

Evaluating the Costs and Benefits of Innovations in Chronic Wound Care Products and Practices

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Theresa Hurd, RN, MScN, MScEd, PhD
Nursing Practice Solutions,
Ontario, Canada
theresa@nursingpracticesolutions.com

Abstract

The management of innovation and change in healthcare can be a major challenge. It has been recognized that a key factor in closing the gap between best practice and common practice is the ability of healthcare providers and organizations to rapidly disseminate innovations.¹ Today's healthcare environment offers a steady stream of innovations, often at a pace that seems much too fast for organizations to evaluate and integrate. Clinicians and administrators can feel overwhelmed and unable to decide which innovations are appropriate and how they might be utilized for optimal outcomes. They face constant pressure to innovate and accelerate the dissemination of innovation. Simultaneously, organizations must ensure the consistent delivery of proven patient care practices at the highest possible quality standards is not compromised in any way as innovations are adopted.

This paper reviews the implementation of healthcare innovations in the field of chronic wound care. Two distinct types of innovation are profiled:

- **Process Innovation:** A comprehensive program of clinical best practices focused on the prevention and care of chronic wounds is currently being implemented by a large community care organization providing in-home care services in Canada. The program incorporates a rigorous framework of measurement, monitoring, and benchmarking that tracks outcomes and resource requirements in order to generate continuous feedback on both cost and benefits.
- **Product Innovation:** An innovative medical device—a portable, disposable negative pressure wound therapy (NPWT) system—has been introduced into clinical practice by wound care providers in acute care and community care organizations. This product innovation has been adopted within the context of best practice wound care and prevention programs so tools are available to assess, evaluate, and monitor the utilization of the new technology.

Results show 98% of patients reported they were pleased or satisfied with the NPWT device. Anecdotal data from patients described improvements ranging from increased social activities and improved self-esteem to a marked improvement in general overall wellness. Similarly, 99% of nurses were pleased or satisfied with the device. Only 2% of nurses reported any difficulty with application of the product. Over the course of the evaluation, 68% of wounds treated with the portable negative pressure device were completely closed with a median time to healing of 9 weeks. This rate needs to be considered in the context of the wounds treated, many of which remained unhealed for a significant time before commencing treatment with portable NPWT (average wound duration before treatment was 9 weeks with a range from 1 to 68 weeks). A comparison of the cost of the single-use negative pressure system and traditional negative pressure systems shows that single-use NPWT can substantially reduce the cost per patient, as a result of fewer dressing changes and nurse visits per week.

This paper provides qualitative and quantitative data related to the adoption of these innovations in a demanding, real-world clinical environment. The intent is to offer practical insights and describe results to date from innovations within a framework of managed adoption and evaluation that is designed to meet healthcare organizations priorities of high-quality care and improved efficiency.

Key Words: chronic wounds, negative pressure wound therapy, portable NPWT device, costs and benefits of NPWT

TABLE 1. Chronic Wound Care: Direct, Indirect, and Intangible Costs

| Direct Cost | Indirect Cost |
|--|---|
| Wound prevention measures | Absenteeism and loss of productivity |
| Consumable products (eg, wound dressings) | Care giver burden |
| Medical devices (eg, castings, offloading devices, and so on) | Government subsidies (eg, worker's compensation, welfare) |
| Medications (eg, antibiotics, pain control) | Insurance costs |
| Labor (eg, nursing visits, physician time, ER time, allied professionals, and so on) | Litigation costs |
| OR time for procedures such as debridement, grafting, and so on | Intangible Cost |
| Hospital bed days (admissions and re-admissions, increased length of stay) | De-conditioning |
| Nutrition | Loss of independence |
| Rehabilitation | Pain and suffering |
| | Quality of life impact |

Chronic wounds represent a large and growing burden for patients and healthcare providers. For patients, chronic wounds can have a significant impact on well-being due to symptoms and side-effects such as pain, loss of mobility, and depression, as well as financial expenses resulting from an inability to work and treatment costs.²⁻⁶ There are also adverse clinical outcomes associated with wounds, including amputation and even an increased risk of death.⁷ For healthcare organizations, chronic wound care places substantial stress on limited human and financial resources. For example, in the United States, chronic wounds affect an estimated 6.5 million patients.⁸ More than \$25 billion is spent annually on the treatment of chronic wounds.⁹ These costs are expected to grow, as chronic wounds are closely associated with many common long-term conditions that are becoming increasingly prevalent throughout most of the developed world as populations age.¹⁰⁻¹²

In this context, many healthcare organizations are attempting to assess the bur-

den of chronic wounds, improve wound care practices, optimize healing times, and reduce the prevalence of chronic wounds. Many innovations are being introduced as wound care practices are transformed. The need to manage these innovations carefully and systematically in a manner that is linked to clinical best practices, and that preserving and enhancing quality of care, will remain important.

The Cost of Chronic Wounds

In recent years, health researchers have begun to define the scale and severity of chronic wounds as a healthcare issue. For example, an estimated 2.5 million pressure ulcers are treated in the United States in acute care facilities alone¹⁶ and the prevalence of pressure ulcers (the measurement of people with pressure ulcers at a given point in time)¹⁷ in the critical care setting is an estimated 22%.¹⁸ It is estimated that 25% of people with diabetes will develop a diabetic foot ulcer at some point.¹⁹ In the United States, it is estimated that 7.8% of the population (23 million) have diabetes.

The prevalence of chronic wounds is expected to grow rapidly due to their association with a variety of common chronic diseases. Chronic wounds are rarely seen in individuals who are otherwise healthy.²⁰ Common disease associations include:

- Diabetic foot ulcers are, by definition, directly associated with diabetes;
- Venous leg ulcers are associated with venous disease;
- Arterial wounds are associated with peripheral vascular disease;
- Malignant ulcers are associated with cancer;
- Pressure ulcers are associated with a broad range of comorbidities, including virtually any condition that restricts or limits patient mobility for extended periods of time;
- Postsurgical infected wounds are associated with multiple comorbidities.

Age is a further risk factor for the development of chronic conditions associated with wounds.²¹ The aging demographics

- A well-defined health intervention – eg, service delivery, treatment, or test to help reduce morbidity, improve outcomes, and/or mortality
- A competing alternative – ideally, the most widely used or the “gold standard” therapy against which the new intervention is compared
- A comparison of the impact of the intervention and comparator on clinical endpoints (eg, wounds healed, infection, and so on)
- A comparison of the impact of the intervention and comparator on patient endpoints (eg, health status, quality of life)
- Comparison of the costs of the intervention and comparator, including any associated treatment costs, such as healthcare professional time
- Presentation of the costs and benefits of the intervention and comparator, including incremental analysis (eg, the cost of any additional benefit accrued)
- Presentation in the most appropriate format such as natural units (eg, wounds healed) or a composite endpoint, such as a disability/quality adjusted life year

Figure 1. The basic elements of a cost-effectiveness analysis are summarized.

throughout most of North America and Europe have been well-documented. In the United States, for example, the percentage of the population age 65 years or older is projected to increase from 12.4% in 2000 to 19.6% in 2030.²²

From a health economics perspective, the prevention, care, and treatment of chronic wounds represent a large and growing burden on limited human and financial healthcare resources. However, the costs of wounds are often poorly documented and not yet well understood.^{23,24} Wounds, in general, maintain a low profile relative to other major disease categories and may be viewed as a subset of a more widely-recognized condition (eg, diabetic foot ulcers as part of diabetes) rather than as a distinct clinical condition. Where wound care costs are tracked, they are often defined very narrowly to include only the most obvious and direct consumable products and materials, such as wound dressings.²⁵ This approach fails to account for much larger costs that are typically hidden within other general cost categories, such as hospital admissions or community nursing visits. In one UK study by Posnett et al,²⁶ cost of wound care products and wound care budgets were tracked in specific health areas to ascertain how

wound care budgets were broken down. The cost breakdown from that study showed:

- **Wound dressings and materials:** These highly visible consumables typically account for just 17%–22% of total wound care costs;
- **Nursing hours:** Nurses perform the bulk of front-line wound care, and nursing hours typically make up as much as 33%–41% of the total costs;
- **Hospitalization:** Hospital admissions and extended hospital stays typically consume 37%–49% of the total cost of wound care.

Hospitalizations for wound care are often poorly coded or attributed to an underlying condition, which may be the cause of the chronic wound (eg, diabetes or venous disease).²⁷ Where wounds, such as pressure ulcers, occur in hospital settings, they can extend hospital stays, although the cost of this is typically attributed to the initial admission.^{18,28}

All such cost items are incurred within the healthcare system and can be considered as direct costs attributable to chronic wound care. There have been few attempts to take any account of the indirect costs of wound care that extend beyond the healthcare system. These costs include loss of workdays

and productivity, insurance costs, and subsidies from government programs. In the United States, for example, it has been estimated that venous ulcers cause the loss of 2 million working days per year.^{29–32} Literature searches have produced few studies and references documenting intangible costs, such as pain and suffering experienced by patients.⁴ Maddox³³ reviewed 11 articles published between 2001 and 2008, seven of which were qualitative studies, three quantitative, and one mixed methods on the quality of life and indirect costs for patients with chronic leg ulcers. Common themes extracted from this review included pain, functional limitations, social isolation, and psychological symptoms of depression. The tools used in the quantitative studies included the Nottingham Health Profile, the Hospital Anxiety and Depression Scale, the Medical Outcomes Study Social Support Survey Scale, and the COPE scale.

Table 1 provides a summary of direct and indirect costs associated with chronic wounds.

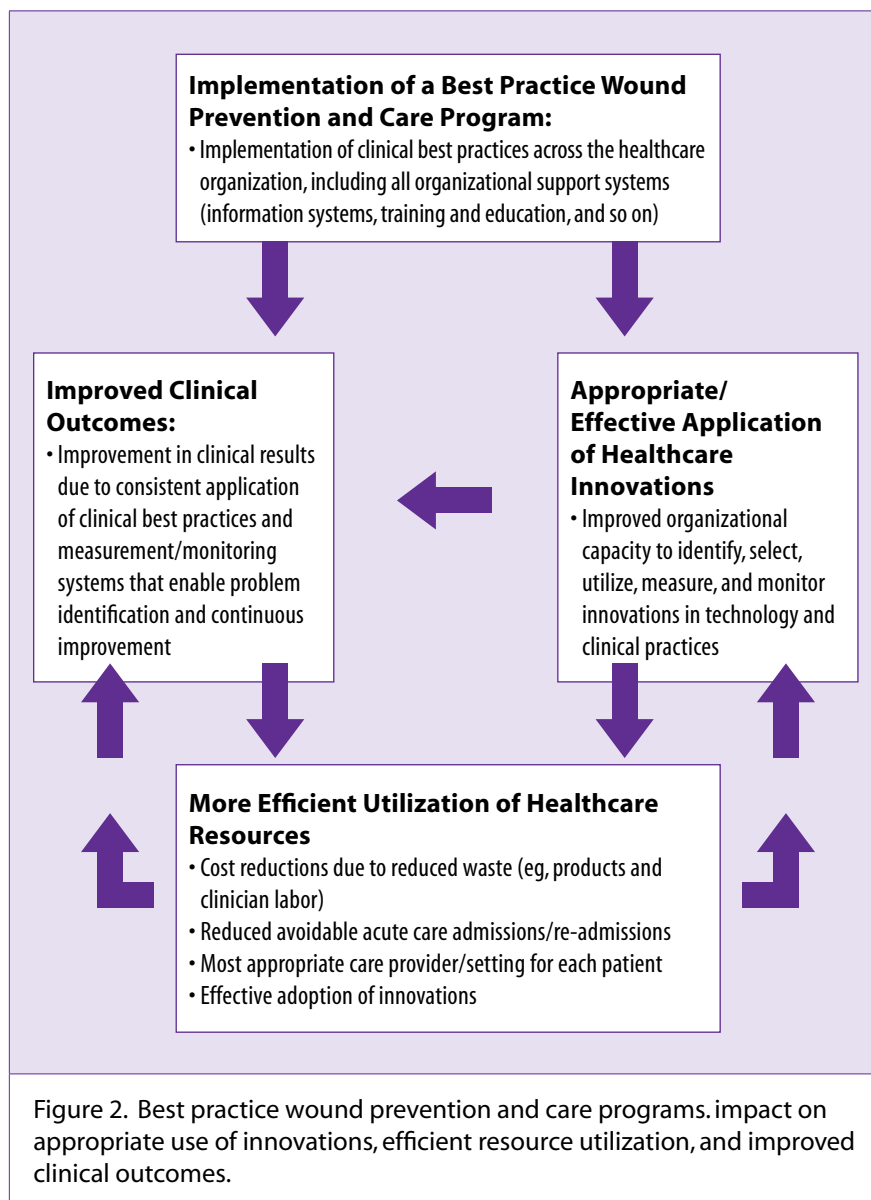
Evaluating Cost Effectiveness in Wound Care

The diverse and complex nature of the costs and benefits of wound care point to the need for some form of cost-effectiveness analysis (CEA) to measure and compare the relative costs and outcomes associated with various interventions as comprehensively as possible.³⁴ The overall objective was to establish recommendations on how to conduct a CEA. Recommendations were developed to form the basis and guide to cost-effective analysis. The basic elements of a CEA are summarized in **Figure 1**.

A CEA framework helps define how the best possible health outcomes can be achieved with limited resources. Chronic wound care is a clinical area where rigorous analyses of cost-effectiveness can be particularly beneficial, given the large and growing burden of chronic wounds and the complex and multifaceted nature of costs and care delivery. Further, a better understanding of cost-effectiveness is essential for clinicians, as well as policy makers and administrators. It is important for clinicians to recognize they play a key role in

TABLE 2. Components of Best Practice Wound Prevention and Care Programs

| | |
|--|--|
| Leadership | <p>Senior management is the driver for change and the face of the project; committed to support all aspects of the program from launch to sustainability</p> <p>Focus on patients and improved clinical outcomes</p> <p>Consistency and discipline: all policies, procedures, protocols, and processes enforced evenly with no exceptions. Fair and consistent treatment for all parties; ensure all parties share goal of improved patient outcomes and quality of life</p> |
| Defined roles, responsibilities | <p>Clear definition of all roles (eg, nurses, care providers, physicians, wound care specialists, other clinicians such as nutritionists and physiotherapists, clinical managers, administrators, senior managers, vendors and suppliers, outside experts, patients, families, and so on)</p> |
| Planning | <p>Detailed project plan with subsidiary plans for training and education, communications, conflict resolution, and so on; timelines, planning tools, and process maps included as appropriate</p> |
| Policies and procedures | <p>Clear policies and procedures, established across the healthcare organization to guide clinical practices based on evidence-based, best practice standards of care</p> |
| Measurement and Monitoring ⁶⁶ | <p>Comprehensive benchmark analysis of current wound prevalence and wound care practices to identify gaps and areas for improvement</p> <p>Key metrics and measurement/data collection systems in place prior to launch</p> <p>Regularly audit and report</p> |
| Best practice, evidence-based protocols/pathways ⁶⁷ | <p>Use available resources and guidelines (standard of care) where appropriate, adapted to suit local requirements, and produce new protocols as needed</p> <p>Provision of care and services based on evidence; avoiding overuse and underuse</p> <p>Practice changes (eg, compression of venous leg ulcers)</p> |
| Business processes and product formulary | <p>Detailed process maps based on clinical evidence and best practices</p> <p>Clear business processes to guide all accounting practices, data recording, record-keeping, and so on related to wound care, standardized throughout the organization</p> <p>Detailed product formulary, linked to clinical protocols, for all products/equipment</p> <p>Clear systems for ordering, storing, accessing wound care products/equipment</p> |
| Documentation | <p>Documentation tools to support process maps, inter-reliability of tools</p> <p>Protocols, pathways, and assessment tools to ensure consistent and clear documentation that drives practice</p> |
| Education and training | <p>Competency-based training/education program and resources for all clinicians, using adult learning principles and linked to clinical protocols</p> |
| Communications | <p>Detailed communication plan guiding regular communication to all groups involved</p> <p>All messaging to staff and service providers focused on best practices and the commitment to providing quality care to patients</p> <p>Successes celebrated and communicated to all involved groups</p> |
| Conflict resolution | <p>Anticipate potential conflict areas</p> <p>Emphasize common goal of improved quality of care</p> <p>Use process maps to guide interactions between groups</p> <p>Reduce inter-professional competition and rivalry</p> |



Best practice wound prevention and care programs incorporate comprehensive process innovations focused on achieving optimal clinical outcomes for chronic wound patients. These programs are designed to put in place evidence-based, clinical best practices across healthcare organizations on a sustainable basis. Best practice protocols for all aspects of care are defined and implemented, along with all of the necessary organizational supports (eg, information systems, training and education programs, product formularies, and the like). Clinical outcomes are measured, monitored, and documented to provide continuous feedback and identify opportunities for improvement. The pursuit of continuous quality improvement in wound care involves the full range of innovations, from new products such as advanced wound dressings to new data management and communications technologies, to re-designed business processes and methods of working. All costs associated with care are monitored and documented to enable an accurate assessment of the costs and benefits of each intervention. The basic components of best practice wound prevention and care programs are summarized in **Table 2.**³⁶⁻³⁸

Effective implementation of best practice protocols should lead to a cycle of continuous improvement. The basic relationships among program implementation, clinical outcomes, and resource utilization (health economics) are summarized in **Figure 2.** Key steps in the process are:

- Program implementation initiates a comprehensive change process designed to integrate best practice wound care protocols permanently into regular clinical practices;
- If implemented consistently and rigorously across the organization, clinical best practices lead to improved clinical outcomes for patients. Examples include faster healing times, reduced infection rates, improved comfort, increased mobility, and improved quality of life;
- The program provides an evidence-based framework for the identification, selection, and implementation of healthcare innovations. Innovations that are implemented appro-

the continuous improvement of patient care practices that lead ultimately to improved outcomes. This requires the constant testing, evaluation, and adoption of innovations at the clinical level. Clinicians are an integral part of the process of determining how limited resources can be used most effectively and ultimately enabling and supporting better patient care.

Innovation in Wound Care through Best Practice Wound Prevention and Care Programs

The Organization for Economic Cooperation and Development³⁵ (OECD) defines four types of innovation:

- Product Innovation: a good or service that is new or significantly improved.

This includes significant improvements in technical specifications, components and materials, software in the product, user friendliness, or other functional characteristics;

- Process Innovation: a new or significantly improved production or delivery method. This includes significant changes in techniques, equipment, and/or software;
- Marketing Innovation: a new marketing method involving significant changes in product design or packaging, product placement, product promotion, or pricing;
- Organizational Innovation: a new organizational method in business practices, workplace organization, or external relations.

appropriately and based on evidence, in turn, contribute to improved clinical outcomes;

- Improved clinical outcomes from successful innovations as well as improvements in the quality of basic care services lead to more efficient resource utilization and cost savings (eg, reduced hospital bed days, reduced labor costs through less frequent dressing changes, improved patient comfort and mobility, appropriate care for each patient, reduced waste and duplication);
- More efficient resource utilization enables continuous program improvement. Clinicians are able to spend more time directly on patient care and focus on patients with the most serious clinical needs. Information systems enable better coordination of multidisciplinary clinical teams. The organization improves its capacity to manage the most high-risk patients and the most complex wounds. This feeds back to support the primary goal of improved outcomes for patients.

Best practice wound prevention and care programs also serve as a framework within which product innovations can be integrated into a broader process of organizational change, rather than simply introduced as add-ons to existing systems. New technologies and innovations are adopted rigorously, consistently, and in a disciplined manner by all clinicians and administrative staff.

Purpose of Research

The purpose of this research is to examine how healthcare organizations can introduce innovative technologies and practices within a framework of managed adoption and evaluation with the intention of promoting high quality care and improved efficiency.

Process Innovation: Implementing a Best Practice Wound Prevention and Care Program in a Community Setting

Setting

The Community Care Access Centre (CCAC) is the coordinating agency for community services delivered throughout a large and diverse region in Ontario, Canada, serving a population



Figure 3. In this case, a 70-year-old male patient had a knee replacement, but after 9.5 months, his surgical incision failed to heal, likely due, in part, to his medication (prednisone), an immunosuppressant that inhibits healing (A, B). He was treated with negative pressure wound therapy using a PICO[®] portable unit and the wound was completely closed in just over 7 weeks (C, D).

of 1.6 million residents across 16,000 square km extending from the highly urbanized, eastern section of greater Toronto to the remote lakes and forests of central Ontario. It includes inner-city neighborhoods, suburbs, small towns, rural villages, cottage areas, and remote settlements and a wide range of socioeconomic groups, and cultural and linguistic communities. The CCAC helps clients locate and access a wide variety of healthcare services so they are able to receive care at home. These services are typically delivered by private nursing agencies and other specialized care providers.

The CCAC faces major service delivery challenges. These include the costs and logistical barriers associated with serving a diverse and growing

population spread throughout a large geographical area and the challenges of serving an aging population with an increasing prevalence of chronic disease. Roughly 20% of the Canadian population is already >60 years old, and this cohort will grow rapidly as the bulk of the baby boom generation turns 60.^{39,40}

The CCAC currently serves an average of 31,500 clients per day. This client roster is growing, and the typical client presents an increasingly complex medical profile, with more comorbidities and more serious conditions. This is exacerbated by the fact that acute care institutions, facing increased demands, are constantly forced to reduce the length of hospital stays, thereby returning patients back (who previously would have

TABLE 3. Client Profile at the Launch of the Pilot Test

| | Intervention Group | Control Group |
|--|--------------------|---------------|
| Patients | 628 | 600 |
| Mean patient age (years) | 70.5 | 68.9 |
| Total number of wounds (mean number of wounds per patient) | 869 (1.38) | 1140 (1.90) |
| Mean wound duration (weeks) | 60 | 43 |

been cared for in the acute care facility) into the community quicker and with greater care needs because of earlier discharges. The CCAC currently manages contracts with several private nursing agencies to provide in-home nursing services, which are compensated on an hourly or per visit basis. Opportunities existed to use nursing visits more effectively and possibly to reduce the number of nursing visits required to achieve the same or better patient outcomes, thereby reducing program costs.

These service delivery pressures are reflected in the financial status of the organization. The CCAC receives funding from the Ontario Ministry of Health. Total funding for the fiscal year ending March 31, 2010 was C\$212 million, compared to total expenditures of C\$216 million, a deficit of more than C\$4 million. At that time, the deficit for the 2010-2011 fiscal year was projected to grow to about C\$20 million, given the increased service demands noted above.

Methods

In this context, an internal team consisting of senior managers and a senior financial officer conducted a review of all high-expenditure areas. The challenge was to find ways to reduce spending with positive outcomes for clients rather than simply making cuts that would reduce the quality or scope of services provided. Given this imperative, the CCAC opted for a strategy focused on improving the quality of care, based on the assumption that the consistent delivery of clinical best practices, aimed at measurable improvements in client outcomes, will lead to resource utilization

efficiencies and, ultimately, to financial savings. Anecdotally, managers knew that there were gaps, duplications, and inefficiencies in service delivery, documentation, measurement, and monitoring. Purchasing practices for clinical supplies were decentralized, inconsistent and, in many cases, driven solely by clinician preferences. Best practice clinical protocols were not applied consistently across the organization. Gaps and inconsistencies were in many cases a legacy of fact that the CCAC was formed as an amalgamation of seven former community care organizations. The intent of the quality improvement program was to reduce waste and duplication, eliminate problem areas, and rationalize existing practices and protocols, with the goal of fewer clinical errors, fewer admissions to hospital, and faster healing/recovery times.

Early in the process of the expenditure review, wound care was identified as a clinical activity that was consuming an extraordinary level of both financial and human resources. Further analysis identified several key reasons for selecting wound care as the logical starting point for the implementation of a quality care strategy:

- Wound care represents a major activity of the CCAC. Approximately 13,000 (41%) of the 31,500 clients receiving services required some form of wound care (sourced from internal client electronic record system);
- No clear metrics and benchmarks were in place to measure the wound care outcomes against best practice standards of care;
- Wound care was viewed as an opportunity for the service teams,

service providers, senior managers, and front-line staff to work together on a high-priority project designed to improve quality of care and also to improve consistency of practices across the large and diverse organization;

- Wound care is linked to several other health issues, such as diabetes and peripheral vascular disease, that also represent top priorities for the CCAC. Managers and clinicians saw an opportunity to use best practice wound care protocols to help patients with comorbidities;
- High prevalence of avoidable wounds can be considered a symptom of quality problems.^{17,27,41,42} Many wounds, such as surgical site infections and advanced-stage pressure ulcers, indicate serious clinical errors. The prevention of these wounds was seen as a basic part of the broader patient safety agenda of the organization;
- The successful implementation of best practice wound care programs had been demonstrated in other jurisdictions. One example of this was a similar program that was implemented in another community area (similar geographically and in size) that demonstrated positive outcomes. Protocols or pathways had been developed based on the Registered Nurses of Ontario Guidelines (RNAO) for assessment and management of specific types of wounds by a group of Advanced Practice Nurses within a company (NPS Inc.) and in collaboration with CCAC. The development of the processes and pathways was completed within a 3-month time frame. Using lean methodology and a Kaizen approach, the complete wound care program was designed in a 4-day Kaizen event.^{41,43} These protocols/pathways and processes were available and could be tailored to suit local requirements. This would support the CCAC's need to move quickly toward implementation.

With wound care identified by senior leadership as a priority, we adopted a five-part strategy for implementation of a quality improvement program:

1. An analysis determined the preva-

TABLE 4. Comparison of Wound Care Practices (Intervention Group vs Control Group)

| | Intervention Group | | Control Group | |
|-----------------------------------|--------------------|------------|---------------|------------|
| | Pre-audit | Post-audit | Pre-audit | Post-audit |
| Mean wound duration (weeks) | 60 | 13 | 43 | 46 |
| Advanced dressing and pathway use | 41% | 88% | 47% | 46% |
| Daily dressing changes | 38% | 13% | 44% | 49% |
| Leg ulcers compressed | 50% | 89% | 24% | 26% |

lence of chronic wounds within the client population in order to establish benchmarks against which program activities can be measured and evaluated and to assess the current status of wound care practices. Metrics and methodologies were selected to maintain compatibility with best practice research standards and to enable comparisons with other healthcare organizations. This analysis was conducted in January 2009 and included a comprehensive survey of 3,326 clients;

2. A comprehensive best practice wound prevention and care program that had been used previously as mentioned above was designed based on findings from the analysis of wound prevalence and current wound care practices;
3. The best practice wound prevention and care program was pilot-tested on a limited scale. The program was fully implemented in one area (eg, the intervention group). No changes were made to wound care practices in the other area (eg, the control group). The objective of the pilot phase was to identify and measure any changes in wound care practices, client outcomes, quality of life, and costs resulting from implementation of the program. A summary of the number of patients and wounds at the outset of the pilot phase is provided in **Table 3**;
4. The best practice wound prevention and care program was implemented across the full service area of the CCAC beginning in March 2010;
5. A second analysis of wound care practices and clinical outcomes, based

TABLE 5. Comparison of Wound Care Costs (Intervention Group versus Control Group)

| | Intervention Group | Control Group |
|--------------------------------------|--------------------|---------------|
| Mean dressing changes per week | 2.78 | 5.82 |
| Nursing cost per change (C\$) | \$57 | \$57 |
| Mean materials cost per change (C\$) | \$39.59 | \$2.75 |
| Treatment cost: Nursing cost (C\$) | \$2060 | \$15260 |
| Materials cost (C\$) | \$1431 | \$736 |
| Total treatment cost (C\$) | \$3491 | \$15996 |

on a survey of 3,154 clients, was completed in April 2011 after approximately 1 year of program operation.

Results: Initial analysis of wound prevalence and wound care practices

This analysis, as noted, was conducted in January 2009, and included a comprehensive survey of 3,326 clients. Findings related to wound prevalence included:

- 1,388 of the clients surveyed (42%) had at least one wound. Surgical wounds affected 34% of clients surveyed; 17% had pressure ulcers; 14% had diabetic foot ulcers; and 12% had leg ulcers;
- The average duration of pressure ulcers was 50 weeks, with a range of 1 to 530 weeks;
- 55% of pressure ulcers were acquired at home; 24% were acquired in hospital; and 9% were acquired in long-term care residences;
- 54% of pressure ulcers were Stage III or greater;
- The average duration of diabetic

foot ulcers was 53 weeks, with a range of 2 to 178 weeks;

- 61% of wounds demonstrated signs of localized infection.

The analysis also revealed several key findings related to wound care practices, including:

- Only 60% of venous leg ulcers were treated with compression therapy, which is considered the gold standard of care for this category of chronic wound;
- 48% of venous leg ulcers were assessed as per best practice guidelines and recommendations for venous leg ulcers using an ankle brachial index (ABI);
- Dry gauze comprised 49% of the dressings used for wound care, despite being widely regarded as an outdated modality for the management of chronic wounds, with the potential to result in adverse outcomes, such as delayed healing and an increased risk of infection;^{44,45}



Figure 4. A 59-year-old patient was admitted with a wound on her right tibia as a result of trauma. Her comorbidities and medication regimen had a known side effect of inhibiting wound healing (A). Clinicians performed sharp debridement of the wound and application of negative pressure wound therapy using the PICO^o device. The unit allowed the patient to remain mobile while facilitating wound healing. The wound was completely closed in 7 weeks (B, C).

TABLE 6. Comparison of costs of conventional negative pressure wound therapy (NPWT) with portable NPWT

| Type of Therapy | Rental Cost of Unit (C\$) | Additional Dressings Cost (Fillers, Drapes, etc.) (C\$) | Purchase Cost (1 Suction Unit, Dressing x2) (C\$) | Total Cost Per Week, Per Patient (C\$) |
|-------------------|---------------------------|---|---|--|
| Conventional NPWT | \$488 - \$623 | \$86 - \$110 | | \$746 - \$956 ^a |
| Portable NPWT | N/A | N/A | \$198.00 | \$198 ^b |

^aConventional NPWT requires average dressing change frequency of three times per week. Cost is dependent on the brand of NPWT device used.

^bPortable, single-use NPWT requires average dressing change frequency of one to two times per week.

- 40% of all wounds required a daily dressing change;
- Wounds were assessed by the advanced practice nursing group to determine the clinical appropriateness of the use of advanced cover dressings versus nonadvanced or gauze use as a cover dressing. This was based on the frequency of dressing change (related to drainage or wound requiring a more absorbent dressing such as a foam versus gauze) or the clinical requirement of advanced dressings (eg, high-risk client that required a dressing designed to resist bacterial infection). The results demonstrated that 51% of the wounds had an inappropriate dressing;
- Sustained-release antimicrobials were utilized on <30% of wounds.

A key theme emerging from the review of existing wound care practices was inconsistency in the practices and protocols used by clinicians and care provider agencies. The review as listed above confirmed managers' expectations that no consistent wound care protocols were in place, and that there were noteworthy gaps in the delivery of best practice wound care. Wound care practices were dependent upon the judgment of clinicians without the benefit of clinical evidence. Due to the fact that no consistent product formulary was in place, the selection and use of wound dressings was inconsistent and based on clinician preference rather than clinical evidence. Access to technology such as negative pressure wound treatment (NPWT) was also inconsistent. Measurement systems that would enable consistent monitoring of wound patients and outcomes were not in place. As a result, there were no clear standards or predictability for outcomes such as healing times. The current system did not have the capacity to provide any reports (if clients had a wound or type of wound) or ability to extrapolate actual wound practices from the database. Therefore, this current system made it impossible to perform any consistent monitoring on the population of clients with wounds of any type. The only way to gather information was to perform a complete au-

dit on the selected population of clients with wounds.

Wound Management Program

A comprehensive best practice wound management program was developed based on findings from the analysis of wound prevalence and wound care practices. Key features of the program included:

- Leadership: Senior management (CEO, CFO, Senior Management of Contracts, and Senior Director of Client Services) was identified as the driver for change, with the responsibility to ensure consistent application of the program across the organization. Implementation was viewed as a process of organizational change designed to produce long-term sustainable outcomes;
- Planning: Input from all stakeholders (Senior Management, middle management, front-line staff, front-line nurses, contracted care providers, including representation from wound specialist to multidisciplinary team members) from across the organization was used to produce a comprehensive plan with clearly defined roles, responsibilities, and timelines;
- Measurement and documentation: Systems were put in place for measurement, monitoring, and documentation of all key indicators for clinical outcomes, practice standards, and costs;
- Best practice clinical protocols: Available protocols from established wound care organizations (through NPS Inc.) were reviewed and adapted as necessary to suit local circumstances;
- Policies and procedures: A framework of policies, product formularies, process maps, and business procedures was established to guide and support the program;
- Education and training: A train-the-trainer, competency-based training curriculum (education with a focus on specific training competencies, such as complete leg assessment including ABI) was provided by NPS Inc. to clinical staff, service managers and case managers, to support capacity building and sustainability;

- Communications: Regular communications, focused on the primary program goal of improved patient outcomes, was delivered to all stakeholders. Program successes were celebrated.

Pilot Testing

Table 3 provides a summary of the client profile at the launch of the pilot test. **Table 4** provides a summary of key findings relating to wound care practices from the pilot test. The number of clients requiring daily dressing changes decreased from 38% in the control group to 13% in the intervention group. The corollary to this is that utilization of advanced dressings in the intervention group increased from 41% to 88%. Leg ulcer compression increased from 50% to 89%. The control group shows no significant shift in wound care practices.

A comparison of wound care costs for the intervention group and the control group (**Table 5**) shows an increase in the cost of materials per dressing change, reflecting the relatively high cost of advanced wound dressings versus dry gauze. However, there is a coincident reduction in the number of dressing changes, resulting in lower labor costs. Because labor is a much larger cost item, the net result is major reduction in total wound care costs.

Program Implementation

The advanced wound management program across the full service area of the CCAC was launched in March 2010. This included a train-the-trainer approach for the education with detailed curriculum provided to trainers. This allowed for rigor and consistency in both competency and messaging. New tools, protocols/pathways, communication, and processes were introduced within the education rollout across the organization. As noted, a second analysis of wound care practices and clinical outcomes, based on a survey of 3,154 clients, was completed in April 2011 after approximately 1 year of program operation. Key findings from the second analysis included:

- The percentage of clients who required a nursing visit due primarily to wound care remained constant at about 44%;

- Use of advanced dressings increased from 51% to 73%;
- The percentage of leg ulcers that utilized compression increased from 60% to 90%;
- The percentage of clients receiving daily (or more frequent) dressing changes was reduced from 39% to 19%;
- Wounds healed quicker. The average age of wound was reduced from 39 weeks in 2009 to 29 weeks in 2011;
- The more rapid and effective healing of wounds enabled many clients to reduce the length of time they required CCAC services. The average length of service for clients surveyed was reduced from 50 weeks in 2009 to 39 weeks in 2011. A program evaluation analysis was performed, which had specific metrics established before program implementation. As demonstrated above, all of these metrics were met.

The total financial savings to the CCAC resulting from the wound prevention and care program for the 2010-2011 fiscal year was estimated at C\$11.8 million, or roughly 5.5% of the annual budget of C\$212 million. This was attributed mainly to the reduction in nursing visits required for dressing changes, the reduced need for more complex and extensive care interventions due to fewer serious wound cases, and the efficiencies gained through consistent application of protocols, and business practices throughout the organization.

Product Innovation: Introducing Portable Negative Pressure Wound Treatment (NPWT) into the Community Care Setting

Since its introduction in 1952,⁴⁶ NPWT has become an integral and widely used component in the treatment of many types of challenging wounds. NPWT technology has improved and changed through the decades, allowing it to become a fundamental part of wound care treatment. This technology has been shown to accelerate the closure of particularly complex and problematic wounds and result in improved healing times and clinical outcomes.^{47,48}

The use of NPWT by clinicians to heal wounds (particularly complex wounds or recalcitrant wounds) has increased over the past decade.^{49,50} Ad-

vancements in the selection of NPWT products have included an upsurge of options and opportunities for clinicians. The most recent technological development is the availability of a portable, single-use, disposable NPWT system (PICO[®], Smith & Nephew). The pocket-sized system comprises a pump and two high-performance NPWT dressings that are capable of handling up to 300 mL of exudate in 1 week, replacing the need for a canister, as used with traditional NPWT devices. The new device is indicated for acute and chronic wounds, high-risk surgical incisions, and skin grafts. Each dressing can be worn for up to 7 days and the pump delivers nominal 80 mm Hg of negative pressure. This new modality for delivering NPWT allows the clinician to deliver NPWT that is less disruptive to the patient as well as cost-effective, thereby making NPWT therapy accessible to a larger group of patients.

Although portable NPWT offered significant promise, it was important to consider how this technology could be integrated into best practice clinical protocols and pathways. This would involve the identification of cases where the utilization of the technology is clinically appropriate and systems to measure and monitor outcomes were established. The introduction of this new technology required an evaluation that investigated the clinical and economic effectiveness as well as the benefits for the patients, nurses, and organizations. The framework established by the best practice wound prevention and care program allowed the portable NPWT system to be introduced into practice in a managed policy approach with NPWT standardized documentation (pathways and criteria), practices, stakeholder feedback/involvement, and clear processes ensuring the use of the technology was subject to evaluation before widespread adoption.

A team of eight advanced practice nurses (APNs) led the evaluation across Southern Ontario, Canada in two community settings and two acute care settings. Patients enrolled in the evaluation were eligible for NPWT as per policy and protocols in each health-care center. The centers have policies contiguous to the utilization of the

technology. Best practice or clinical interventions concerning the etiology of the wound would first be implemented before patients become eligible for NPWT. For example, policies concerning glucose control for patients with diabetes, offloading for patients with pressure ulcers, and proper nutrition are examples of components of the total care plan/bundle for the patient.

Methods

The evaluation included the observation of patients with a chronic wound treated with portable NPWT over an 8-month period. All patients eligible for conventional NPWT were considered for treatment. Patients were excluded if their wounds were unsuitable for treatment with portable NPWT (eg, copious amounts of drainage, wounds > 2 cm in depth and with a surface area in excess of the portable NPWT dressing area). In addition to this, patients treated with heparin or Fragmin (dalteparin) were excluded, as were any wounds classified as receiving maintenance therapy (nonhealing). Patients' wounds were measured at baseline and then weekly thereafter. Results were recorded by the nurses' evaluation data on weeks 3, 6, and 8, and then on a weekly basis. Nurses completed the evaluation forms and patients completed post-evaluation forms, describing their experience with the NPWT unit, daily function, pain, conformability, and ease of application. NPWT pathways were implemented in the CCAC based on NPS Inc. NPWT pathway that had been used in other CCACs with success. These tools guide NPWT interventions based on current NPWT guidelines.⁵¹⁻⁵⁹ The pathways have an assessment component that the nurses complete and send into the CCAC as part of the continued measurement. These include the type of the wound, size of the wound, type of wound filler, additional dressings used, percentage of healing, volume of wound, appearance of the wound bed in percentages (eg, 20% slough, 80% granulation), presence and measurement of tunnels and/or undermining, condition of periwound area, pressures of NPWT, length of time on the unit, and any deviation

of pathway or change in client condition. The data were extrapolated from the NPWT pathway assessment sheets.

A total of 325 patients were treated with NPWT over the evaluation period. The mean age of the population of patients in the study was 57 years. The patients presented with wounds of mixed etiology, including pressure ulcers (16%), leg ulcers (6%), diabetic foot ulcers (5%), trauma wounds (6%), and chronic and open surgical wounds (48%) that were treated in the community.

Results

Patient outcomes

The results of the evaluation were positive. The quality of care, as measured by patient satisfaction, was very high, with 98% of patients reporting they were pleased or satisfied with the NPWT product. Anecdotal data from patients described improvements ranging from increased social activities and improved self-esteem to a marked improvement in general overall wellness. Similarly, 99% of nurses were pleased or satisfied with the product, and only 2% of nurses reported any difficulty with the application of the product. Over the course of the evaluation, 68% of wounds treated with the portable negative pressure device were completely closed with a median time to healing of 9 weeks. This rate needs to be considered in the context of the wounds treated, many of which remained unhealed for a significant time before commencing treatment with portable NPWT (average wound duration before treatment was 9 weeks with a range from 1 to 68 weeks).

In many instances, portable NPWT opened up new treatment options for patients. In some cases, portable NPWT was used as a direct replacement for traditional NPWT, offering the patient optimum therapy but in a more convenient, suitable, appropriate, and patient-centered device, considering all the patients' needs, comfort, choices, and modality.⁶⁰ In other cases, the portable nature of the device made NPWT accessible for patients who otherwise would not have tolerated the traditional NPWT devices, due to their size, weight, or lack of discretion. The two case studies below illustrate how this novel technology con-

tributed to the management of patients with hard-to-heal wounds.

Economic outcomes

Critically, the beneficial effects on patient outcomes reported were achieved while simultaneously improving health-care efficiency. A comparison of the cost of the single-use negative pressure system and traditional negative pressure systems is presented in **Table 6**. The comparison shows that single-use NPWT can substantially reduce the cost per patient, as a result of fewer dressing changes and nurse visits per week. This offers the health service provider the opportunity to: 1) decrease total expenditure on NPWT while treating the same number of patients and 2) maintain expenditure levels and increase the number of patients accessing the therapy.

Case Studies

Case study 1. A 70-year-old male patient had a knee replaced. He was taking prednisone at the time, but otherwise presented no other comorbidities. Unfortunately, his surgical incision failed to heal after 9.5 months, despite numerous conventional wound treatments. The barriers to more rapid healing in this case most likely included the prednisone, which is an immunosuppressant drug that inhibits healing processes,⁶¹ as well as frequent movement at the knee related to the patient's desire to pursue physiotherapy and restore functionality. NPWT using a PICO[®] portable negative pressure unit was selected as a treatment option in order to create an appropriate healing environment while simultaneously allowing the patient to pursue his physiotherapy regimen. The wound was completely closed in just over 7 weeks following initial application of the portable NPWT. A follow-up examination 3 months later showed the incision remained closed. This case highlights the capacity of portable NPWT to preserve patient mobility; physiotherapy may not have been possible or optimal in this case using conventional NPWT. It also illustrates the potential savings attributable to this technology. Early application of portable NPWT in this case and other high-risk surgical cases can prevent long, avoidable delays

in healing time that are costly to both patients and providers.

Case Study 2. A 59-year-old female patient had an inflammatory disease and took methotrexate to help manage her symptoms. She was admitted to the hospital shortly after acquiring a wound on her right tibia as a result of trauma. She was assessed shortly after admission as a high-risk wound patient and a poor candidate for conventional wound treatments because of her comorbidities and medication regimen, which has the known side effect of inhibiting wound healing.^{62,63} Systemic corticoid steroid use in patients will show immunosuppressant properties by inhibiting cytokine release and chemotaxis as well as fibroblast dysfunction, which decreases wound healing tensile strength. Clinically, this will result in wound dehiscence, wound infection, and overall delay in wound healing.^{64,65}

Clinicians performed a sharp debridement of the wound and then initiated application of NPWT using the PICO[®] portable NPWT technology. The portable unit enabled the patient to maintain her mobility and quality of life, while facilitating wound healing in clinically challenging circumstances. The wound was completely closed in 7 weeks. This case demonstrates how portable NPWT can be applied for high-risk wound patients. A decision-tree, based on clinical best practices, was in place to allow clinicians to identify the patient as a high-risk patient and candidate for portable NPWT during her initial wound assessment. She could then be placed on a pathway toward optimal healing with minimal risks and the ability to return to her home and resume her daily routines. The new technology was used in a focused, appropriate manner for a patient meeting specific best practice criteria.

This innovative study shows how service improvements can be achieved through the managed adoption of new technologies within well-defined protocols. Critically, the technological part of the innovation, portable NPWT, was integrated into the broader drive for improved quality of care and organizational efficiency, rather than simply introduced as an

add-on to existing services. The result is improved patient and clinical outcomes simultaneous to improvements in healthcare efficiency.

Conclusions

This paper reviews two types of healthcare innovations in the field of chronic wound care:

- **Process Innovation:** the implementation of a comprehensive best-practice wound prevention and care program, including a range of process improvements from clinical pathways and protocols to measurement and monitoring systems; and
- **Product Innovation:** the adoption of a disposable NPWT system within the context of best practice wound care and prevention programs that include tools to assess, evaluate, and monitor utilization of the new technology.

Both innovations are currently being implemented within complex and demanding clinical settings.

Results to date from the best practice wound prevention and care program indicate that process innovation can improve the quality and consistency of patient care, while concurrently reducing care delivery costs incurred by the healthcare organization. The program is serving as a starting point for broader quality improvement and cost-efficiency efforts and offers valuable lessons and potential models that can be applied in other clinical and service areas.

Results from the use of the portable NPWT demonstrate how a product innovation also can lead to improved clinical outcomes and reduced costs. In this case, the ability to implement the new technology within the framework of a comprehensive program that provides evaluation, assessment, and monitoring tools is an important factor in driving both clinical and economic outcomes.

This research also illustrates the importance of capturing the costs and benefits associated with any healthcare innovation as comprehensively as possible. Innovations such as portable NPWT may appear expensive initially and require significant initial investments. However, the potential benefits

can be much greater than the acquisition cost, particularly when factors such as patient comfort, mobility, and quality of life are taken into account.

Finally, the research offers insight into the important relationships between the quality of patient care and the efficiency of healthcare resource utilization. The clinical and economic dimensions of healthcare are integrally related and, in effect, represent two aspects of the same challenge to provide the best possible care for patients. Investments in wound care innovations, when carefully directed within a framework of evidence-based metrics aimed at optimal clinical outcomes, are being used to achieve better patient care and improved cost-efficiency. ■

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