing and reduced costs. Moreover, the model showed that costs associated with EpiFix over SOC were more cost effective and most importantly dominated SOC in quality of life years.

MiMedx

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