Developing Evidence-Based Algorithms for Negative Pressure Wound Therapy in Adults with Acute and Chronic Wounds: Literature and Expert-based Face Validation Results

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Abstract
Negative pressure wound therapy (NPWT) is used extensively in the management of acute and chronic wounds, but concerns persist about its efficacy, effectiveness, and safety. Available guidelines and algorithms are wound type-specific, not evidence-based, and many lack clearly described relative and absolute contraindications and stop criteria. The purpose of this research was to: 1) develop evidence-based algorithms for the safe use of NPWT in adults with acute and chronic wounds by nonwound expert clinicians, and 2) obtain face validity for the algorithms. Using NPWT meta-analyses and systematic reviews (n = 10), NPWT guidelines of care (n = 12), general evidence-based guidelines of wound care (n = 11), and a framework for transitioning between moisture-retentive and NPWT care (n = 1), a set of three algorithms was developed. Literature-based validity for each of the 39 discreet algorithm steps/decision points was obtained by reviewing best available evidence from systematic literature reviews (n = 331 publications) and abstraction of all NPWT-relevant publications (n = 182) using the patient-oriented Strength of Recommendation (SORT) taxonomy. Of the 182 NPWT studies abstracted, 25 met criteria for level 1 and 2 evidence but only one general assessment step had both level 1 evidence and an “A” strength of recommendation. Next, an Institutional Review Board-approved, cross-sectional mixed methods survey design face validation pilot study was conducted to solicit comments on, and rate the validity of, the 51 discreet algorithm-related statements, including the 39 decisions/steps. Twelve (12) of the 15 invited interdisciplinary wound experts agreed to participate. The overall algorithm content validity index (CVI) was high (0.96 out of 1). Helpful design suggestions to ensure safe use were made, and participants suggested an examination of commonly used wound definitions in follow-up studies. Results of the literature-based face validation confirm that the evidence base for using NPWT remains limited, especially for chronic wounds, and that safety guidance may be affected by the fact that evidence-based ratings cannot accurately reflect relative or absolute product contraindications because they simply are not included in clinical studies. These findings, the positive expert panel comments, and the high CVI confirm the need for an algorithm with explicit NPWT start-and-stop criteria and suggest that follow-up content and construct validation of these algorithms is warranted.

Keywords: wounds, algorithms, negative pressure wound therapy, validation studies, evidence-based medicine/classification

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Ever since devices to replace improvised systems for the removal and collection of excess wound exudate became commercially available, negative pressure wound therapy (NPWT) systems have been widely used. Initially, only one type of NPWT system was marketed by a single manufacturer, but recently many other NPWT devices have been introduced into the healthcare professional market-place.

Major impetus for generating a new perspective on NPWT usage are its clinical cost and limited knowledge about its cost effectiveness for the wide variety of clinical indications. General evidence to substantiate current indications and contraindications for use is limited and sometimes contradictory. Algorithms providing a step-by-
step visual interpretation of some NPWT guidelines have been developed for specific types of wounds, but most are based on expert consensus, have not been validated, and do not include guidance for when NPWT treatment should be discontinued.3-7

The purpose of this research was to: 1) develop an evidence-based algorithm for nonwound expert clinician use of NPWT that would provide stepwise evaluation and assessment strategies for optimal use and strategies for transitioning between moist wound healing and NPWT in adults with acute and chronic wounds; 2) obtain face validity for the algorithms, and ultimately, 3) obtain algorithm content validity.

Background

In the fall 2009, following Food and Drug Administration (FDA) reports about adverse events related to NPWT use, a research proposal was constructed by the researchers at the request of industry (Convatec, Inc, Skillman, NJ) in preparation for possible grant funding to La Salle University, targeting these issues, including specifically to: 1) develop a set of evidence-based algorithms targeting safe use of NPWT in adults with acute or chronic wounds; 2) test the newly formulated NPWT algorithms for face validity, 3) revise algorithms as needed, and 4) obtain full content validation of the algorithms with possible further revisions as needed.

As part of the initial process, also in the fall of 2009, an expert consensus meeting with international and national wound care clinicians was held to discuss goals and considerations for NPWT use, goals of moist wound healing, and overall wound management issues for pressure ulcers, diabetic foot ulcers, venous and arterial ulcers, skin grafts/skin substitutes, and complex trauma and surgical wounds. Preliminary feedback was synthesized, and the final formalized consensus guidelines subsequently were published.9

Evidence-Based Algorithm Development

Initial literature review and algorithm framework development. To start the process of algorithm development, a systematic literature search was conducted to identify meta-analyses and systematic reviews of NPWT published between 2005 and 2009 using CINAHIL, PubMed, and EMBASE, as well as the Cochrane and Joanna Briggs Institute databases. Ten (10) publications were identified,2,4,10-17 Indications and contraindications were abstracted and references cited in the documents obtained (see Figure 1).

Next, existing NPWT algorithms for specific wound types and guidelines of care were retrieved using the same databases and expanding the publication range to between the years 2003 and 2010. This search initially yielded 12 references.3,5,7,9,18-24

The abstracted information was reviewed and summarized, and a general indications and contraindications framework was developed. Next, the algorithm framework was compared to published evidence-based guidelines and algorithms of patient and wound care25-36 in order to rule out any inconsistencies or discrepancies.

Before initiating the broader literature searches, a spreadsheet was created containing all variables that affect NPWT wound treatment decisions (exudate amount, depth, wound bed characteristics, surrounding skin condition, and other factors)5,26-28,36-40 and that might serve as potential NPWT start/stop criteria. In addition, an existing algorithm (Solutions®, Convatec, Skillman, NJ) was reviewed for information affecting transition to moist wound healing.41 The Solutions Algorithms were selected because they are the only validated wound care algorithms for acute and chronic wounds. They are listed in the National Guidelines Clearinghouse.

Wound debridement status, study type, design, sample size, outcomes, complications, and general conclusions or recommendations from the research were abstracted and the quality of the evidence and strength of recommendation recorded.42

Strength-of-evidence ratings. The Strength of Recommendation (SORT) Taxonomy42 was used to abstract and record the level of evidence (study quality) and strength of recommendation in the spreadsheet for all publications reviewed. Study quality is based on patient-oriented evidence (expressed as a number grade of 1 through 3). Strength of recommendation is expressed using letter grades, where A means the recommendation is based on consistent and good quality patient-oriented evidence, B denotes inconsistent or limited-quality patient-oriented evidence, and C is based on consensus, usual practice, opinion, disease-oriented evidence, or case series. All information from previous and subsequent literature search-
Figure 1. NPWT algorithm development and face validation.
Ongoing literature review. Systematic literature searches were conducted at the start of the algorithm development process and periodically updated for the next 2 years until September 2011. Using the same databases as those used for the initial search and starting with a 2005 year of publication, the following search terms were used to obtain NPWT publications: negative pressure wound therapy, VAC therapy, negative pressure dressings, topical negative pressure, vacuum-assisted closure, negative pressure therapy, subatmospheric pressure dressing, subatmospheric pressure, and TNP. Older “classic” articles identified in the literature also were included, as were pertinent technology reviews. Preclinical study results were not included in the evidence database, but publications were reviewed to glean potential information that might affect NPWT indications, usage, and/or transition to a moisture-retentive dressing regimen.

Literature review result. A total of 331 publications, including the literature used to develop the initial framework, was retrieved and reviewed. Of those, 182 were clinical studies and clinically relevant publications on NPWT that were systematically reviewed, graded, and abstracted. This process revealed important trends. For example, many more studies support the use of NPWT for acute than for chronic wounds. Clinically relevant publications and studies on the use of NPWT for acute wound conditions included: mediastinitis, surgical myocutaneous flaps, laparotomy wounds, lower extremity amputation or surgically debrided wounds in persons with diabetes mellitus, abdominal compartment syndrome or open abdomen, skin graft recipient, fractures and trauma, skin graft donor sites, and other complex acute or surgical wounds.

Clinical studies or clinically relevant publications about the use of NPWT on pressure ulcers and other chronic, non-healing wounds were much less available.

Literature reviews, guidelines, and consensus statements on the use of NPWT in various wound care scenarios or articles describing individual case studies or recommendations were frequently encountered.

Of all the NPWT studies identified, 25 met the SORT criteria for level 1 or 2 evidence. Of those, 12 described study results of acute wounds and seven described chronic wounds and six detailed chronic and acute wound study results. In developing the algorithm framework, the researchers identified a need to review other literature sources and obtain evidence level on algorithm components such as patient goals of care. For example, wound healing may not be a goal of a palliative protocol of care.

Apligraf® Essential Prescribing Information

Device Description: Apligraf is supplied as a living, bi-layered skin substitute manufactured from cells processed under aseptic conditions using neonatal foreskin-derived keratinocytes and fibroblasts with bovine type I collagen. (1)

Intended Use/Indications: Apligraf is indicated for use with standard therapeutic compression in the treatment of uninfected partial and/or full-thickness skin loss ulcers due to venous insufficiency of greater than 1 month duration and which have not adequately responded to conventional ulcer therapy. (2)

Apligraf is indicated for use with standard diabetic foot ulcer care for the treatment of full-thickness foot ulcers of neuropathic etiology of at least three weeks duration, which have not adequately responded to conventional ulcer therapy and extend through the dermis but without tendon, muscle, capsule or bone exposure. (2)

Contraindications: Apligraf is contraindicated for use on clinically infected wounds and in patients with known allergies to bovine collagen or hypersensitivity to the components of the shipping medium. (3, 4, 5, 8)

Warnings and Precautions: If the expiration date or product pH (6.8-7.7) is not within the acceptable range DO NOT OPEN AND DO NOT USE the product. A clinical determination of wound infection should be made based on all of the signs and symptoms of infection. (4, 5)

Adverse Events: All reported adverse events, which occurred at an incidence of greater than 1% in the clinical studies are listed in Table 1, Table 2 and Table 3. These tables list adverse events both attributed and not attributed to treatment. (6)

Maintaining Device Effectiveness: Apligraf has been processed under aseptic conditions and should be handled observing sterile technique. It should be kept in its tray on the medium in the sealed bag under controlled temperature 68°F-73°F (20°C-23°C) until ready for use. Apligraf should be placed on the wound bed within 15 minutes of opening the package. Handling before application to the wound site should be minimal. If there is any question that Apligraf may be contaminated or compromised, it should not be used. Apligraf should not be used beyond the listed expiration date. (9)

Use in Specific Populations: Apligraf has not been established in pregnant women, acute wounds, burns and ulcers caused by pressure.

Patient Counseling Information: VLU patients should be counseled regarding the importance of complying with compression therapy or other treatment, which may be prescribed in conjunction with Apligraf. DFU patients should be counseled that Apligraf is used in combination with good ulcer care including a non-weight bearing regimen and optimal metabolic control and nutrition. Once an ulcer has healed, ulcer prevention practices should be implemented including regular visits to appropriate medical providers.

Treatment of Diabetes: Apligraf does not address the underlying pathophysiology of neuropathic diabetic foot ulcers. Management of the patient’s diabetes should be according to standard medical practice.

How Supplied: Apligraf is supplied sealed in a heavy gauge polyethylene bag with a 10% CO2 atmosphere and argon to maintain viability. Each Apligraf is supplied ready for use and intended for application on a single patient. To maintain cell viability, Apligraf should be kept sealed in its tray on the medium in the sealed bag at controlled temperature 68°F-73°F (20°C-23°C) until use. Apligraf is supplied as a circular disk approximately 75 mm in diameter and 0.75 mm thick. (8)

Patent Number: 5,536,656

Manufactured and distributed by: Organogenesis Inc. Canton, MA 02021

REV: December 2010

300-111-B


Please see complete prescribing information at www.Apligraf.com

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The literature was reviewed for moist wound healing indications and wound debridement.

In addition, the need to obtain updated literature on risk factors for delayed wound healing and chronic wound development was identified to support the underlying algorithm structure, specifically publications addressing care of venous ulcers, arterial ulcers, pressure ulcers, diabetic ulcers and wound pain management/quality of life, patient education, and nutritional support issues.

Algorithm refinement.

Using the previously developed framework and observations from the literature, the algorithms were developed to provide a step-by-step approach to NPWT implementation and discontinuation in adults only, but the pediatric literature was reviewed to glean usage criteria that may not have been included in other publications.

The first algorithm takes users through the initial patient and wound assessment steps to: 1) develop goals of patient and wound care, and 2) assess patient and wound variables affecting safe and appropriate use of NPWT and potential alternatives (eg, moist wound healing). NPWT contraindications and safety-related stop criteria are highlighted. The next two algorithms help users decide when to continue or stop NPWT when managing acute (algorithm 2) or chronic wounds (algorithm 3) (see Figures 2, 3, 4).

In addition, using information from the literature...
search results, the algorithms’ structure was derived from several sources, including the validity of decision points and data inherent in previously content and construct validated Solutions’ Wound Care Algorithms,©27,28,192 consensus conference suggestions for transitioning to moist wound care provided by an expert group,© and established algorithm development criteria.193

Face Validation Methods and Procedures

Literature-based validation. SORT level of evidence and strength of recommendation tables were developed for the 39 discreet decision points/steps in the algorithms. The abstracted information was used to populate the evidence table, containing 39 algorithm components. When evidence gaps were identified in the NPWT or other recommendations, additional literature searches were conducted to identify (in this order): meta-analyses, systematic reviews, validated decision rules, randomized controlled clinical studies, noncontrolled clinical studies, case studies, and consensus documents. If publications with higher levels of evidence were found to support a decision, the literature search for that particular variable was stopped. The detailed literature reviews and evidence development process led to several revisions (five drafts) before the algorithm was presented for external (expert) face validation (see Figures 2, 3, and 4).

Expert face and content validation. The purpose of

Figure 3. NPWT Algorithm II — Surgical/Acute Wounds.
Algorithm #3 Chronic Wound  For use in adult patients only.

**To be completed at every dressing change**

**Wound Assessment**

(A) Wound Bed/Exudate

<table>
<thead>
<tr>
<th>Moist / Wet</th>
<th>Dry / Moist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderately / Heavily Exuding</td>
<td>Minimal moisture / Lightly Exuding</td>
</tr>
</tbody>
</table>

(B) Goal of Patient Care/ Patient Care Plan

Reduce risk factors for chronic wound development and delayed healing including presence of infection (see 1 C)

(C) Wound Depth

Partial or Full Thickness (sufficient depth to accommodate dressing) | Superficial

(D) Wound Bed/Tissue

Wound bed contains: < 25% moist necrotic tissue/slush and > 75% granulation tissue | Wound bed contains: 100% granulation tissue | Wound bed contains: Dry necrotic tissue and/or > 25% moist necrotic tissue/slush

STOP/DEBRIDE

Complete initial assessment (Algorithm 1) and wound assessment (Algorithm 2) following debridement

(E) Wound Bed/Anatomical Considerations

Tendons, ligaments, blood vessels, nerves, organs and other vital structures are covered by granulation tissue or muscle flap.

**CAUTION**

No exposed vital structures. Review product package insert procedures re. use of appropriate interface or appropriateness of moist wound healing (Solutions® Algorithms)

(F) Wound Type/Goal of Wound Care

Tertiary intention healing
Facilitate granulation tissue formation

Secondary intention healing
Facilitate granulation tissue formation and re-epithelialization

(G) Follow Up

Complete wound assessment algorithm every 2 to 3 days (3 A).
Discontinue use if algorithm no longer applies and/or surgical closure is indicated.*

Complete wound assessment algorithm every 2 to 3 days (3 A). Assess risk factors and patient care plan (1 C) and algorithm appropriateness if wound size reduction < 20% after 2-4 weeks of care.* Consider appropriateness of moist wound healing (Solutions® Algorithms)

* Examples of when to discontinue NPWT include: development of contraindications listed in 1 (D), patient refuses NPWT, wound has minimal/no exudate, is superficial or almost healed, not improving or deteriorating, or surgical closure is indicated.

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Figure 3. NPWT Algorithm III — Chronic Wounds.
Table 1. Expert face validation participants demographic data (N = 12)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Sample size N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>US state of practice</td>
<td></td>
</tr>
<tr>
<td>• AZ (8%)</td>
<td>1 (8%)</td>
</tr>
<tr>
<td>• CT (8%)</td>
<td>1 (8%)</td>
</tr>
<tr>
<td>• MA (16%)</td>
<td>2 (16%)</td>
</tr>
<tr>
<td>• NC (16%)</td>
<td>2 (16%)</td>
</tr>
<tr>
<td>• NY (8%)</td>
<td>1 (8%)</td>
</tr>
<tr>
<td>• PA (16%)</td>
<td>2 (16%)</td>
</tr>
<tr>
<td>• TN (8%)</td>
<td>1 (8%)</td>
</tr>
<tr>
<td>• TX (8%)</td>
<td>1 (8%)</td>
</tr>
<tr>
<td>• No response</td>
<td>1 (8%)</td>
</tr>
<tr>
<td>Professional degree</td>
<td></td>
</tr>
<tr>
<td>• MD (25%)</td>
<td>3 (25%)</td>
</tr>
<tr>
<td>• PT (17%)</td>
<td>2 (17%)</td>
</tr>
<tr>
<td>• RN (8%)</td>
<td>1 (8%)</td>
</tr>
<tr>
<td>• APN (NP/CNS) (25%)</td>
<td>3 (25%)</td>
</tr>
<tr>
<td>• PA (8%)</td>
<td>1 (8%)</td>
</tr>
<tr>
<td>• Podiatrist</td>
<td>2 (17%)</td>
</tr>
<tr>
<td>Types of wound care certification</td>
<td></td>
</tr>
<tr>
<td>• CWOCN (42%)</td>
<td>5 (42%)</td>
</tr>
<tr>
<td>• CWS (16%)</td>
<td>2 (16%)</td>
</tr>
<tr>
<td>• Other (42%)</td>
<td>5 (42%)</td>
</tr>
<tr>
<td>Level of highest education</td>
<td></td>
</tr>
<tr>
<td>• Diploma</td>
<td>0</td>
</tr>
<tr>
<td>• Baccalaureate</td>
<td>0</td>
</tr>
<tr>
<td>• Master’s</td>
<td>5 (42%)</td>
</tr>
<tr>
<td>• PhD/EdD/MD</td>
<td>7 (58%)</td>
</tr>
<tr>
<td>Years of nursing/health clinician experience</td>
<td></td>
</tr>
<tr>
<td>• 30 and above</td>
<td>5 (42%)</td>
</tr>
<tr>
<td>• 25–29</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>• 20–24</td>
<td>1 (8%)</td>
</tr>
<tr>
<td>• 15–19</td>
<td>3 (25%)</td>
</tr>
<tr>
<td>• 10–14</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>• 5–9</td>
<td>2 (17%)</td>
</tr>
<tr>
<td>• 0–4</td>
<td>1 (8%)</td>
</tr>
<tr>
<td>Estimated (or actual) average number of wound patients encountered per year</td>
<td></td>
</tr>
<tr>
<td>• 200 and above</td>
<td>8 (67%)</td>
</tr>
<tr>
<td>• 150–199</td>
<td>1 (8%)</td>
</tr>
<tr>
<td>• 100–149</td>
<td>1 (8%)</td>
</tr>
<tr>
<td>• 50–99</td>
<td>0 (0%)</td>
</tr>
<tr>
<td>• 0–49</td>
<td>2 (17%)</td>
</tr>
<tr>
<td>Most common wound types&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>• Surgical</td>
<td>8 (67%)</td>
</tr>
<tr>
<td>• Burns</td>
<td>1 (8%)</td>
</tr>
<tr>
<td>• Trauma</td>
<td>4 (33%)</td>
</tr>
<tr>
<td>• Pressure ulcers</td>
<td>5 (42%)</td>
</tr>
<tr>
<td>• Venous stasis</td>
<td>4 (33%)</td>
</tr>
<tr>
<td>• Diabetic foot ulcers</td>
<td>6 (50%)</td>
</tr>
<tr>
<td>Most common wound types using NPWT&lt;sup&gt;b&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>• Surgical</td>
<td>10 (83%)</td>
</tr>
<tr>
<td>• Trauma</td>
<td>4 (33%)</td>
</tr>
<tr>
<td>• Myocutaneous flap/skin grafts</td>
<td>4 (33%)</td>
</tr>
<tr>
<td>• Dehiscence/evisceration</td>
<td>2 (17%)</td>
</tr>
<tr>
<td>• Pressure ulcers</td>
<td>7 (58%)</td>
</tr>
</tbody>
</table>

<sup>a</sup> Percentage adds to >100 due to multiple reporting
negative pressure wound therapy algorithms

mographic data sheet (education, clinical practice issues, types of wounds encountered), 2) content validation rating sheets for all general algorithm descriptions and each decision point/step, and 3) open-ended questions related to participants’ perceptions of specific decision points and the overall process.

The validation instrument consisted of 51 discreet statements related to the construct of the algorithm general statements and 39 decision points/steps. Steps that are repeated in each algorithm were only tested once; hence, the number of decision points/steps tested decreased from 20 for algorithm 1 to 14 for algorithm 3.

Each discreet statement was accompanied by a modified 4-point Likert style rating scale: 1 = not relevant/appropriate; 2 = unable to assess relevance/appropriateness without revision; 3 = relevant but needs minor alteration; and 4 = very relevant and appropriate. After rating the relevance of the components to safe use of NPWT, participants were asked to write comments about statement omissions, provide suggestions for improvement, present

<table>
<thead>
<tr>
<th>Algorithm (number)</th>
<th>Mean content validity index (range, number of response)</th>
<th>Number of publications supporting evidence</th>
<th>Level of evidence/strength of recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial assessment (algorithm 1)</td>
<td>0.96 (0.75–1.0; n = 236)</td>
<td>157 (10%)</td>
<td>Good quality (level 1) evidence n ( %)</td>
</tr>
<tr>
<td>Acute wounds (algorithm 2)</td>
<td>0.97 (0.83–1.0; n = 201)</td>
<td>76 (12%)</td>
<td>25 (33%)</td>
</tr>
<tr>
<td>Chronic wounds (algorithm 3)</td>
<td>0.95 (0.83–1.0; n =152)</td>
<td>43 (9%)</td>
<td>18 (42%)</td>
</tr>
</tbody>
</table>

* Some publications were used to support >1 discreet step in more than one algorithm. Level of evidence/strength of recommendation might vary by step.

<table>
<thead>
<tr>
<th>Algorithm (number of steps)</th>
<th>Level of evidence and strength of recommendation (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
</tr>
<tr>
<td></td>
<td>Good quality (level 1) evidence</td>
</tr>
<tr>
<td>Initial assessment (n = 20)</td>
<td>1</td>
</tr>
<tr>
<td>Acute wounds (n = 17)</td>
<td>0</td>
</tr>
<tr>
<td>Chronic wounds (n = 14)</td>
<td>0</td>
</tr>
</tbody>
</table>
Table 4. Steps/decision points with A level strength of recommendation

<table>
<thead>
<tr>
<th>Algorithm</th>
<th>Step/decision point</th>
<th>Strength of recommendation (level of evidence)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial assessment (algorithm 1)</td>
<td>Reduce risk factors for delayed healing and chronic wound development: venous ulcers — assess/manage edema with elevation, ambulation, compression, ankle flexes. Review surgical/medical management options to improve arterial circulation if appropriate</td>
<td>A (1)</td>
</tr>
<tr>
<td>Initial assessment (algorithm 1)</td>
<td>Reduce risk factors for delayed healing and chronic wound development: pressure ulcers — pressure, shear, friction, dry or moist skin condition</td>
<td>A (2)</td>
</tr>
<tr>
<td>Acute wounds (algorithm 2)</td>
<td>Considering wound type, the goal of care should be to facilitate healing skin graft recipient site</td>
<td>A (2)</td>
</tr>
</tbody>
</table>

an alternative, and provide references to the literature (if possible).

Data collection and analysis. All data were entered into an Excel Version 2003 spreadsheet (Microsoft Corporation) and uploaded into SPSS version 16.0 (SPSS, Inc, Chicago, IL) for analysis. Summary statistics were calculated for demographic variables. Mean, modal, and content validity index (CVI) scores were analyzed. The CVI is calculated by comparing items rated 3 and 4 (relevant/very relevant) versus items rated 1 and 2 (not relevant/unable to assess relevance). Scores closer to 1.0 suggest stronger content validity. A contract transcriptionist with a confidentiality agreement transcribed all participants written responses and comments. Using qualitative data reduction techniques, researchers scrutinized the typed comments for themes and subthemes.

**Results**

Expert validation. Fifteen (15) email invitations were sent and 12 consented (participation rate of 80%). Participants’ average age was 51.6 years (range: 32 – 62, SD 3.81). Seven (7) were women, and all (12) had attended formal wound care classes, obtained wound care certification, and practiced in acute (n = 6), subacute (n = 2), long-term (n = 2), or home care (n = 2). Eight (8) worked in large (>300-bed) and three (3) worked in smaller sized (200- to 999-bed) facilities. All but one were English-speaking only, and all had obtained their basic medical/nursing or healthcare education in the United States; they practiced in eight (8) different US states (see Table 1). The most commonly encountered wounds for which they used NPWT were surgical wounds and pressure ulcers.

Literature-based face validity. The majority of publications available to support the discreet steps in all algorithms consisted of low-level evidence. The percentage of good quality (level 1) evidence ranged from 12% for the acute wound (algorithm 2) to 9% for algorithm 3 (chronic wounds). The percentage of publications with a high strength-of-recommendation level and consistent, good-quality patient-oriented evidence was even lower (1% for acute and 5% for chronic wound algorithms) (see Table 2). Subsequent synthesis of the evidence to support each algorithm step also showed the majority of studies were low-level evidence with a C grade (consensus, usual practice, opinion, or disease-oriented evidence, or case series for studies of diagnosis, treatment, prevention, or screening) for strength of recommendation (see Table 3). Three steps/decision points had an A strength of recommendations (see Table 4).

Quantitative data. On a scale of 1 to 4, the mean score for all algorithm component ratings (N = 589) was 3.72 (SD 0.43, range 3.25 – 4.0). The CVI for all algorithms was 0.96 (out of 1). Ratings that were lower (<3.5) but still rated appropriate were found for 1) considering separate goals of wound care for primary intention (sutured) healing or palliative care, 2) proceed with caution only if coagulation is controlled, and 3) assess wound as surgical/acute or chronic wound. Mean scores and CVI results suggested that the expert panel rated the face validity of content for the NPWT algorithms as “strong and appropriate”.

Qualitative data. Themes of positive response and concern targeted several noteworthy findings, including disagreement and lack of uniformity on definitions of acute versus chronic wound; descriptions for primary-, secondary-, and tertiary-intention healing; and “controlled” coagulation. Other suggestions included areas where clarification was needed (palliative care issues), sepsis specific to wound care, control of coagulation issues (how to operationalize), timing issues in changing NPWT dressings, and clarifications regarding NPWT discontinuation and switching therapy (see Table 5).

The expert panel’s overall comments were organized into four themes (utility/ease of use, helpful guidance, need for definitions, and references needed). Participants believed the NPWT algorithms were user-friendly and helpful, but they recommended two notable areas requi-
Table 5. Qualitative analysis (N = 12), face validation: comments regarding algorithms’ components

<table>
<thead>
<tr>
<th>Step description</th>
<th>Comments/Suggestions</th>
</tr>
</thead>
</table>
| Classify a wound as surgical versus nonsurgical? 1. (A).a                        | • Need reference to literature to support terminology  
• Include post amputation, flaps, fasciotomy wound  
• Add foot ulcers following surgical debridement |
| Classify a nonsurgical wound as acute or chronic? 1. (A).b                       | • Add a time element for chronic (e.g., >2–4 weeks)  
• Chronic is similar to pressure ulcer/leg or foot ulcers medically managed without surgery |
| Consider separate goals of wound care for primary intention (sutured) healing or palliative care? 1. (B).a | • Need reference to literature to support  
• Is palliative the right word?  
• Include the “Solutions Algorithms” here  
• Chronic wounds do not heal by primary intention  
• Add an arrow |
| Consider goals of care and appropriateness of moist wound healing for sutured wounds and palliative care? 1. (B).b | • Somewhat confusing — need large box that says sutured or palliative and if yes, stop  
• Clarify this means NPWT not indicated |
| Develop a patient care goal/care plan that reduces risk factors for delayed healing and chronic wound development in acute and chronic wounds 1. (C).a | • What about healibility and adherence factor?  
• Some goals of care are applicable even to palliative care (e.g., pain management) |
| For all surgical/nonsurgical wounds: confirm presence of and treat infection, assess, and manage wound pain, assess and optimize nutritional status, assess patient/caregiver knowledge and provide education, maintain glycemic control 1. (C).b | • Suggest assessing for necrotic tissue  
• If factors cannot be treated or corrected, then what? |
| Identify presence of NPWT contraindications/precautions 1. (D).a                | • Suggest adding necrotic tissue and lack of perfusion to site  
• Add uncontrolled pain |
| Do not proceed with NPWT in the presence of; untreated osteomyelitis, sepsis, or coagulopathy 1. (D).b | • Sepsis has to be wound related (e.g., urosepsis is not contraindication)  
• Is coagulopathy the same as anti-coagulation therapy? |
| Proceed with caution only if: coagulation is controlled 1. (D).f                 | • Keep exposed blood vessel separate from tendon  
• Need reference to literature to support  
• Define “controlled” (coumadin versus low molecular weight heparin versus heparin drip)  
• Need better explanation of coagulation |
| Assess level of wound exudate as moist/wet versus dry/moist 1. (E).a             | • Use arrow “moist → wet” “dry → moist”  
• Dry wound not documented as lightly exuding; usually called dry |
| Do not proceed with NPWT/consider appropriateness of moist wound healing if wound is dry or has minimal moisture 1. (E).b | • Most consider tissue-interface dressing uses |
| Assess wound depth as partial-/full-thickness versus superficial depth 1. (F).a | • Define partial- versus full-thickness  
• Partial-thickness typically not deep enough to accommodate (NPWT) dressing  
• Partial-thickness is clinically “superficial” |

Continued
Table 5. Qualitative analysis (N = 12), face validation: comments regarding algorithms’ components

<table>
<thead>
<tr>
<th>Feature</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assess wound as surgical/acute or chronic wound 1.(G).a</td>
<td>• Consider adding time element for chronic (burn &gt;2 years is chronic) • Define acute versus chronic • Could have a chronic surgical wound</td>
</tr>
<tr>
<td>Consider NPWT if chronic wound not responsive to 2–4 weeks of appropriate care 1.(G).b</td>
<td>• Define chronic wound • Could present an alternative</td>
</tr>
<tr>
<td>Consider appropriateness of moist wound healing if wound responsive to appropriate care (&gt;20% reduction in size after 2–weeks of care) 1.(G).c</td>
<td>• Depends on size of wound even after size reduction &gt;20% • I would say &gt;20% in 2 weeks and 50% in 4 weeks • Should be near top of algorithm — 2–4 weeks of conservative care needed to qualify for NPWT</td>
</tr>
<tr>
<td>Complete a wound assessment at every dressing change 2.</td>
<td>• Helpful to take pictures to document wound progression • May not be needed at every dressing change</td>
</tr>
<tr>
<td>Debride if wound bed contains dry necrotic tissue and/or &gt;25% moist necrotic tissue/slough 2. (D)</td>
<td>• Is this algorithm reference 2D? • Present an alternative • Stable eschar on heels not debrided; must ensure adequate flow and wound etiology</td>
</tr>
<tr>
<td>Assess anatomical components of wound bed (exposed tendons, ligaments, nerves, organs, blood vessels) 2. (E).a</td>
<td>• In box suggest saying “tendons, ligaments …. Structures are not exposed” or “are covered by granulation tissue” • Present an alternative • If structures are likely to see damaged by NPWT, likely is not appropriate wound care</td>
</tr>
<tr>
<td>If vital structures are exposed, remind user about use of appropriate interface or consider appropriateness of moist wound healing 2. (E).b</td>
<td>• Would recommend “to include wound bed preparation for surgical closure” • Add prepare for skin graft/flap closure • Consider saying “stabilization/take in parentheses after facilitate healing”</td>
</tr>
<tr>
<td>Considering wound type, the goal of care should be to facilitate: healing skin graft recipient site 2. (F).a</td>
<td>• Every 5–7 days? • Some recipient sites have to be 5 days before first change; make 5 to 7 days • Provide reference to literature to support</td>
</tr>
<tr>
<td>For skin graft recipient site complete wound assessment every 3 to 7 days 2.(G).a</td>
<td>• 3–5 days</td>
</tr>
<tr>
<td>For tertiary intention healing complete, wound assessment every 2–3 days 2. (G).b</td>
<td>• Recommend to include “wound bed preparation for surgical closure” • Review current clinical picture and alter therapy if needed • If wound with large defect continues to granulate with NPWT, still appropriate to continue</td>
</tr>
<tr>
<td>Discontinue NPWT if: surgical closure is indicated 2. (G).d</td>
<td>• Can use NPWT in conjunction with moist interface • Debride and reapply NPWT?</td>
</tr>
<tr>
<td>Wound has minimal no exudate 2.(G).g</td>
<td>• Need reference to literature to support • Necrosis with undermining in chronic wounds (ie, pressure ulcers)</td>
</tr>
<tr>
<td>Wound is not improving or deteriorating 2.(G).i</td>
<td></td>
</tr>
</tbody>
</table>
Debride if wound contains dry necrotic tissue and/or >25% moist necrotic tissue/slough 3, (D), b

For tertiary intention healing complete wound assessment every 2–3 days 3, (G), a

For secondary intention healing complete wound assessment every 2–3 days 3, (G), b

For secondary intention healing, assess patient care plan and algorithm appropriateness of wound size reduction <20% after 2–4 weeks of care 3, (G), c

Discontinue NPWT if: surgical closure is indicated 3, (G), d

- Need explanation for improved clarity/succinctness/appropriateness
- Every 3–5 days
- Is this at the time of dressing change?
- Tertiary intention is not a term used for chronic wound healing
- Put in red letters (wound size reduction <20% after 2-4 weeks of care)
- Good
- Would recommend to include wound bed preparation for surgical closure
- If wound still with large defect continues to granulate with NPWT, it is still appropriate to continue
- Consider adding if pain is unmanageable with dressing changes

Another component with some disagreement was assess wound as surgical/acute or chronic wound. Reviewers called for clear evidence- or literature-based references for “chronic” wound. Some described situations in which acute or chronic wound could be confused.

The small number of problematic, lower-rated steps was relatively unsurprising, given the fact the algorithms were constructed based on an exhaustive systematic literature review, existing evidence-based reviews, expert consensus, and controlled trials — ie, using known criteria for guideline development197 and generally following the Appraisal of Guidelines for Research and Evaluation (AGREE) items and domains for clinical guideline development.198

On the other hand, the confusion over wound terminology among experts was somewhat surprising, but these concerns continue to be identified27, 28, 192, 199 and need to be addressed in future research. Interestingly, the NPWT literature itself may add to the ongoing confusion. For example, among the NPWT studies reviewed, it is not uncommon for research conducted in postamputation (acute) wounds78 to be described as evidence for diabetic foot24 or chronic wound treatment.112

Evidence levels. Although face validity results were strong and confirmed the literature-based recommendations used for algorithm development, the overall level of evidence and strength of evidence for using NPWT was low, confirming the results of previously published systematic reviews using different evidence rating criteria.2, 14, 15

Table 5. Qualitative analysis (N = 12), face validation: comments regarding algorithms’ components

<table>
<thead>
<tr>
<th>Comment</th>
<th>Component</th>
</tr>
</thead>
<tbody>
<tr>
<td>Need explanation for improved clarity/succinctness/appropriateness</td>
<td>Debride if wound contains dry necrotic tissue and/or &gt;25% moist necrotic tissue/slough 3, (D), b</td>
</tr>
<tr>
<td>Every 3–5 days</td>
<td>For tertiary intention healing complete wound assessment every 2–3 days 3, (G), a</td>
</tr>
<tr>
<td>Is this at the time of dressing change?</td>
<td>For secondary intention healing complete wound assessment every 2–3 days 3, (G), b</td>
</tr>
<tr>
<td>Tertiary intention is not a term used for chronic wound healing</td>
<td>For secondary intention healing, assess patient care plan and algorithm appropriateness of wound size reduction &lt;20% after 2–4 weeks of care 3, (G), c</td>
</tr>
<tr>
<td>Put in red letters (wound size reduction &lt;20% after 2-4 weeks of care)</td>
<td>Discontinue NPWT if: surgical closure is indicated 3, (G), d</td>
</tr>
<tr>
<td>Good</td>
<td>Need explanation for improved clarity/succinctness/appropriateness</td>
</tr>
<tr>
<td>Would recommend to include wound bed preparation for surgical closure</td>
<td>Every 3–5 days</td>
</tr>
<tr>
<td>If wound still with large defect continues to granulate with NPWT, it is still appropriate to continue</td>
<td>Is this at the time of dressing change?</td>
</tr>
<tr>
<td>Consider adding if pain is unmanageable with dressing changes</td>
<td>Tertiary intention is not a term used for chronic wound healing</td>
</tr>
</tbody>
</table>

* Only algorithm steps with written comments are included in table. First number refers to algorithm number. Capital (upper case) letter refers to major algorithmic step within algorithm. Small (lower case) letter refers to choices within the specified step within the algorithm.
Evidence-rating criteria, including SORT used for this review, have strengths and weaknesses that must be taken into account. The authors chose the SORT, patient-outcome oriented evidence assessment because 1) the ultimate goal of care, including use of these algorithms, is to improve patient outcomes, and 2) the criteria used make a clear and important distinction between the type of studies needed to obtain evidence for diagnosis, treatment/prevention/screening, and prognosis.

However, even though 25 of the 182 NPWT publications (14%) met the initial criteria for level 1 or 2 evidence, only one NPWT-related recommendation had sufficient and consistent evidence for an A strength of recommendation (see Table 4). Many NPWT studies report disease-oriented outcomes. Although interim outcomes (eg, reduced amount of exudate) can be useful, unless they have been shown to directly correlate with a patient outcome, their clinical utility is limited.

Another important limitation is that some well-established interventions, such as the need to assess a wound before dressing application, have not been studied and are unlikely to be the subject of future research, given potential ethical barriers. As a result, their level of evidence and strength of recommendation are low and unlikely to increase using standard strength-of-evidence ratings. Finally, for some recommendations, the collective evidence of the “opposite” action or decision point, instead of the actual step, was strong or a particular type of wound was simply not included in studies. For example, the algorithms guide users toward debridement of wounds containing necrotic tissue and transitioning to a moisture-retentive dressing protocol of care for superficial wounds and those with limited amounts of exudate. Technically, these recommendations could not be supported with high levels of evidence or a strong recommendation, but the collective evidence of the “opposite” was strong because almost all NPWT studies only include wounds that are: 1) full-thickness, 2) highly exuding, or 3) clean/debrided. In other words, the recommendation not to use NPWT on lightly exuding, superficial, or nondebrided wounds is based on the absence of evidence to do so. From a clinical and practical point of view, this is an important limitation when using any type of strength-of-evidence rating system for clinical algorithms. Also, it is possible that some evidence ratings would be stronger if a clinical guideline instead of an algorithm format is used, because, by definition, algorithm steps are more narrowly defined than guideline recommendations.

Implications for Clinical Practice, Education, and Research

The NPWT algorithms were developed with the intention of providing evidence-based guidance on safe, appropriate use of NPWT for acute and chronic wound care (surgical and nonsurgical wounds) in adults. In general, the literature- and expert-based face validation phase supported their preliminary content validity among a small panel of international experts. With revisions incorporated, they will be submitted for larger content validation with a substantially larger group of wound experts. If content validity can be established, and with appropriate education, these algorithms should be easier to implement in clinical practice than currently available sets of guidelines. Designed for nonexpert users, the NPWT algorithms may help patient safety by clearly recognizing safe and potentially unsafe patient care situations, but such thinking awaits further testing.

The research implications for the NPWT algorithms are substantial. Further content validation is needed, and effect on patient outcomes should be tested.

Limitations

In addition to some of the evidence-level limitations described, any extant research has some degree of limitations, and this face validation study is no exception. Although developed based on the current best available evidence on NPWT and wound expert consensus, the NPWT algorithms must be tested. This face validation phase provides a critical but still preliminary step in establishing the construct validity of these algorithms. As previously stated, there is more evidence for the use of NPWT in acute than in chronic wounds, and the content of the algorithms is based on the science as currently constructed.

Another limitation is the focus of the NPWT algorithms on adults. No effort was made to scrutinize care issues for pediatric use. This is an area crying out for further research.

Finally, face validation is usually performed with a small group of experts in a selected area (eg, wound care). Similar to a pilot study, the instrument or algorithm must subsequently be tested or validated with a substantially larger sample size.

Conclusion

Safety in wound care delivery is a major concern for all clinicians, and it has become a strong focus in the use of NPWT. Algorithms may help clarify and expedite clinical decisions about when to safely start and when to stop using NPWT. This study has confirmed the face validity of a new set of algorithms designed to guide care for NPWT in adults with acute and chronic wounds. The results also suggest a need for further analysis of wound care definitions and terminology.

Acknowledgment

The authors are grateful for the constructive and helpful comments provided by all wound expert study volunteers.

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