Supplement to *WOUNDS*® December 2021

WOUNDS®
A Compendium of Clinical Research and Practice

Inclusion of Single-Use Negative Pressure Wound Therapy for the Prevention of Closed-Incision, Surgical Site Complications in Multispecialty, Perioperative Care Bundles: Insights From an International Panel

Ronald W Singer, MD; Ann Fowler, CNS; Jeanette Harris, MS, MSM, MT(ASCP), CIC, FAPIC; Darly Mathew, FRCOG; Jaume Masia, MD, PhD; Ikran Nizam, MB, CHB, MRCS, MS, FRACS, FAORTHA; V Seenu Reddy, MD, MBA, FACS, FACC; and Adam Sassoon, MD, MS

This supplement was subject to the *WOUNDS*® peer-review process.
Supported by Smith+Nephew.

HMP Global

Ronald W Singer, MD[1]; Ann Fowler, CNS[2]; Jeanette Harris, MS, MSM, MT(ASCP), CIC, FAPIC[3]; Darly Mathew, FRCOG[4]; Jaume Masia, MD, PhD[5]; Ikran Nizam, MB, CHB, MRCS, MS, FRACS, FAORTHA[6]; V Seenu Reddy, MD, MBA, FACS, FACC[7]; and Adam Sassoon, MD, MS[8]

[1]OrthoCarolina, Charlotte, NC; [2]Clinical Nurse Specialist, Coffs Harbour Hospital, Coffs Harbour, New South Wales, Australia; [3]Evergreen Health at Evergreen Healthcare, Enumclaw, WA; [4]Consultant Obstetrician and Gynecologist, Chesterfield Royal Hospital, Chesterfield, Derbyshire, UK; [5]Professor and Chief, Plastic Surgery Department, Hospital de la Santa Creu i Sant Pau/Hospital del Mar, Barcelona, Spain; [6]Ozorthopaedics, Malvern VIC, Australia; [7]Director of Cardiac Surgery, Tristar Centennial Medical Center, Nashville, TN; [8]Department of Orthopedics Surgery, UCLA Health, Los Angeles, CA

Address correspondence to:
Ronald W Singer, MD
OrthoCarolina
Charlotte, NC
rsinger@mac.com

Disclosure: All panelists received honoraria for their participation in the panel. Dr Singer has received speaker honoraria and served as a consultant/paid advisory board member for Smith+Nephew. Dr Reddy and Ms Fowler served as consultant/paid advisory board members for Smith+Nephew.

Acknowledgments: The authors thank Laurie Bayer, PA-C, and Barbara Zeiger for their contributions to the manuscript preparation and writing process.

This supplement was subject to the *WOUNDS*® peer-review process.
Supported by Smith+Nephew.

Inclusion of Single-Use Negative Pressure Wound Therapy for the Prevention of Closed-Incision, Surgical Site Complications in Multispecialty, Perioperative Care Bundles: Insights From an International Panel

Ronald W Singer, MD[1]; Ann Fowler, CNS[2]; Jeanette Harris, MS, MSM, MT(ASCP), CIC, FAPIC[3]; Darly Mathew, FRCOG[4]; Jaume Masia, MD, PhD[5]; Ikran Nizam, MB, CHB, MRCS, MS, FRACS, FAORTHA[6]; V Seenu Reddy, MD, MBA, FACS, FACC[7]; and Adam Sassoon, MD, MS[8]

ABSTRACT: *Introduction.* Negative pressure wound therapy (NPWT) is a preemptive option to avoid surgical site complications (SSC) such as dehiscence, hematoma, and infection. *Methods.* An international, multispecialty advisory panel participated in individual virtual interviews during January and February 2021 to assess single-use NPWT (sNPWT) as part of a care bundle that potentially could maximize clinical and financial efficacy. Participants completed surveys regarding perioperative surgical planning and management, institutional support mechanisms, and stakeholder roles to guide the interviews and determine commonalities and differences among surgical specialties concerning sNPWT use. Participants supplemented opinion with clinical and economic studies supporting sNPWT use in surgical risk factors and healing. Survey results, anecdotal reports, and relevant literature were organized into a document intended to support the proliferation of sNPWT as part of a closed-incision surgical care bundle. The panel used a modified consensus approach to approve document content. *Results.* The panel comprised 3 orthopedic surgeons, a director of cardiac surgery, a consultant obstetrician and gynecologist, a plastic surgery department chief, a clinical nurse specialist, and an infection control specialist. Anecdotal and published reports showed sNPWT could diminish incision-related postsurgical complications in persons at risk. In turn, this could allow for expedient hospital discharge and lessen the clinical and financial ramifications of longer acute care stays. *Conclusions.* The panel found that sNPWT could mitigate risk factors for complications known to respond to NPWT and supported the prophylactic use of sNPWT for all patients at high risk for SSC, as well as for patients at potential risk who might benefit from its use. Influencing care teams and administrative stakeholders to incorporate sNPWT into care bundles is a worthwhile challenge.

KEY WORDS: surgical site complications, risk factors, incisional, single-use negative pressure wound therapy, care bundle

INDEX: *Wounds* 2021;33(Suppl 12):S11–S23.

Safe, expedient progression to next-stage care following surgery has become increasingly important in the current health care environment, where the number of procedures in both inpatient and freestanding ambulatory surgery centers is growing.[1] As noted in the enhanced recovery after surgery (ERAS) data,[2] implementing a comprehensive perioperative care plan that utilizes a multidisciplinary team can help patients restore physiologic function, decrease stress, accelerate recovery time, potentially decrease opioid medication use, and shorten hospital stays. The perioperative stress response has been shown to be a factor in the systemic inflammatory response that can impair immune function, making patients vulnerable to wound healing difficulty and potentially extending the need for care.[3,4]

The longer the patient's hospital stay, the higher the risk of complications, particularly hospital-acquired infections. These infections affect 3.2% of all hospital admissions in the United States[5] and upwards of 7.9% internationally[6] and can

Table 1. Factors for the Development of Surgical Site Complications.[10]

Patient	Procedure-Related	Facility	Preoperative	Intraoperative
Glycemic control	Complex surgery	Room ventilation	Pre-existing infection	Duration of surgery
Nicotine use, alcoholism	Wound classification	Operating room traffic	Inadequate skin preparation	Blood transfusion
Nutritional status (albumin <3.5)	Emergency	Equipment sterilization	Hair removal	Maintenance of asepsis
Obesity			Antibiotic choice, administration, duration	Poor-quality surgical hand scrubbing and gloving
Immunosuppression				Hypothermia (temperature <36°C)
Advanced age				Poor glycemic control
Recent radiotherapy				
History of skin or soft tissue infection				

occur despite optimizing perioperative policies and procedures.

Surgical complications

Surgical site complications (SSC) include wound dehiscence, wound infection, and hematoma; other SSC include any deviations from the normal postoperative course that require pharmacological interventions (eg, antibiotics), wound exploration, and blood transfusion as well as more serious interventions like reoperation and implant removal that affect patient experience and morbidity.[7] The incidence of wound dehiscence ranges from 1.3% to 9.3%[8]; it is known to increase morbidity and mortality rates and extend hospital length of stay. Data[9] suggest that at least 50% of all SSC can be avoided; implementing practices designed to reduce surgical site infection (SSI) and anesthetic complications have been shown to reduce overall complications. Surgical closure technique and mechanical stress are known to contribute to wound dehiscence. Incisions closed with tension on the skin or subcutaneous tissue, large flaps and flap donor sites, surgical sites in patients who are obese, and the development of seromas or hematomas increase risk of wound dehiscence and SSC.[8]

Surgical site complications are reported far less frequently than SSI, perhaps because hospitals often mandate specific SSI documentation. As such, the true impact of SSC is unknown but likely substantial.[7] The American College of Surgeons[10] (ACS) patient-, procedure-, and facility-related risk factors for developing SSC are detailed in **Table 1**.

Surgical site infections

Surgical site infection, defined as postoperative infection occurring within 30 to 90 days of a surgical procedure, is the most common hospital-acquired infection.[10-12] The Centers for Disease Control and Prevention[11] (CDC) has established SSI distinctions that apply to all operative procedures. *Superficial incisional SSI* occurs within 30 days, involves only skin and subcutaneous tissue of the incision, and exhibits one or more of the following: purulent drainage, organisms identified via a microbiologic testing method (the incision is deliberately opened for culture), signs or symptoms of infection, and a clinician's diagnosis. *Deep incisional SSI* occurs within 30 to 90 days and involves deep soft tissue of the incision. The patient exhibits one or more of the following: purulent drainage from the deep incision and/or deep incision that spontaneously dehisces or is opened by a surgeon or designee. In addition, an infectious organism is identified via microbiologic testing, the patient has a temperature greater than 38°C and/or localized pain or tenderness and/or an abscess, and other evidence of infection is detected. *Organ/space SSI* also can occur within 30 or 90 days; this type of infection involves any part of the body deeper than the fascial/muscle layers that are opened or manipulated during the operative procedure. The patient exhibits one or more of the following: purulent drainage from a drain placed into the organ/space, organisms identified from aseptically obtained microbiologic testing, and abscess or other evidence of infection involving the organ/space detected by exam or imaging.

In the United States, SSI has been estimated to result in more than 1 million additional inpatient days and $1.6 billion in annual health care expenditures.[13] In a comprehensive review of data from 6 European countries, Badia et al[12] noted an SSI incidence as high as 36%, with prolonged hospitalization resulting in increased primary health care costs, antibiotic costs, and other hospital costs. Hospital costs included extensive use of resources (eg, catheters, laboratory tests including cultures), nursing time, and treatment of postdischarge SSIs.[14]

In addition to the financial impact of SSI, Badia et al[12] pointed to other concerns, such as the patient's inability to work and the negative effects on physical and mental health. Other authors have noted quality-of-life implications of SSI, such as pain, insecurity, the side effects of antibiotics, and anxiety during readmissions, as well as loss of mobility and delayed referral to physical therapy (eg, after hip arthroplasty).[15,16]

The World Health Organization[17] (WHO) 2016 guidelines for preoperative measures for SSI prevention include perioperative discontinuation of immunosuppressive agents, enhanced nutritional support, preoperative bathing using an antiseptic soap, nasal decolonization with mupirocin ointment, mechanical bowel prep with or without oral antibiotics (colorectal surgery), hair removal, optimal timing of perioperative antibiotics, surgical hand preparation, surgical site preparation, and antimicrobial skin sealants. Incorporating a surgical safety checklist[18] as part of the care regimen also reduces the rates of death and major complications after surgery.

Negative pressure wound therapy

Argenta and Morykwas[19,20] first described the use of negative pressure wound therapy (NPWT) as a method for expediting wound healing in 1997; this therapy revolutionized wound care, specifically the treatment of surgical wounds. Less than 10 years later, the use of NPWT on closed surgical incisions became an option to help reduce SSC. Surgeons began using various NPWT devices prophylactically to decrease fluid accumulation within the surgical space and risk of infection and lower the incidence of wound dehiscence.[21] In 2006, in an effort to reduce perioperative wound complications, Gomoll et al[22] recommended using NPWT over closed incisions in foot and ankle trauma. While other practitioners were already using this therapy, this publication was the first to outline and document the use of NPWT for closed-incisional management. This led to a significant number of publications and recommendations for the use of incisional NPWT, especially in the orthopedic literature.[23] Muenchow et al[24] noted that applying incisional NPWT on intact skin increased capillary-venous oxygen saturation and improved hemoglobin levels and local blood flow and blood velocity in the microvessels. In addition, a randomized, controlled trial[25] (RCT) showed incisional NPWT reduced lateral tension along the incision edges, improved lymphatic drainage, and prevented wound contamination. In 2017, a consensus recommendation[26] for using closed-incisional NPWT was published. Additionally, in a prospective, randomized controlled study, Madsen et al[27] examined closed-incision NPWT in select populations. Still, to date, there is no consensus on its use as part of a care protocol.

The development of single-use NPWT (sNPWT) systems enhanced portability, and research shows that outcomes achieved and costs expended when using sNPWT are similar to traditional NPWT.[28]

In summary, the previously noted research and additional case studies, RCTs, and systematic reviews/meta-analyses[29-38] have demonstrated that sNPWT applied prophylactically has efficacy in reducing SSC across various surgery types, including orthopedic, breast, plastic, gynecological, obstetrical, vascular, cardiac, and colorectal. Additionally, protocol-driven use of sNPWT has been shown to provide cost savings by reducing the incidence of postoperative infections, readmissions, additional postoperative clinic visits, and dressing changes.[39,40] A pilot, pre/post-intervention study[41] of women undergoing cesarean sections in Australia has shown that adherence with a focused perioperative protocol, which includes sNPWT SSC prophylaxis, can further reduce SSI especially in patients who are obese.

Because SSC represents a significant health care burden, preventive wound care strategies with dedicated protocols (care bundles) are developed to maximize clinical effectiveness, decrease surgical morbidity, and deliver cost savings to health care systems. Care bundles are constructed using evidence-based practices that include prevention of surgical complications; among the strategies is closed surgical incisional management using NPWT.[42,43]

To date, no consensus has been reached regarding whether sNPWT should be part of a surgical care bundle and, if so, how best to employ this approach as part of closed-incisional NPWT. Although the cited research may infer that closed-incision NPWT can offer substantial clinical and economic benefits for selected populations, its impact on SSC and SSI occurrence remains an area of debate and study. To address this concern, a panel was assembled to investigate ways to incorporate prophylactic use of sNPWT into perioperative incision management protocols and to create a guidance document that utilizes existing clinical evidence, clinical experience, and a proposal for establishing change.

Methods

Participants

An international, multispecialty advisory board was convened virtually over 30 days in January and February 2021. Field teams worldwide working for the device manufacturer invited participants based on their specialties and/or familiarity (current and previous use) with the device. Panelists participated in 6 individual meetings of approximately 90 minutes in small groups and individually.

Study device

The sNPWT reviewed in this study was PICO sNPWT (Smith+Nephew), a canister-free sNPWT system consisting of a sterile pump and multilayered adhesive dressings. Each dressing has 4 layers: a silicone adhesive wound contact layer, which is designed to minimize pain and damage during peel-back and to reduce lateral tension; an airlock layer for even distribution of pressure; an absorbent layer to remove exudate and bacteria from the wound; and a top film layer, which acts as a physical barrier and allows moisture to evaporate. The pump is operated by 2 AA batteries and delivers a continuous negative pressure of −80 mm Hg to a sealed wound. Once activated using a push button, the battery drives the pump for up to 7 days, and LEDs provide alerts for low-battery status and pressure leaks. Standard dressings for this device come in 8 sizes: 10 cm × 20 cm, 10 cm × 30 cm, 10 cm × 40 cm, 15 cm × 15 cm, 15 cm × 20 cm, 15 cm × 30 cm, 20 cm × 20 cm, and 25 cm × 25 cm. Dressings for multisite use are available in 2 sizes: small (15 cm × 20 cm) and large (20 cm × 25 cm).

This particular sNPWT device differs from conventional negative pressure wound dressings. It has no separate canister, is portable and disposable, and has a dressing layer with proprietary technology designed to allow even distribution of negative pressure across the incision and zone of injury.[44,45] The device has been shown to help reduce SSCs by helping decrease lateral tensile forces[46] and edema[47-49] while increasing perfusion[50,51] and lymphatic drainage[52] across a closed surgical incision.

A systematic review and meta-analysis[53] of recently published research involving this device included 29 studies on the outcomes of 5614 patients across different countries and surgical specialties (orthopedic, gynecologic/obstetric, cardiothoracic, colorectal, and vascular). Results demonstrated that utilization of this sNPWT device on closed surgical incisions resulted in significant reduction of SSIs by 63% (OR, 0.37; 95% CI, 0.28–0.50; *P* <.001, numbers needed to treat [NNT], 20); the odds of seroma by 77% (OR, 0.23; 95% CI, 0.11–0.45; *P* <.001; NNT, 13); and the odds of dehiscence by 30% (OR, 0.7; 95% CI, 0.53–0.92; *P* =.01; NNT, 26) compared with standard dressings. A significant benefit of these reduced odds was an almost 2-day reduction in length of stay (mean difference, -1.75; 95% CI, - 2.69 to -0.81; *P* <.00) compared with standard dressings, suggesting potential for substantial efficiency gains across the health care system.

The National Institute of Health and Care Excellence[44] (NICE) in the UK National Health Service (NHS) has stated the following to help prevent SSI:

> Evidence supports adopting this specific sNPWT device for closed surgical incisions in the NHS; it is associated with fewer SSIs and seromas than standard wound dressings. The use of this device should be considered an option for closed surgical incisions in people at high risk of developing SSIs[1]; cost modeling suggests that this device provides extra clinical benefits at a similar overall cost compared with standard wound dressings.

Procedure

One month before the first call/meeting, participants received literature and materials to review. In addition, all panel members were asked to complete a survey before meeting with the organizers to guide future discussion. The surveys were geared toward type and management of SSC. They included open-ended questions about perioperative surgical management, methods of identifying patients at risk of SSC, the type of communication that occurred among the surgical team to plan for the potential use of sNPWT prophylaxis, institutional support mechanisms, and how to identify stakeholders.

Panel members participated in individual Zoom interviews to identify commonalities, synergies, and differences across surgical specialties and care settings and to identify potential surgical incision management pathways to maximize clinical efficacy.

Developing the consensus document

The interview content and survey responses were aggregated into a document according to specialty and conclusions regarding surgical risk stratification, which crossed all specialties. A medical writer who had participated in all of the interviews and kept notes to enhance transcription of the recordings composed the consensus document, enhancing the participants' knowledge of the device and supportive content they shared with additional evidence-based research.

The document was organized by participant specialty; it also included other specialties noted in the research to benefit from incorporating sNPWT into perioperative protocols. Particular focus was on understanding how to shift individual and organizational users within a clinical setting to embed prophylactic use of sNPWT into a surgical care bundle. The panel discussed best practices among different surgical specialties and identified clinical and administrative stakeholders and patient assessment tools to identify patients at high risk for SSC. Participants also identified a list of clinical risk factors that were particularly important when deciding whether to use sNPWT prophylactically; a clinical guideline was suggested.

A draft consensus manuscript was distributed to all panel members; the manuscript included the panel members' experiences and general perceptions of sNPWT use. The document then was organized by surgery type, addressing and providing research support for how sNPWT might best be utilized as a part of the perioperative protocol. A consensus approach,[54] modified to accommodate restrictions imposed by the pandemic, was used to gain approval of the document from all panel members. The draft manuscript was emailed to all panelists, and the panel members' revisions were incorporated into the final document. Follow-up discussions and edits were performed if necessary. Overall, the panel was in agreement without dissenting comments even though the panel did not meet as a group.

Results

General findings

The panel comprised 3 orthopedic surgeons, a director of cardiac surgery, a consultant obstetrician and gynecologist, a chief of a plastic surgery department, a clinical nurse specialist, and an infection control specialist; they hailed from the United States, Australia, the United Kingdom, and Spain (**Table 2**).

Table 2. Panel Participants.

Panelist	Facility	Specialty/Position
Ronald W Singer, MD	OrthoCarolina, Charlotte, NC	Orthopedic surgeon
V Seenu Reddy, MD, MBA, FACS, FACC	Tristar Centennial Medical Center, Nashville, TN	Director of cardiac surgery
Adam Sassoon, MD, MS	UCLA Health, Los Angeles, CA	Hip and knee orthopedic surgery
Jaume Masia, MD, PhD	Hospital de la Santa Creu i Sant Pau/Hospital del Mar, Barcelona, Spain	Professor and chief of plastic surgery
Ann Fowler, CNS	Coffs Harbour Hospital, New South Wales, Australia	Clinical nurse specialist
Darly Mathew, FRCOG	Chesterfield Royal Hospital, Chesterfield, Derbyshire, UK	Consultant obstetrician and gynecologist
Jeanette Harris, MS, MSM, MT(ASCP), CIC, FAPIC	Evergreen Health at Evergreen Healthcare, Enumclaw, WA	Hospital infection prevention
Ikram Nizam, MB, CHB, MRCS, MS, FRACS, FAORTHA	Ozorthopaedics, Malvern VIC, Australia	Orthopedic surgeon (hip and knee specialist)

Panel member use of sNPWT. All but 1 panel member had experience using the study device. Reasons for use were both clinical and economic. Clinical reasons included reducing surgical complications, enhancing wound healing, and protecting the incision. Anecdotal and published research supported the panelists' views that using sNPWT resulted in a substantial decrease in readmissions for wound complications, especially regarding orthopedic, colorectal, and obstetrical/gynecological surgeries.

Risk factors that may be mitigated by sNPWT use. Most participants agreed with ACS SSI guidelines[10] regarding SSC risk mitigation by using sNPWT—namely, the major patient-related risk factors for SSC. The main reasons for using sNPWT were body mass index (BMI) greater than 35 kg/m^2, poor nutrition, poor diabetic control, immunosuppression, chronic inflammatory disease, advanced age, nicotine use, history of radiation therapy, and anticoagulation or bleeding disorders. The surgeon participants also included reoperations and orthopedic revisions, emergency or trauma-related procedures, implant placement, and long preoperative stay.

Risk assessment. In discussions about the importance of a holistic team approach to preoperative evaluation, participants determined risk assessment was primarily the responsibility of the surgeon or surgical team. It was noted that most of the participants' facilities did not have written guidelines or a formal process risk assessment. In institutions where an established protocol of identifying closed-incision complication risk was in place, sNPWT was part of the perioperative SSC prevention and mitigation strategy. Panelists agreed that a risk-based algorithm should be used to identify high-risk patients before surgery, enabling the surgical team to plan incision management before the patient's arrival to the operating room.

Although some participants advocated using sNPWT on all patients in some instances (eg, total joint replacements, regardless of comorbidities), others preferred a more selective approach with specific risk stratification. Applying sNPWT first on high-risk patients and showing positive results could influence hospital administration and payors to support its use. Panel members advocated looking at the expense of the entire longitudinal episode of care, not only cost of initial hospitalization.

Economic considerations. Economic incentives for using sNPWT and challenges obtaining stakeholder buy-in were discussed in detail. The economic benefits of sNPWT, observed by the panel and reviewed in the literature,[39,55] were decreased infections and hospital length of stay and improved wound healing, all of which can avoid costly readmissions. The participants were aware of the impact of readmissions, which can be expensive for the hospital, especially considering the 90-day global payment period for surgical patients and other country-specific payment and reimbursement requirements. Revisits to the clinic for SSC were also perceived to be inconvenient for the patient and resulted in less time for the surgeons to see new patients (requiring treatment).

The panel agreed that the role of convincing hospital administration to support purchasing the device, which, in most cases adds to the expense of the procedure, usually falls to the surgeon. However, the panel believed an organized effort among multidisciplinary clinicians (including perioperative nurses, the surgical team, wound care specialists, and physical therapists) could help demonstrate the financial benefits of using sNPWT. The panel noted that formal clinical audits were conducted in some settings, comparing the significant morbidity reported following SSC, which required complex and expensive management, including returning to the operating room and prolonging hospital stays. Panelists anecdotally noted that fewer wound complications occurred when sNPWT was utilized.

The device's price is often cited as a barrier to widespread adoption of prophylactic use of sNPWT. However, the reported clinical efficacy of the featured sNPWT system has the potential to offset the additional cost of SSCs. Potential cost savings from preventing emergency department visits, readmissions, and infections can outweigh the cost of using sNPWT. One example noted is joint replacement surgery; the risk of developing an SSI or SSC could result in a risk to the permanent implant. The cost of treating a periprosthetic infection can reach tens of thousands of dollars, especially if an infected implant requires reoperation for implant removal, surgical washout, subsequent reimplantation, and extended hospital stays.[56]

Single-use NPWT in practice. Postoperative incision management using sNPWT involved diverse protocols, but none specifically formalized for comprehensive use. All panelists recognized the importance of communication among the surgical and postoperative clinical team, patient, family, and home care nurses. For example, cesarean section patients undergo a preoperative assessment; this information is documented in the patient's medical notes/chart and includes an indication for sNPWT.

Panelists reached a consensus that as long as the patient was in the hospital, the dressing should be checked postoperatively for drainage, erythema, and marginal necrosis, not unlike other types of dressings applied to surgical sites. The device should be left undisturbed for up to 7 days, depending on the type of device, and subject to manufacturer recommendations, surgical procedure, and surgeon preference.

All participants advocated for written or pictorial instructions for the patient, family, and nurses to follow throughout the postoperative period. Panel members stated that instructions should be written simply and be available in various languages for diverse patient groups based upon the specific local population of the implementing care facility.

More and more patients are same-day discharged as part of ERAS,[2] and the panel agreed that sNPWT should be part of the post-discharge protocol. The consensus document to follow was developed to foster the inclusion of sNPWT into the perioperative surgical protocol.

Limitations

Most of the panelists used the sponsoring company's sNPWT device; intrinsic biases were revealed in the discussions. Regardless, robust discussions regarding perioperative risk and specific use of sNPWT offered insights into participants' experience and opinions and the results of evidence-based studies on the use of sNPWT. Before creating the guidance document, much of the discussion dealt with identifying challenges to and methods for adding sNPWT into the perioperative surgical bundle; as such, much of the document content was based on anecdotal evidence and the panelists' opinions.

It should be noted that the panel's objective was to better improve outcomes by optimizing the implementation of sNPWT prophylaxis into care protocols to prevent SSC across multiple surgical specialties and care settings. It was not the panel's intention to extol the use of one sNPWT device over another product, single-use or traditional. However, it could be argued that the published clinical and anecdotal evidence regarding the study device demonstrates its superiority, if not over other similar products, then at least vs standard care.

Conclusions

Despite steps taken for infection control and improvements in surgical practices, SSC remains a substantial clinical and financial burden. Perioperative care bundles, the mainstay of many surgical programs, have been shown to improve outcomes. A large and growing body of clinical evidence supports that postoperative complications can be mitigated by identifying at-risk patients preoperatively and providing sNPWT as part of the surgical care bundle. The challenges of implementing selective and pragmatic use of sNPWT into an already financially burdened health care system can be addressed when clinical and administrative teams work together, utilizing the scientific, therapeutic, and health economic evidence necessary to inform and implement necessary change.

Consensus by Specialty

Orthopedics

Surgical site infection after primary or revision knee and hip arthroplasty can result in prolonged antibiotic therapy and the need for implant removal.[57] Single-use NPWT can be beneficial for hip and knee arthroplasty in high-risk patients; some panel members made a case for use in all patients, given the high consequences of implant removal even in healthy patients. Many arthroplasty patients have inflammatory diseases such as rheumatoid arthritis, systemic lupus erythematosus, and spondylarthritis and receive corticosteroids, methotrexate, or biologics. These immunosuppressive agents commonly are factors in SSC,[58] and their use supports the implementation of sNPWT.

The panelists agreed that joint revisions and orthopedic trauma such as lower extremity fractures put the patient at higher risk for SSC because of preoperative and/or postoperative implants (eg, screws, pins, and plates) and the potential for significant soft tissue injury. Once the incision is closed, a protocol that advocates using sNPWT to decrease the accumulation of postoperative fluid in the soft tissues and keep the incision covered and secured may subsequently reduce the incidence of SSC.[21] Panelists noted that decreasing edema in the tissues around the joint may decrease pain and inflammation, thus increasing the range of motion and function. As a result, patients can be discharged earlier and can rehabilitate more rapidly.

Obese patients (ie, BMI >35–40 kg/m^2) have loose fat and/or a pannus; the panel included these patients, especially those undergoing direct anterior approach hip replacement, in their list of patients at higher risk of incision dehiscence and infection, occurrences potentially mitigated by sNPWT. Healing in extremely thin patients or persons with poor nutrition also may be compromised[59]; the panel believed they, too, may benefit from sNPWT.

Maintaining incisional integrity for 7 days postoperatively may mitigate wound dehiscence. Anticoagulated patients are at higher risk of bleeding and developing a hematoma perioperatively. Applying pressure on the incision and subcutaneous tissues was noted to prevent blood and/or fluid from collecting in dead spaces. Incisional NPWT also has shown utility in reducing the incidence of SSC after spinal fusion for reducing wound dehiscence and postoperative infection.[60]

Total knee arthroplasty has been removed from the Medicare inpatient-only list of procedures. It is exempt from applying the 3-midnight rule, so it can now be performed in an outpatient setting.[61] Overall, NPWT has been found effective in reducing complications and re-intervention after total knee arthroplasty.[62,63]

Recommendation: *Because it has been shown to reduce postsurgical complications in several orthopedic procedures (including total knee and hip arthroscopy), sNPWT can help expedite discharge.*

Abdominal surgery

Surgical site complication incidence after open abdominal surgery is particularly high; in a prospective cohort study,[64] the rate was 16.3%. Based on a meta-analysis[65] of 13 studies, the use of closed-incisional NWPT showed a decrease in SSI, especially in high-risk patients. A 2020 Cochrane review[66] concluded that prophylactic sNPWT appeared superior to conventional dressings in preventing SSI in closed laparotomy incisions in general and colorectal surgery.

A prospective cohort study by Lawrence et al[42] of 300 consecutive patients who underwent pancreaticoduodenectomy showed the implementation of a 4-part bundle that included a double-ring wound protector, gown/glove and drape change before fascial closure, irrigation of the wound with bacitracin solution, and a negative pressure wound dressing decreased SSI rate from 22% to 11%, even though patients undergoing colorectal surgical procedures such as laparotomies and ostomies are perceived to be at higher risk of seroma, hematoma, and infection due to the large surface area and the presence of interstitial fluid.

Recommendation: *Knowing the high prevalence of complications following abdominal surgery, sNPWT should be used to prevent or reduce the complexities of healing.*

Obstetrical and gynecological surgery

A retrospective analysis[65] of 1233 patients undergoing laparotomy for known or suspected gynecological cancer found sNPWT reduced both superficial and deep infections compared with standard dressings. Additionally, the number of all adverse wound outcomes was reduced in high-risk patients. Hyldig et al[31] noted that prophylactic use of sNPWT after cesarean section reduced SSI. Panelists experienced with patients undergoing obstetrical and gynecologic surgery advocated for using sNPWT in patients with risk factors that included increased prepregnancy BMI (generally, >35 kg/m^2), diabetes, nicotine use, presence of a large pannus, use of immunosuppressive medications, patients with a long preoperative stay, and patients with repeat cesarean sections. Panel members also noted that re-explorations of the abdomen and repeat cesarean sections were additional risk factors for SSC and acknowledged sNPWT could provide preventive benefits. Of note, emergency cesarean section has a slightly increased risk of SSI compared with elective.[66]

In addition to the clinical benefits observed with sNPWT, a review of the literature[67] found infections following cesarean sections can be painful and traumatic for women at a time when they would rather be focused on taking care of their newborn. A narrative review[68] has shown that peripartum infection has health implications on the neonate later in life, including alterations in the neonate microbiome associated with childhood obesity, atopic and allergic disease, and higher asthma rates.

Recommendation: *Using sNPWT to prevent infection or complications after a cesarean section has the potential to impact the patient and newborn positively.*

Cardiac surgery

A review of the literature[69] found postoperative SSC following cardiac surgery is associated with significant morbidity and mortality. Panelists recognized that preventing mediastinal SSI (ie, thwarting a superficial sternal wound infection from progressing to a deeper infection with sinus track) could significantly decrease morbidity and the overall cost of care. Single-use NPWT could be a worthwhile intervention.

To help stratify infection risk in patients undergoing coronary artery bypass grafting (CABG), Raja et al[70] developed the Brompton Harefield Infection Score (BHIS). The BHIS includes diabetes, BMI of 35 kg/m^2 or higher, female sex, emergency procedure, and left ventricular ejection fraction higher than 45%. Panelists similarly agreed that patients perceived to be at high risk of wound dehiscence and potentially mediastinitis include persons with diabetes and obesity. The panelists also believed low albumin, poor tissue due to age or steroids, prior methicillin-resistant *Staphylococcus aureus* infection, and previous sternotomies also should be considered risk factors. Secondary risks may include emergency surgeries and people who smoke and may or may not have chronic obstructive pulmonary disease. Panelists advocated using sNPWT over sternotomy incisions; reports supporting this recommendation have been published in this surgical specialty. The literature includes a comparative study[71] showing that the use of sNPWT reduces the risk of superficial sternal infection in off-pump CABG with left internal mammary harvest and a survey indicating a decrease in incisional complications, mediastinitis, and superficial SSIs, as well as an economic benefit.

A systematic review and meta-analysis[72] showed patients at risk for wound complications or those with postoperative sternal dehiscence may be closed with rigid fixation with titanium plates. Similar to orthopedic surgeries involving metal implants, sternotomies closed with additional hardware may benefit from using sNPWT to protect the incision from bacterial contamination and keep the incision stable (ie, reduce lateral tension).

Recommendation: *Using sNPWT in patients who underwent cardiac surgery may help prevent infection and keep the incision stable.*

Plastic surgery

Galiano et al[29] treated 200 patients who had a bilateral reduction mammoplasty with sNPWT for up to 14 days utilizing within-person comparison to assess outcomes. Significantly fewer healing complications were noted in NPWT-treated breasts (113; 56.8%) as compared with standard care of adhesive strips covered with gauze or a nonadherent dressing (123; 61.8%; *P* =.004). As observed by day 21, NPWT also lowered the incidence of dehiscence (32 patients; 16.2%) vs the 52 patients (26.4%) who received standard care by day 21 (*P* <.001). In a pilot study (N = 10), Fang et al[73] used sNPWT on deep inferior epigastric perforator flap abdominal donor site incisions for reconstructions. The flap harvest site creates a large incision, and the authors found significant improvement in scar pigmentation, vascularity, and pliability over time with no SSC noted in the treatment group.

Risk factors for SSC in breast reconstruction after mastectomy are similar to other types of surgeries—namely diabetes, obesity, and nicotine use, with the added challenge of cancer treatments including perioperative radiation and chemotherapy.[73] Timely healing after breast reconstruction facilitates prompt commencement of adjuvant therapy. Authors of a small case study[30] suggested sNPWT would help reduce healing time and prevent complications.

In addition, plastic surgeons often are called upon to assist other specialties in the closure of complex orthopedic, oncological, or general surgical procedures, some of which could be contaminated after trauma or from abdominal contents.

Recommendation: *Patients requiring plastic surgery and who may have operative risk factors for SSC could benefit from using sNPWT to decrease infection, antibiotic use, reoperation, and hospital stay.*

Inclusion of sNPWT in Care Bundles

Clinical care

The panel agreed that designing clinical systems using risk stratification, a bundled perioperative approach, and team communication can greatly decrease surgical complications. An increasing number of clinical groups and hospitals have employed a care bundle approach for perioperative management and/or to predict postoperative complications. Critical to a bundle approach is that all elements of the bundle must be performed to see a difference in outcomes; preventing SSC by utilizing a stratified, proactive approach is the primary goal of the care bundle.

Risk stratification. The CDC National Healthcare Safety Network[11] includes guidance for developing a risk stratification protocol for specific procedures and documenting and reporting surgical complications. Programs using a formal risk assessment process should delineate team members (ie, surgeons, nurses, advanced practice professionals) to determine which patients will benefit from using sNPWT. The key should be interdisciplinary collaboration; the panel suggests meetings as frequently as every 2 weeks to discuss patient outcomes, complications, and strategies for improvement.

Recommendation: *The panel believed identifying patients at risk for complications is paramount to demonstrating where sNPWT can be most effective.*

Care team approach. Perioperative success should include a collaborative team approach among all team members, including the surgeon, perioperative nurses, surgical trainees, nutritionists, endocrinologists (to manage diabetes), and wound care specialists (hospital and community) for pre- and post-procedure evaluation and management. Identifying wound irregularities early in the postoperative course by patients, caregivers, home nurses, or general practitioners can prevent future serious complications.

A retrospective review[73] and a clinical trial[74] demonstrated safety interventions that combine teamwork training and systems rationalization are more effective than either approach alone. Therefore, developing a program comprising quantitative results with explanations of the causal relationship between interventions and outcomes may positively influence surgical outcomes.[75] A qualitative study[76] has shown that although surgeons often are identified as key players in adherence, they are not always aware of compliance with guidelines for SSI prevention, despite the preponderance of evidence. They may feel challenged to change personal and professional behavior to comply with protocols and checklists. Providing an environment and culture focused on safety may help offset clinician reticence to adopt protocol changes.[77]

Recommendation: *All players on the health care team must understand and accept their roles and the rationale for the interventions that need to be put in place.*

Single-use NPWT as part of surgical care bundles

Single-use NPWT has become a noteworthy part of these protocols.[60,61] A recent consensus document,[78] comprehensive meta-analyses,[21] and the UK NICE[44] review of the published clinical evidence recommend using sNPWT for patients at risk of developing SSC, as does a systematic literature review and meta-analysis.[53] Although clear in their conclusions, these publications do not offer explicit guidance on how to successfully adopt and incorporate the use of sNPWT in their organizations. The presence of preoperative risk factors, as identified by the CDC Hospital Infection Control Advisory Committee,[79] the Society for Healthcare Epidemiology of America,[80] Infectious Diseases Society of America,[81] and ACS and Surgical Infection Society guidelines,[10] support using sNPWT postoperatively.

Recommendation: *Panel members agreed that a canister-free sNPWT device should be used as part of a surgical bundle.*

Examples of bundles. Care bundles utilized to decrease SSI include a protocol for colorectal care[82] and scheduled cesarean sections.[83] Institutions may use a formal ERAS[84] protocol to minimize the risk of SSC that includes early patient identification, comprehensive preoperative testing, clear liquids after midnight instead of nil by mouth, strict glucose management, antimicrobial wipes (either total body or surgical site depending on hospital protocol), maintenance of normothermia (>36°C), warm room temperatures during surgery, and standardized dressings using sNPWT (**Figure 1**). Procedures for the cesarean section bundle might describe: nasal decolonization, blood glucose optimization, a chlorhexidine gluconate wash chin to toes the night before surgery, skin closure with sutures (vs staples), perioperative antibiotics given at the appropriate time, sNPWT dressing applied to the incision for up to 7 days, wound specialist consult immediately (should an issue arise), and patient and family education.

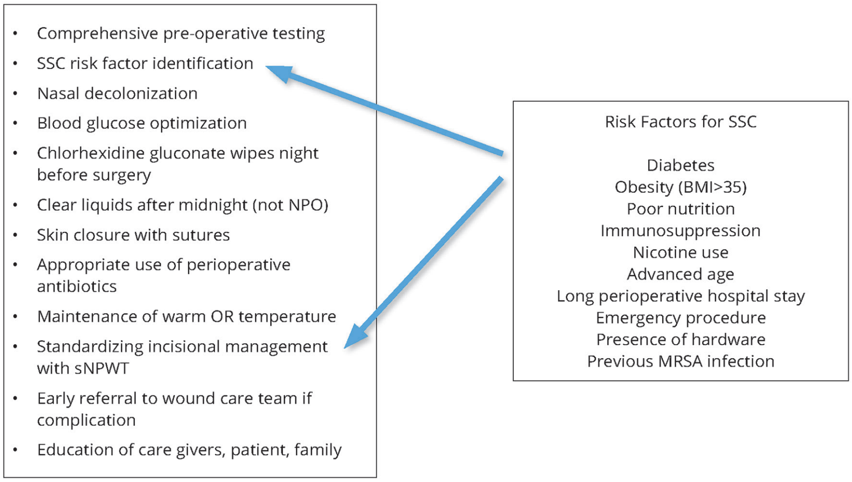

Figure 1. Care bundle for surgical procedures. Risk factors for surgical site complications can be identified as part of the care bundle and used to support incisional management with sNPWT.
BMI: body mass index; MRSA: methicillin-resistant *Staphylococcus aureus*; NPO: not to eat or drink after midnight the night before surgery; OR: operating room; sNPWT: single-use negative pressure wound therapy; SSC: surgical site complication

A study involving 7 hospitals[73] demonstrated a decreased incidence of SSI was achieved when a strong workplace safety culture was cultivated among the surgical team. A few of the changes implemented were feedback and communication about error, continuous improvement initiatives, and administrative support.

The patient's role

As part of the care bundle, patients should be educated about early recognition of wound infection and how to report symptoms immediately for treatment. Any dressing that protects the wound by keeping it covered and sealed, such as sNPWT, may help avoid the need for systemic antibiotics beyond perioperative use. Surgeons and others involved in perioperative care should be acutely aware of being good stewards of postoperative antibiotic use.

Recommendation: *Care team members need to ensure surgical patients are informed about and involved in their care and monitored throughout the healing process.*

The need to reassess

Periodic and thoughtful reassessment is essential to any care bundle. Evaluating the preoperative assessment tool for thoroughness is critical, allowing for revision as needed. Monitoring whether the surgical team routinely reviews all preoperative data to develop a comprehensive perioperative risk assessment is essential. For example, the incision (regardless of

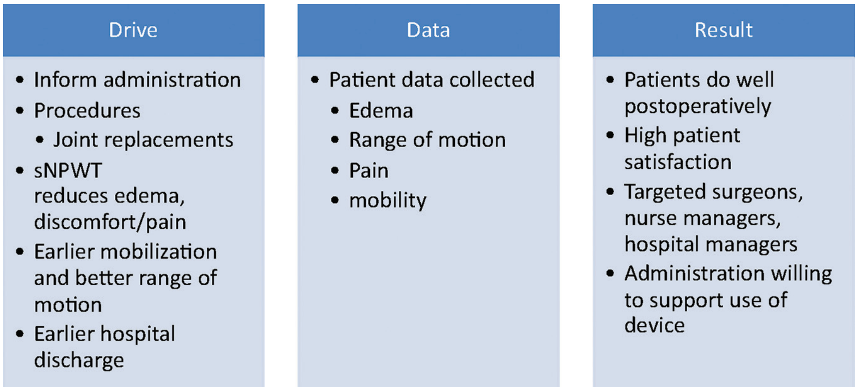

Figure 2. Example of steps to take to include sNPWT in a care bundle for joint replacement, including identifying stakeholders and elucidating goals, collecting data and reporting results.
sNPWT: single-use negative pressure wound therapy

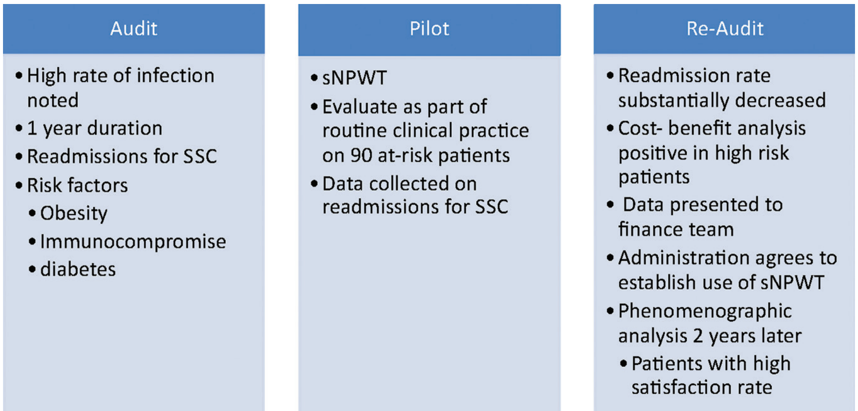

Figure 3. Sample audit and pilot program using sNPWT for gynecological/obstetrical surgeries including purpose of the program, specific risk-based protocol and data points, and review of results.
SSC: surgical site complication; sNPWT: single-use negative pressure wound therapy

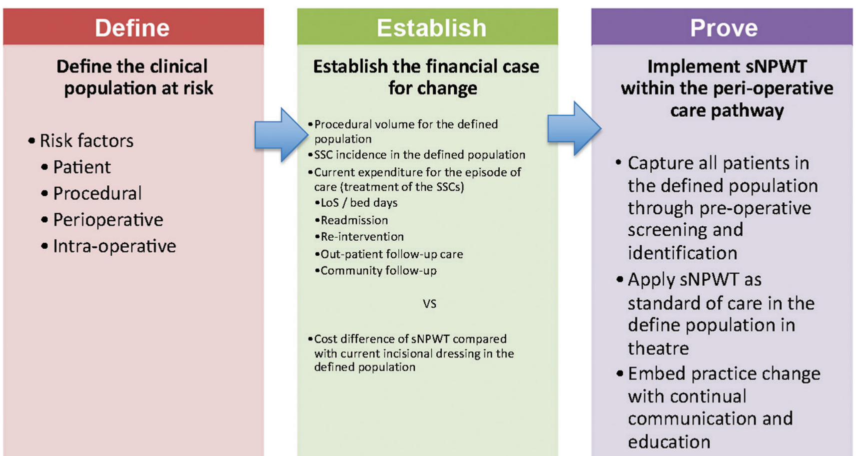

Figure 4. Establishing and embedding the use of prophylactic, incisional single-use negative pressure wound therapy as the standard postoperative management for the prevention of surgical site complications, including infection.
LoS: length of stay; SSC: surgical site complication; sNPWT: single-use negative pressure wound therapy

sNPWT implementation) should be evaluated postoperatively at regular intervals, and the patient, family, and/or nurses educated on the identification of complications, such as redness, blistering (around or under the dressing), pain, itching, or fever. Because the adhesive drape of the sNPWT device is transparent, any skin changes can be observed. Patients should be provided written educational materials specific to incision care and information on the sNPWT device, including contact information on who can answer questions or concerns.

Recommendation. *Care team members need to ensure the bundle is working to achieve good outcomes.*

Follow-up

Some panel members noted that postoperative follow-up could fall below the standard expectations unless there is a commitment from all perioperative team members and education of the patient, family, and caretakers. In some sectors, sNPWT is used indiscriminately with no standardization.

Recommendation. *Postoperative care should include monitoring the extended use of sNPWT.*

Health economics

Adding sNPWT to a care bundle: panel members' experiences. The panel identified several barriers to change related to convincing clinical and administrative stakeholders to change practice and standard of care. Individual panel members experienced varying success while attempting to provide sNPWT for all (or at least the highest risk) patients. Several panelists were required to make a formal request to their hospital/institution's value analysis committee.

Demonstrating value must go beyond a like-for-like cost per unit comparison as a function of procedural volume. The upfront cost of purchasing an sNPWT device for a specific patient population should be compared with the current expenditure for treating SSCs (including infection). Considerations include the clinical and financial burdens of additional inpatient days, readmissions, and/or surgical reintervention in that same population (ie, cost-effectiveness). Not all surgeons consider efficacy compared with the standard practice. Often, the conversation begins by citing a complicated surgical patient on whom sNPWT was applied with good results. Once information is shared regarding successful sNPWT use on a broader range of patients, skeptical clinicians may be asked instead to explain why they would choose not to use sNPWT.

Some panel members advocated limiting sNPWT use to the patients at highest risk because it may not be cost-effective for all patients. For example, routine procedures on healthy patients who, in aggregate, do not carry a high risk of complications may not have the same rate of SSC and hence not benefit from sNPWT. The use of sNPWT was advocated in high-consequence patients, such as a healthy patient undergoing joint replacement, who may not necessarily be at high risk for SSI, but where the consequences of a deep infection could be catastrophic.

In some settings, a more defined approach to wound management may be better than providing sNPWT across the board. If sNPWT use has been identified for a patient preoperatively, the device and dressings could be sent to the operating room along with the patient. If the patient was identified as not needing the device, no device would be readily available, thus preventing indiscriminate use.

Gaining acceptance. Several panelists described that once the financial data were presented to hospital administration with cost savings described, including preventing emergency room visits and readmissions for infection or other complications, sNPWT usually was approved. Surgeons on the panel in private practice, where no formal vetting process must be approved, had more freedom to use a new product. However, additional costs associated with SSC can be much more burdensome in private practice. It was noted that rural health care systems and those in a public health domain receive less funding than their counterparts in private systems. In public hospitals, the decision-making process is much more rigorous; adding sNPWT to the formulary is much more challenging.

Overall, the panel concluded that using sNPWT can potentially reduce postoperative expenses, which can far outweigh the initial outlay of funds.[12] Some surgeons on the panel hoped to use their own surgical specialty clinical and cost data to support the use of sNPWT throughout their hospital system as a whole. Examples of care bundles are presented for orthopedics and obstetrics in **Figures 2 and 3**.

In summation, strong economic evidence and clinical data reviewed regularly are critical to incorporating an sNPWT device into a care bundle or protocol (**Figure 4**). Current informed opinion and research support incorporating sNPWT into surgical site care bundles.

References

1. NQF-Endorsed Measures for Surgical Procedures, 2015-2017. *Final Report*. Accessed March 20, 2021. https://www.qualityforum.org/Publications/2015/02/NQF-Endorsed_Measures_for_Surgical_Procedures.aspx.
2. Smith TW Jr, Wang X, Singer MA, Godellas CV, Faince FT. Enhanced recovery after surgery: a clinical review of implementation across multiple surgical subspecialties. *Am J Surg*. 2020;219(3):530–534. doi:10.1016/j.amjsurg.2019.11.009
3. Cusack B, Buggy DJ. Anaesthesia, analgesia, and the surgical stress response. *BJA Educ*. 2020;20(9):321–328. doi:10.1016/j.bjae.2020.04.006
4. Helander EM, Webb MP, Menard B, et al. Metabolic and the surgical stress response considerations to improve postoperative recovery. *Curr Pain Headache Rep*. 2019;23(5):33. doi:10.1007/s11916-019-0770-4
5. Magill SS, O'Leary SJ, Janelle DL, et al. Changes in prevalence of health care-associated infections in US hospitals. *N Engl J Med*. 2018;379(18):1732–1744. doi:10.1056/NEJMoa1801550
6. Mitchell R, Taylor G, Rudnick W, et al. Trends in health care-associated infections in acute care hospitals in Canada: an analysis of repeated point-prevalence surveys. *CMAJ*. 2019;191(36): E981–E988. doi:10.1503/cmaj.190361
7. Slankamenac K, Graf R, Barkun J, et al. The comprehensive complication index: a novel continuous scale to measure surgical morbidity. *Ann Surg*. 2013;258(1):1–7. doi:10.1097/SLA.0b013e318296c732
8. Sandy-Hodgetts K, Carville K, Leslie GD. Determining risk factors for surgical wound dehiscence: a literature review. *Int Wound J*. 2015;12(3):265–275. doi:10.1111/iwj.12088
9. Anderson DJ, Podgorny K, Berrios-Torres SI, et al. Strategies to prevent surgical site infections in acute care hospitals: 2014 update. *Infect Control Hosp Epidemiol*. 2014;35(suppl 2):S66–S88. doi:10.1086/676022
10. Ban KA, Minei JP, Laronga C, et al. American College of Surgeons and Surgical Infection Society: surgical site infection guidelines. 2016 update. *J Am Coll Surg*. 2017;224(1):59–74. doi:10.1016/j.jamcollsurg.2016.10.029
11. National Healthcare Safety Network Surgical Site Infection. Accessed February 14, 2021. https://www.cdc.gov/nhsn.
12. Badia JM, Casey AL, Petrosillo N, Hudson PM, Mitchell SA, Crosby C. Impact of surgical site infection on healthcare costs and patient outcomes: a systematic review in six European countries. *J Hosp Infect*. 2017;96(1):1–15. doi:10.1016/j.jhin.2017.03.00
13. Aasen DM, Bronsert MR, Rozeboom PD, et al. Relationships between predischarge and postdischarge infectious complications, length of stay, and unplanned readmissions in the ACS NSQIP database. *Surgery*. 2021;169(2):325–332. doi:10.1016/j.surg.2020.08.009
14. Alfonso JL, Pereperz SB, Canoves JM, Martinez MM, Martinez IM, Martin-Moreno JM. Are we really seeing the total costs of surgical site infections? A Spanish study. *Wound Repair Regen*. 2007;15(4):474–481. doi:10.1111/j.1524-475X.2007.00254.x
15. Andersson AE, Bergh I, Karlsson J, Nilsson K. Patients' experiences of acquiring a deep surgical site infection: an interview study. *Am J Infect Control*. 2010;38(9):711–717. doi:10.1016/j.ajic.2010.03.017
16. Palmer CK, Gooberman-Hill R, Blom AW, Whitehouse MR, Moore AJ. Post-surgery and recovery experiences following one- and two-stage revision for prosthetic joint infection—a qualitative study of patients' experiences. *PLoS One*. 2020;15(8):e0237047. doi:10.1371/journal.pone.0237047
17. Allegranzi B, Bishkoff P, deJong S, et al. New WHO recommendations on preoperative measures for surgical site infection prevention: an evidence-based global perspective. *Lancet Infect Dis*. 2016;16(12):e276–e287.

doi:10.1016/S1473-3099(16)30398-X

18. Haynes AB, Weiser TG, Berry WR, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. *N Engl J Med*. 2009;360(5):491–499. doi:10.1056/NEJMsa0810119
19. Argenta LC, Morykwas MJ. Vacuum-assisted closure: a new method for wound control and treatment: clinical experience. *Ann Plast Surg.* 1997;38(6):563–576.
20. Morykwas MJ, Argenta LC. Nonsurgical modalities to enhance healing and care of soft tissue wounds. *J South Orthop Assoc.* 1997;6(4):279–288.
21. Strugala V, Martin R. Meta-analysis of comparative trials evaluating a prophylactic single-use negative pressure wound therapy system for the prevention of surgical site complications. *Surg Infect (Larchmt)*. 2017;18(7):810–819. doi:10.1089/sur.2017.156
22. Gomoll AH, Lin A, Harris MB. Incisional vacuum-assisted closure therapy. *J Orthop Trauma.* 2006;20(10):705–709. doi:10.1097/01.bot.0000211159.98239.d2
23. Nam D, Sershon RA, Levine BR, Della Valle CJ. The use of closed incision negative pressure therapy in orthopaedic surgery. *J Am Acad Orthop Surg.* 2018;26(9):295–302. doi:10.5435/JAAOS-D-17-00054
24. Muenchow S. Horch RE, Dragu A. Effects of topical negative pressure therapy on perfusion and microcirculation of human skin. *Clin Hemorheol Microcirc.* 2019;72(4):365–374. doi:10.3233/CH-180536
25. Karlakki SL, Hamad AK, Whittall C Graham NM, Banarjee RD, Kuiper JH. Incisional negative pressure wound therapy dressings (iNPWTd) in routine primary hip and knee arthroplasties: a randomised controlled trial. *Bone Joint Res.* 2016;5(8):328–337. doi:10.1302/2046-3758.58.BJR-2016-0022.R1
26. Willy C, Agarwal A, Andersen CA, et al. Closed incision negative pressure therapy: international multidisciplinary consensus recommendations. *Int Wound J.* 2017;14(2):385–498. doi:10.1111/iwj.12612.
27. MasdenD, Goldstein J, Endara M, Xu K, Steinberg J, Attinger C. Negative pressure wound therapy for at-risk surgical closured in patients with multiple comorbidities: a prospective, randomized controlled study. *Ann Surg.* 2012;255(6):1043–1047. doi:10.1097/SLA.0b013e3182501bae
28. Briet J, Bouret C, Jeantin E, Grangeasse L. OHP-018 Single-use canister free negative pressure wound therapy (npwt): an economical alternative. *Eur J Hosp Pharm*. 2017;24:A186. doi:10.1136/ejhpharm-2017-000640.412
29. Galiano RD, Hudson D, Shin J, et al. Incisional negative pressure wound therapy for prevention of wound healing complications following reduction mammaplasty. *Plast Reconstr Surg Glob Open*. 2018;6(1):e1560. doi:10.1097/GOX.0000000000001560
30. Holt R, Murphy J. PICO incision closure in oncoplastic breast surgery: a case series. *Br J Hosp Med (Lond)*. 2015;76(4):217–223. doi:10.12968/hmed.2015.76.4.217
31. Hyldig N, Vinter CA, Kruse M, et al. Prophylactic incisional negative pressure wound therapy reduces the risk of surgical site infection after caesarean section in obese women: a pragmatic randomised clinical trial. *BJOG.* 2019;126(5):628–635. doi:10.1111/1471-0528.15413
32. Fleming CA, Kuteva M, O'Hanlon K, O'Brien G, McGreal G. Routine use of PICO dressings may reduce overall groin wound complication rates following peripheral vascular surgery. *J Hosp Infect.* 2018;99(1):75–80. doi:10.1016/j.jhin.2017.10.022
33. Witt-Majchrzak A, Zelazny P, Snarska J. Preliminary outcome of treatment of postoperative primarily closed sternotomy wounds treated using negative pressure wound therapy. *Pol Przegl Chir.* 2015;86(10):456–465. doi:10.2478/pjs-2014-0082
34. O'Leary DP, Peirce C, Anglim B, et al. Prophylactic negative pressure dressing use in 33 closed laparotomy wounds following abdominal operations: a randomized, controlled, open-label trial: the PICO Trial. *Ann Surg.* 2017;265(6):1082–1086. doi:10.1097/SLA.0000000000002098
35. Sahebally SM, McKevitt K, Stephens I, et al. Negative pressure wound therapy for closed laparotomy incisions in general and colorectal surgery: a systematic review and meta-analysis. *JAMA Surg.* 2018;153(11):183467. doi:10.1001/jamasurg.2018.3467
36. Schlosser KA, Otero Javier, Lincourt A, Augenstein VA. Management of surgical incisions using incisional negative-pressure therapy. *Plast Reconstr Surg.* 2019;143(1 suppl):15S–20S. doi:10.1097/PRS.0000000000005307
37. Costa ML, Achten J, Knight R, et al. Effect of incisional negative pressure wound therapy vs standard wound dressing on deep surgical site infection after surgery for lower limb fractures associated with major trauma. The WHIST Randomized Clinical Trial. *JAMA.* 2020;323(6):519– 526. doi:10.1001/jama.2020.0059
38. Hickson E. Harris J, Brett D. A journey to zero: reduction of postoperative cesarean surgical site infections over a five-year period. *Surg Infect (Larchmt).* 2015;16(2):174–177. doi:10.1089/sur.2014.145
39. Hyldig N, Joergensen JS, Wu C, et al. Cost-effectiveness of incisional negative pressure wound therapy compared with standard care after caesarean section in obese women: a trial-based economic evaluation. *BJOG.* 2019;126(5):619–627. doi:10.1111/1471-0528.15573
40. Payne C, Edwards D. Application of the single-use negative pressure wound therapy device (PICO) on a heterogeneous group of surgical and traumatic wounds. *ePlasty.* 2014;14:e20.
41. Bolte M, Knapman B, Leibenson L,l Ball J, Giles M. Reducing surgical site infections post-caesarean section in an Australian hospital, using a bundled care approach. *Infect Dis Health*. 2020;25(3):158–167. doi:10.1016/j.idh.2020.01.006
42. Lawrence SA, McIntyre CA, Pulverenti A, et al. Perioperative bundle to reduce surgical site infection after pancreaticoduodenectomy: a prospective cohort study. *J Am Coll Surg.* 2019;228(4):595–601. doi:10.1016/j.jamcollsurg.2018.12.018
43. Zywot A, LAUCSM, Fletcher HS, Paul S. Bundles prevent surgical site infections after colorectal surgery: meta-analysis and systematic review. *J Gastrointest Surg.* 2017;21(11):1915–1930. doi:10.1007/s11605-017-3465-3
44. NICE (2019) PICO negative pressure wound dressings for closed surgical incisions. September 20, 2020. https://www.nice.org.uk/guidance/mtg43
45. Smith & Nephew Internal Report. Project Opal PICO 7 System Stability Testing, Initial Time Point. DS/17/253/R October 2017.
46. Loveluck J, Copeland T, Hill J, Hunt A, Martin R. Biomechanical modeling of the forces applied to closed incisions during single-use negative pressure wound therapy. *ePlasty.* 2016;16:e20.
47. Birke-Sorensen H, Malmsjo M, Rome P, et al. Evidence-based recommendations for negative pressure wound therapy: treatment variables (pressure levels, wound filler and contact layer)—steps towards an international consensus. *J Plast Reconstr Aesthet Surg.* 2011;64(suppl):S1–S16. doi:10.1016/j.bjps.2011.06.001
48. Scalise A, Calamita R, Tartaglione C, et al. Improving wound healing and preventing surgical site complications of closed surgical incisions: a possible role of incisional negative pressure wound therapy. A systematic review of the literature. *Int Wound J.* 2016;13(6):1260–1281. doi:10.1111/iwj.12492
49. Shim HS, Choi JS, Kim SW. A role for postoperative negative pressure wound therapy in multitissue hand injuries. *Biomed Res Int.* 2018;2018. doi:10.1155/2018/3629643
50. Malmsjö M, Huddleston E, Martin R. Biological effects of a disposable, canisterless negative pressure wound therapy system. *ePlasty.* 2014;14:e1–e15.
51. Innocenti M, Santini M, Dreassi E, et al. Effects of cutaneous negative pressure application on perforator artery flow in healthy volunteers: a preliminary study. *J Reconstr Microsurg.* 2019;35(3):189–193.

doi:10.1055/s-0038-1668157
52. Kilpadi DV, Cunningham MR. Evaluation of closed incision management with negative pressure wound therapy (CIM): hematoma/seroma and involvement of the lymphatic system. *Wound Repair Regen*. 2011;19(5):588–596. doi:10.1111/j.1524-475X.2011.00714.x
53. Saunders C, Nherera LM, Horner A, Trueman P. Single-use negative-pressure wound therapy versus conventional dressings for closed surgical incisions: systematic literature review and meta-analysis. *BJS Open*. 2021;5(1):zraa003. doi:10.1093/bjsopen/zraa003
54. Murphy MK, Black NA, Lamping DL, et al. Consensus development methods, and their use in clinical guideline development. *Health Technol Assess.* 1998;2(3):i-iv,1–88.
55. Nherera LM, Trueman P, Shmoeckel M, Fatoye FA. Cost-effectiveness analysis of single-use negative pressure wound therapy dressings (sNPWT) compared to standard of care in reducing surgical site complications (SSC) in patients undergoing coronary artery bypass grafting surgery. *J Cardiothorac Surg.* 2018;13(1):103.
56. Yao JJ, Hevesi M, Vissher SL, et al. Direct inpatient medical costs of operative treatment of periprosthetic hip and knee infections are twofold higher than those of aseptic revisions. *J Bone Joint Surg Am*. 2021;103(4):312–318. doi:10.2106/jbjs.20.00550
57. Ritter MA, Farris A. Outcome of infected joint replacement. *Orthopedics.* 2010;33. doi:10.3928/01477447-20100129-09
58. Zisa D, Goodman SM. Perioperative management of rheumatic disease and therapies. *Med Clin North Am*. 2021;105(2):273–284. doi:10.1016/j.mcna.2020.09.011
59. Bendersky V, Sun Z, Adam MA, et al. Determining the optimal quantitative threshold for preoperative albumin level before elective colorectal surgery. *J Gastrointest Surg.* 2017;21(4):692–699. doi:10.1007/s11605-017-3370-9
60. Adogwa O, Fatemi P, Perez E, et al. Negative pressure wound therapy reduces incidence of postoperative wound infection and dehiscence after long-segment thoracolumbar spinal fusion: a single institutional experience. *Spine J*. 2014;14(12):2911–2917. doi:10.1016/j.spinee.2014.04.011
61. Total Knee Arthroplasty (TKA) Removal from the Medicare Inpatient-Only (IPO) List and Application of the 2-Midnight Rule. Accessed August 21, 2021. https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE19002.pdf.
62. Alkaaki A, Al-Radi OO, Khoja A, et al. Surgical site infection following abdominal surgery: a prospective cohort study. *Can J Surg.* 2019;62(2):111–117. doi:10.1503/cjs.004818
63. Helito CP, Sobrado MF, Giglio PN, et al. The use of negative-pressure wound therapy after total knee arthroplasty is effective for reducing complications and the need for reintervention. *BMC Musculoskelet Disord*. 2020;21(1):490.
64. Fowler AL, Barry MK. Closed incision negative pressure therapy: results of recent trials and recommendations for clinical practice. *Surgeon*. 2020;18(4):241–250. doi:10.1016/j.surge.2019.10.007
65. Chambers LM, Morton M, Lampert E, et al. Use of prophylactic closed incision negative pressure therapy is associated with reduced surgical site infections in gynecologic oncology patients undergoing laparotomy. *Am J Obstet Gynecol*. 2020;223(5):731.e1–731.e9. doi:10.1016/j.ajog.2020.05.011
66. Grabarz A, Ghesquiere L, Debarge V, et al. Cesarean section complications according to degree of emergency during labour. *Eur J Obstet Gynecol Reprod Biol*. 2021;256:320–325. doi:10.1016/j.ejogrb.2020.11.047
67. Villers MS. Reducing cesarean delivery surgical site complications. *Obstet Gynecol Clin North Am*. 2020;47(3):429–437. doi:10.1016/j.ogc.2020.04.006.
68. Douville SE, Callaway LK, Amoako A, Roberts JA, Eley VA. Reducing post-caesarean delivery surgical site infections: a narrative review. *Int J Obstet Anesth*. 2020;42:76–86. doi:10.1016/j.ijoa.2019.08.007
69. Lazar HL, Vander Salm T, Engelman R, Orgill D, Gordon S. Prevention and management of sternal wound infections. *J Thorac Cardiovasc Surg.* 2016;152(4):962–972. doi:10.1016/j.jtcvs.2016.01.060
70. Raja SG, Rochon M, Jarman JWE. Brompton Harefield Infection Score (BHIS): development and validation of a stratification tool for predicting risk of surgical site infection after coronary artery bypass grafting. *Int J Surg.* 2015;16(Pt A):69–73. doi:10.1016/j.ijsu.2015.02.008.
71. Tabley A, Aludaat C, Le Guillou V, et al. A survey of cardiac surgery infections with PICO negative pressure therapy in high-risk patients. *Ann Thorac Surg.* 2020;110(6):2034–2040. doi:10.1016/j.athoracsur.2020.03.087
72. Cataneo DC, Dos Reis TA, Felisberto G, Rodrigues OR, Cataneo AJM. New sternal closure methods versus the standard closure method: systematic review and meta-analysis. *Interact Cardiovasc Thorac Surg.* 2019;28(3):432–440. doi:10.1093/icvts/ivy281
73. Fang CL, Changchien CH, Chen MS, Hsu CH, Tsai CB. Closed incision negative pressure therapy following abdominoplasty after breast reconstruction with deep inferior epigastric perforator flaps. *Int Wound J.* 2020;17(2):326–331. doi:10.1111/iwj.13273
74. Rudolph M, Moore C, Pestana IA. Operative risk stratification in the obese female undergoing implant-based breast reconstruction. *Breast J.* 2019;25(6):1182–1186. doi:10.1111/tbj.13434
75. McCulloch P, Morgan L, New S, Catchpole KR. Combining systems and teamwork approaches to enhance the effectiveness of safety improvement interventions in surgery: the Safer Delivery of Surgical Services (S3) Program. *Ann Surg.* 2017;265(1):90–96. doi:10.1097/SLA.0000000000001589
76. Flynn LC, McCulloch PG, Morgan LJ, et al. The Safer Delivery of Surgical Services Program (S3): explaining its differential effectiveness and exploring implications for improving quality in complex systems. *Ann Surg.* 2016;264(6):997–1003. doi:10.1097/SLA.0000000000001583
77. Badia JM, Rubio-Perez I, Lopez-Menendez J, et al. The persistent breach between evidence and practice in the prevention of surgical site infection. Qualitative study. *Int J Surg.* 2020;82:231–239. doi:10.1016/j.ijsu.2020.08.027.
78. Fan CJ, Pawlik TM, Daniels T, et al. Association of safety culture with surgical site infection outcomes. *J Am Coll Surg*. 2016;222(2):122–128. doi:10.1016/j.jamcollsurg.2015.11.008
79. Ciprandi G, Djohan R, Dohmen PM, Sibai BM, Sugrue M, Tanner J. World Union of Wound Healing Societies Consensus Document. Closed surgical incision management; understanding the role of NPWT. *Wounds Int*. Accessed August 22, 2021. https://www.woundsinternational.com/resources/details/consensus-document-closed- surgical-incision-management-understanding-the-role-of-npwt-wme
80. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR. Guideline for prevention of surgical site infection, 1999. Hospital Infection Control Practices Advisory Committee. *Infect Control Hosp Epidemiol*. 1999;20(4):250–278.
81. The Society for Healthcare Epidemiology of America. Accessed September 1, 2021. https://www.shea-online.org
82. Lutfiyya W, Parsons D. A colorectal "care bundle" to reduce surgical site infections in colorectal surgeries: a single-center experience. *Permanente J.* 2012;16(3):10–16.
83. Carter EB, Temming LA, Fowler S, et al. Evidence-based bundles and cesarean delivery surgical site infections: a systematic review and meta-analysis. *Obstet Gynecol*. 2017;130(4):735-746. doi:10.1097/AOG.0000000000002249
84. Gustafsson UO, Scott MJ, Hubner M, et al. Guidelines for perioperative care in elective colorectal surgery: Enhanced Recovery After Surgery (ERAS) Society recommendations: 2018. *World J Surg.* 2019;43(3):659–695. doi:10.1007/s00268-018-4844-y

70 E. Swedesford Road, Suite 100, Malvern, PA 19355

HMP is the force behind Healthcare Made Practical and is a multichannel leader in healthcare events and education with a mission to improve patient care. The company produces accredited medical education events and clinically relevant, evidence-based content for the global healthcare community across a range of therapeutic areas. For more information, visit hmpglobal.com.