Evidence, Research, and Clinical Practice: A Patient-Centered Framework for Progress in Wound Care

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Abstract
Traditional criteria used in selecting wound care interventions are being slowly replaced with an evidence-based practice approach. The value of such an approach for providing optimal care has been established, but the definition of evidence-based care and the process used to generate evidence continue to evolve. For example, the role of studies developed to demonstrate efficacy, randomized controlled trials (RCT), the value of effectiveness studies designed to evaluate outcomes in real world practice, and the use of disease-oriented (interim) study outcomes for wound care research such as reduces wound fluid or improves granulation tissue formation have been topics of international conversations and consensus documents. In addition, the use in some clinical studies and most systematic study reviews of ingredient- or characteristic-based categories to group products that may not share a common operational definition of how they function has led to a high variability in outcomes, resulting in inconclusive or low-level evidence. These concerns and debates, along with their influence on practice, may cast doubt on the value of evidence-based practice guidelines for some clinicians, slowing their rate of implementation and extending the discussion about definitions of evidence-based care and the relative merits of various research designs. At the same time, amid growing concerns about medical device safety, clinicians must answer three questions about an intervention and its related products or devices in order to provide safe and effective care: 1) Can it work? 2) Does it work? 3) Is it worth it? Reviewing current knowledge about wound care, wound treatment modalities, and the basic principles of research within the existing framework of questions to be answered suggests a clear path toward obtaining much-needed evidence. In wound care, using clearly defined processes to study patient-centered outcomes (eg, quality of life, complete healing) and only product groupings that meet an operational definition of functioning (eg moisture-retentive) will help clinicians decide whether an intervention can work and does work and whether the value of the clinical and economic benefits is greater than the potential harm and cost.

Keywords: wounds, evidence-based practice, patient-centered care, bandages, policy

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During the past three decades, chronic wounds have evolved from a largely neglected area of care to an important public health concern that consumes considerable resources and negatively affects health and quality of life.¹ Knowledge about the epidemiology, etiology, and pathophysiology of chronic wounds has increased, along with the number and sophistication of wound care interventions and associated products. Preventing and managing chronic wounds require the clinician to identify and apply timely, safe, and effective interventions supported by a variety of devices and products such as topical dressings, support surfaces, footwear, and various skin and wound care products.

When selecting the most appropriate intervention and associated devices or products, wound care clinicians historically have relied on a combination of criteria, including tradition, expert opinion, and available product and treatment information.²⁻⁴ Although the value of providing evidence-based instead of tradition-based care is generally accepted,
especially among healthcare practitioners with advanced degrees, the change to evidence-based wound prevention and care has been slow. Evidence-based medicine involves the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. In the treatment of wounds, evidence-based practice requires the identification of current best evidence based on two primary criteria: safety and effectiveness.

Safety. The Institute of Medicine defines safety as the avoidance of injuries to patients arising from care that is intended to help them. Safety is the foundation of all healthcare activities and a necessary prerequisite before any intervention can be deemed effective. The US Food and Drug Administration’s (FDA) guidance document for the development of chronic and burn wound treatment states “Products intended for wound management may provide important patient benefit without improving the incidence or timing of wound closure relative to standard care. However, it is important to demonstrate that such products do not significantly impede healing.”

Evaluating the safety of an intervention, device, or product in the context of clinical research is deceptively complex. In an ideal world, safety can be defined as an absence of adverse side effects, but overwhelming experience in the clinical practice and research settings demonstrates that the vast majority of interventions are associated with some risk of adverse side effects. Therefore, judgment about safety must carefully weigh the benefits of a given treatment against the risk of harm when experiencing an adverse side effect. The patient’s and clinician’s willingness to tolerate adverse side effects is profoundly influenced by the clinical context in which the intervention is delivered. For example, tolerance of adverse side effects associated with an intervention used to treat a rapidly progressive and potentially lethal condition such as necrotizing fasciitis differs significantly from tolerance of adverse side effects associated with an intervention used to treat a noninfected, partial-thickness wound.

Within the context of clinical evidence, safety is measured as the incidence and severity of adverse events associated with an intervention or product; the incidence must be monitored in every clinical study and reported in the research report. Similarly, manufacturers must monitor reports of product-related safety problems, and the FDA relies on reports from both the healthcare provider and manufacturing sectors to monitor the rate of adverse events through MedWatch (FDA Medwatch).

Effectiveness and efficacy. Effectiveness is defined as the effect of a specific intervention administered to a particular patient at a given point in the course of an illness or condition. Selecting the best treatment when caring for a patient with a chronic wound not only requires the clinician be aware of current best evidence, but it also demands knowledge of the physical characteristics of the wound, local and systemic factors likely to influence treatment response, and the patient’s preferences for treatment.

Key Points
- Despite substantial increases in the wound care knowledge base, current levels of evidence and the implementation rate of evidence-based practice remain low.
- To address this concern, recent national and international discussions generally have focused on the utility of traditional scientific methods, such as randomized clinical studies, to develop evidence-based guidelines for topical wound care.
- At the same time, an ingredient-based wound dressing category system continues to confuse clinicians and yield ambiguous results when used to generate evidence.
- The authors conclude that progress can be made by focusing on common ground, a patient-centered framework for examining evidence, and by replacing the current dressing categories with a system based on valid operational definitions (function).

Because systematic research, by definition, evaluates group responses to treatment rather than the response of an individual patient, current best evidence is built on research that evaluates the efficacy of an intervention, device, or product. Efficacy is defined as the likelihood that an intervention will achieve the desired outcome in a group of subjects when evaluated in a research setting that controls for random effects produced by extrinsic factors. Beginning in the mid-twentieth century, the randomized controlled trial (RCT) emerged as the gold standard for evaluating the efficacy of an intervention (see Table 1). However, because of the highly controlled environment required for conducting an RCT, clinicians and researchers recognize that findings do not necessarily indicate a given treatment will yield similar results when applied in daily clinical practice. Nevertheless, RCT-demonstrated efficacy is considered an essential step toward establishing effectiveness because it compares the presence and the magnitude of response to the intervention to a placebo or sham intervention or to standard treatment when comparison to an inactive intervention is deemed unethical. RCTs also allow researchers and clinicians to compare the occurrence of adverse side effects to determine which effects are attributable to the intervention or device and which occur regardless of treatment choice. In other words, if an intervention is not safe and efficacious, it cannot be effective. At the same time, safety and efficacy do not guarantee effectiveness in clinical practice.

Research designs and evidence-based practice. Despite the critical role RCTs play in establishing efficacy, clinicians and researchers recognize these studies do not address every
criterion clinicians must bring to bear when making treatment decisions in daily clinical practice. For example, because the RCT measures treatment response in a highly controlled situation, as many as 80% to 90% of patients likely to be deemed eligible for treatment in daily clinical practice may be excluded from participation.\textsuperscript{14,15} Additionally, in order to control the potentially extraneous variables (eg, diabetes mellitus, malnutrition, systemic infection, or arterial disease) likely to influence the comparison of an active treatment to a placebo or sham device, RCTs tend to exclude patients with the aforementioned multiple comorbid conditions, which are especially common among persons with chronic wounds.\textsuperscript{16,17} In addition, the process of inclusion in a research study and random allocation preclude considerations of patient preference and cost, both of which profoundly influence daily clinical practice.

Growing awareness of the gaps between basing effectiveness exclusively on RCTs used to demonstrate efficacy has led researchers, clinicians, and public policy makers to reevaluate processes used to generate clinical evidence and to reexamine the role of additional criteria that might be used to assess the effectiveness of various treatment options. However, some reevaluations dismiss the value of RCTs altogether, fail to take the existing evidence base and regulatory requirements of commonly used wound treatments into consideration, or describe the various roads to evidence-based practice as an either/or approach. As a result, definitions of the term evidence-based care remain a topic of debate.\textsuperscript{18} Scientific progress is incremental and inevitably accompanied by discussion and debate;\textsuperscript{19-22} the process can be bewildering for clinicians, cast doubt on the value of evidence-based guidelines for their patient outcomes, and slow the rate of implementing evidence-based care.\textsuperscript{23}

Finally, the availability of valid and reliable evidence in wound care continues to be hampered by a limited number of operational definitions for dressing function and not take into account those that exist. For example, dressing moisture vapor transmission rate (MVTR) is a valid operational definition for a dressing’s ability to provide a moist environment.\textsuperscript{24} This characteristic is relatively easy to measure and has shown an excellent correlation with healing.\textsuperscript{24} Yet, it is not uncommon for researchers to group dressings with widely varying functional characteristics and operational definitions together (eg, dry gauze and impregnated gauze or various foam and hydrocolloid dressings). For example, dry gauze has a higher MVTR than impregnated gauze and hydrocolloid dressings do not have the same operational definition as foam dressings because the latter have a lower MVTR than the former.\textsuperscript{24} When products that do not meet a pre-defined operational definition of function are grouped, even a superbly designed RCT will yield widely varying results (eg, healing time ranges) and will be difficult to interpret.\textsuperscript{25}

Similar variability in outcomes and resultant inconclusive and low-level evidence can be expected when operational definitions are not addressed in systematic literature reviews and meta-analysis.\textsuperscript{24} Unfortunately, the latter is encouraged by the continued use of an ingredient or physical-character-based wound device classification system. When the currently used dressing categories were first proposed 30+ years ago, few could have predicted that a system originally designed to distinguish gauze from “modern dressings,” and later used for reimbursement purposes, would be used to evaluate clinical evidence. For example, all transparent film dressings are grouped together for reimbursement and literature review purposes even though their suggested use (and MVTR) varies. However, to generate solid clinical evidence and reduce variability, all research designs and meta-analyses in wound care must take into account known and unknown differences between products within these currently used wound product categories.\textsuperscript{24,26,27}

**Purpose**

The purpose of this review is to address concerns about the on-going wound care evidence deficit and reframe related

### Table 1. Clinical study design glossary of terms

<table>
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<th>Term</th>
<th>Description</th>
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<tr>
<td>Randomized controlled clinical trial (RCT)</td>
<td>Quantitative, comparative, controlled experiment in which two or more interventions are studied in a series of individuals who receive them in random order. RCTs can be open label, single-blind, or double-blind. The latter means the investigator does not know which treatment is applied to whom and the actual intervention is not identified until all data have been analyzed.</td>
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<tr>
<td>Cohort clinical study</td>
<td>The potential effect of an intervention or suspected risk factor is evaluated prospectively or retrospectively (eg, through chart reviews). If the study has more than one group, the effect of risk or an intervention can be compared.</td>
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<tr>
<td>Observational study, case study, case series</td>
<td>Study usually involves extensive review of one or more patients. An observational study can include a control group but the natural course of events is observed with minimal or no study-related intervention.</td>
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discussions by: 1) summarizing pertinent conclusions from recent wound care-related consensus documents that have centered on this ongoing international conversation, 2) describing a new framework to explain relationships between evidence-based activities and research designs, 3) discussing the importance of evidence in wound patients from a patient-centered outcomes perspective and the limitations of using a product classification system that is not based on treatment function, and 4) illustrating how clearly defined processes and patient-centered outcomes fit together and may facilitate the development of optimal guidelines of patient care.

Generating Clinical Evidence: A Regulatory and Reimbursement Perspective

Regulatory concerns. Both the FDA and the European Medicines Agency have established demanding standards for claims related to new or existing drugs because of the potential for harm to multiple individuals. Specifically, the agencies require consistent findings from at least two RCTs demonstrating efficacy before a new drug can be labeled safe and effective for a given indication. These demanding criteria are considered necessary to ensure public safety, but they also create a lengthy and expensive process that is ultimately reflected in the costs of new pharmacologic agents.

In contrast to the processes demanded for approval of a new drug application, many wound care interventions incorporate products or devices the FDA classifies as low-risk (Class I). Higher-risk devices may require a FDA premarket submission to demonstrate the proposed device or product is substantially equivalent to a legally marketed device (a 510[k]). However, many wound care products, including occlusive, hydrophilic wound dressings and nonabsorbable external and internal gauze dressings, are Class I 510(k) exempt and require no premarket notification. As a result, when a new device is cleared for marketing, it is important for the healthcare professional to determine before implementation whether sufficient evidence is available to support efficacy and effectiveness.

Reimbursement issues. Approval to market a device or product does not automatically ensure that payors such as Medicare will reimburse the product. Reimbursement requirements vary, but many countries usually require the manufacturer to provide evidence of safety, effectiveness, and cost-effectiveness. A number of health technology assessments (HTAs) have been conducted that evaluate evidence of effectiveness based on cost/benefit analysis. Many HTAs conclude that the evidence supporting efficacy and effectiveness of many interventions, products, and devices used to prevent or manage chronic wounds is limited. As a result of these observations, the European Wound Management Association (EWMA) and the US-based Advanced Medical Technology Association (AdvaMed) have generated and endorsed recommendations to improve the quality of evidence in wound management.

Lack of evidence. There are several reasons for the paucity of evidence associated with many chronic wound prevention and treatment interventions. First, completing a high-quality RCT for efficacy in this patient population is challenging, and public financing for chronic wound studies remains limited. Challenges associated with completing an RCT in patients with chronic wounds include the use of complete wound closure as the main study endpoint, especially when evaluating interventions or products used for chronic or nonhealing wounds that often require far longer than the 12 weeks of data collection employed in most clinical trials. In addition, outcomes related to intermediate findings, such as the effects of various antimicrobial wound care products, are controversial. For example, while complete wound closure may be the ultimate goal of a multi-intervention treatment plan, it may not be the best means to evaluate the properties of an antimicrobial product or device. Instead, a more traditional outcome, such as reduction in bacterial count or resolution of infection, might be considered a more reasonable outcome for evaluating efficacy.

Second, when available information is systematically reviewed and analyzed in an HTA, products usually are grouped by a common ingredient or physical characteristic instead of function. As Bolton observed, “Biology, physics, and chemistry have surged forward with clear operational definitions all could use to test hypotheses about the way the world works. Imagine what wound care could accomplish if we all spoke the same language and ‘walked the talk.’”

Third, the prevalence of subjects with multiple comorbid conditions and the general frailty of patients with chronic wounds confound recruitment and retention in clinical trials. Although wound care clinicians and researchers recognize these challenges, they also recognize the need to continue to complete additional trials in multiple areas of chronic wound care and prevention in order to provide high-quality evidence of the efficacy of various interventions commonly used in the management of chronic wounds.

Evidence and Clinical Decision Making: A Patient-Centered Approach

The challenges associated with generating the high-quality evidence needed to support clinicians in choosing the best treatment for an individual patient are not unique to chronic wound care. Luce et al examined three commonly used activities intended to guide healthcare professionals in clinical decision making: 1) evidence-based medicine, 2) HTAs, and 3) comparative effectiveness research (CER). They found considerable overlap in the principal questions these processes seek to clarify (efficacy, effectiveness, and value) that paradoxically may create rather than resolve confusion about clinical decision-making. Furthermore, some definitions of evidence-based care or CER include language about reimbursement or cost-effectiveness; others do not. Nevertheless, the authors ultimately concluded that these processes for
generating evidence are complementary and clear distinctions in their primary functions can be distinguished (see Table 2). Although definitions of patient-centered outcomes continue to evolve, a review of the literature consistently reveals support for a patient-centered approach—an evaluation of outcomes that patients care about—to assess the effectiveness of various interventions used in chronic wound care.

The patient-centered definitions of evidence-based medicine and CER presented are consistent with the grading system used by the Joanna Briggs Institute and the Strength of Recommendation Taxonomy (SORT) literature evidence grading system proposed in 2004 by Ebell et al. Both taxonomies adopt a patient-centered rather than the traditional disease-centered approach. Because a disease-centered approach sometimes is based on intermediate outcomes such as serum glucose or blood pressure, even the most promising study results may not yield measurable benefits when evaluated using a patient-centered approach.

**Joanna Briggs Institute.** The Joanna Briggs Institute uses grades of recommendation based on the feasibility, appropriateness, meaningfulness, and effectiveness of an intervention. Thus, whereas a meta-analysis of randomized controlled clinical studies for the effectiveness of a particular intervention could yield a “1” for level of evidence, a review of feasibility and appropriateness evidence may lead to an overall low-level recommendation for clinical practice.

**SORT.** Using SORT for treatment, prevention, and screening, RCTs are rated based on their quality and relevance to patient-centered outcomes rather than their ability to achieve the main outcome measures stated by the researchers. For example, studies of disease-oriented or interim outcomes such as reduction in blood pressure or laboratory markers, regardless of their design, are rated as level 3 (“other”) evidence. Thus, even the highest quality randomized controlled clinical trials will not result in an “A” strength of recommendation if they measure an interim (disease) instead of a patient-centered outcome. Ebell et al. cite several examples of promising RCTs with disease-centered outcomes that fail to prove effective from a patient-centered approach—eg, treatments that lower blood pressure or suppress arrhythmias but increase mortality; an intervention that improves urinary flow rate but does not affect symptom scores; and a treatment that increases bone density but does not reduce fracture rate (see Table 2).

**Applying the Framework to Wound Care**

**Can it work?** To find out if an intervention can work, researchers rely on results of experimentation in highly controlled environments. In some cases, testing begins with preclinical studies using *in vivo* (animal) models, *in vitro* studies using cell or tissue cultures, or physical models that can measure product characteristics such as the force required to remove a wound dressing. In other scenarios, the preclinical evaluation may begin with a study to determine whether the dressing adheres to the skin of healthy volunteers without causing irritation. Preclinical studies are conducted to determine feasibility and provide an initial evaluation of safety. Products or substances that prove unsafe or have little or no effect on the outcomes evaluated in preclinical models are highly unlikely to prove safe or effective for use in humans.

After a product is evaluated in preclinical trials, researchers rely on results of an RCT to determine whether the intervention provides the intended benefit when applied to human subjects in a tightly controlled environment. Although these trials are needed to demonstrate efficacy, they do not determine whether an intervention produces the intended effect in every patient who may benefit from the intervention. Rather, the RCT is designed to demonstrate whether a causal relationship exists between a treatment intervention and an outcome. The RCT also may provide insights as to why the intervention works by minimizing potential confounding...
variables. The value of the RCT in determining efficacy is well established and is sometimes essential to meet regulatory requirements for safety and efficacy.29

Debate is rare regarding the ability of the RCT to determine whether an intervention can work (efficacy). Instead, most discussions focus on the prominent position these trials occupy in the hierarchies used to determine levels of evidence and to construct clinical practice guidelines and HTAs.19,22,35 One alternative is to use the patient-centered taxonomies described previously. Although such studies cannot overcome the current paucity of clinical evidence and lack of high-quality RCTs, these taxonomies offer a more patient-centered focus. In addition, because the value of patient-centered outcomes in clinical studies is likely to increase, arguments for use of surrogate outcomes such as a percentage reduction in wound size must be carefully considered.19,20 For example, when conducting a study evaluating the efficacy of debridement, it is clearly appropriate to include wound bed status as an outcome. However, if debridement is the only study endpoint, the contribution of this intervention to time to wound healing, generally considered the most clinically relevant outcome measure, is not addressed. Other disease-centered outcome examples commonly reported in the literature that may, or may not, affect a patient goal of care include improves

<table>
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<tr>
<th>Question to be answered</th>
<th>Purpose</th>
<th>Examples of clinical study designs/evidence reviews</th>
<th>Strength of recommendation taxonomy (SORT)</th>
<th>Wound evidence considerations</th>
</tr>
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<tr>
<td>Can it work? (Efficacy)</td>
<td>• Evidence generation • Decision making (regulatory approval)</td>
<td>Randomized controlled study Systematic study review</td>
<td>Disease-oriented study: C Good quality, patient-oriented evidence, multiple studies, consistent findings: A</td>
<td>Evidence of safety and efficacy can be obtained using in vitro and in vivo research methods20,21 followed by an RCT with patient-centered endpoints (eg, complete healing, patient quality of life). In RCTs and systematic study reviews, only products that meet a common operational definition of functioning should be grouped24</td>
</tr>
<tr>
<td>Does it work? (Effectiveness)</td>
<td>• Evidence generation • Evidence synthesis (clinical guidelines) • Decision making to guide practice</td>
<td>Comparison cohort or RCT conducted in routine practice Systematic review of evidence Observational study</td>
<td>Good quality, patient-oriented evidence, multiple studies, consistent findings: A Inconsistent or limited-quality patient-oriented evidence: B Case series: C</td>
<td>In effectiveness studies, disease-oriented outcomes (eg, reduces amount of wound fluid) should be included only if it is a valid and reliable measure of patient-centered outcome (eg, quality of life). In all studies and systematic evidence reviews, only products that meet a common operational definition of functioning should be grouped24</td>
</tr>
<tr>
<td>Is it worth it? (Economic value)</td>
<td>• Evidence generation • Evidence synthesis • Decision making (coverage/reimbursement)</td>
<td>All of the above + economic evaluation n/a</td>
<td>Cost-effectiveness studies must include patient-oriented outcomes as well as direct and indirect costs.26 In all studies and systematic evidence reviews, only products that meet a common operational definition of functioning should be grouped24</td>
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granulation tissue formation, removes wound fluid, and reduces bacterial count. Until such time as these disease-centered or interim outcomes are shown to affect patient-centered outcomes, their utility in assessing whether an intervention can work for patients remains undetermined.

Does it work? To answer the question, “Does it work?” researchers and clinicians must evaluate results in the real world of daily clinical practice. A number of study designs may be used to evaluate effectiveness.

Comparison cohort and/or observational studies. Comparison cohort studies (sometimes referred to as pragmatic clinical studies) and observational studies summarize daily clinical practice via analysis of data from large patient databases.10,11,39 (see Table 1). These trials may use retrospective or prospective data; they are distinguished from classic RCTs by their broad inclusion criteria and limited exclusion criteria primarily based on safety concerns rather than attempts to control variability between groups. In addition, the interventions assessed in these trials are purposely designed to reflect real world practice as closely as possible. Comparisons are made between alternative treatment approaches rather than comparing treatment outcome to a placebo or sham device. Other aspects of care, such as wound, patient, and risk assessment, also may be evaluated by following two groups of patients and comparing their outcomes using a comparison cohort study design. For example, the best method to evaluate the predictive ability of a given risk assessment scale would be to conduct a cohort study.46

The interventions evaluated in comparative effectiveness trials tend to be applied with greater flexibility than the more rigid controls used in the RCT designed to measure efficacy. Study designs should allow for some degree of patient preference, the addition of other treatments based on patient response, and dosing flexibility.

Retrospective studies. A retrospective comparison of treatment approaches documented in large patient databases also can help determine whether an intervention does or does not work in real world practice. However, the data analysis challenges and limitations of retrospective studies should not be underestimated. Wound care clinicians managing patients who transfer between care environments and are treated with a variety of interventions frequently encounter these challenges. Additional limitations of retrospective research include the inability to retrieve important variables that may not have been collected or recorded and chart entries that are confusing, inaccurate, or incomplete.47

Case studies and multiple case series. Although case studies or multiple case series provide valuable information concerning the feasibility of a specific intervention as well as insights into pragmatic aspects of its application in daily practice, they usually provide very limited evidence of effectiveness and cannot be used to determine efficacy or safety (see Table 2).

In many cases, knowledge about the effectiveness of a treatment is limited to poorly designed cohort studies, case studies, or multiple case series, making it very difficult for clinicians (or patients) to make evidence-based decisions.43

Systematic review of the evidence. Synthesis of effectiveness data, or a systematic review of evidence (SRE), typically includes data from a variety of study designs and, when patient-centered outcomes and appropriate treatment grouping are considerations, this approach can yield strong evidence (see Table 3). As with efficacy studies, the quality of the study and associated publications are crucial, and the potential benefit of using surrogate endpoints for the purpose of efficiency or cost should be carefully weighed against the limitations associated with these indirect outcomes. For example, a review of 176 controlled and comparative chronic wound studies by Gottrup et al30 found that 45% of surrogate endpoints such as wound size reduction rate, change in wound condition, biomarkers, and bacteriology were not adequately defined to determine the effect of the intervention on wound healing. Most studies had several endpoints (total 313 for all studies), but only 18 (5.8%) concerned patient quality of life and 53 (17%) were wound closure endpoints. Clearly, if comparative patient-centered information is essential to translating new discoveries into better health outcomes—ie, into outcomes patients actually care about—opportunities for wound care research abound.

It is worth it? To answer this question, researchers, patients, clinicians, and policy makers must determine whether the value of the clinical and economic benefit derived from applying an intervention is greater than the potential harm and cost of the treatment. The most common criteria used to answer this question are data about efficacy, safety, effectiveness, and cost.18

Evaluation of patient-centered health outcomes is crucial when answering the question, “Is it worth it?” Whether considering value to the patient or value to the payor or society, intermediate or disease-oriented outcomes are secondary to patient-centered outcomes.49

Unlike many other countries, in the US Medicare coverage decisions are not based on explicit cost-effectiveness or cost-utility analyses.78,50 When Neuman et al51 reviewed all Medicare coverage decisions between 1999 and 2007, they reported the evidence available was insufficient to assess the effects on health outcomes for 43% of the technologies they reviewed. Of the 21 medical devices reviewed, 14% had good evidence, but 52% received favorable coverage decisions. The authors encourage on-going exploration of flexible coverage decisions while public and private payors consider ways to slow increasing healthcare costs. Vernon et al50 suggest that manufacturers consider the economic value of the unit of health benefit considered for reimbursement to help guide their research and development budgets. Gottrup et al30 state that “rational (technology) choice requires evidence of the costs and benefits of alternatives.”
As described earlier, most wound care devices and products are grouped based on a common ingredient or their physical and design or performance characteristics, which may not meet a common operational definition of function. Despite known physical and effectiveness (benefit) differences between products within these categories, their reimbursement rate (cost) varies minimally or not at all and, with a few exceptions, the question, Is it worth it? remains difficult to answer. A function-based dressing classification system could potentially 1) help clinicians decide what to use based on what a device is supposed to achieve, 2) stimulate research to develop clinically relevant operational definitions, and 3) encourage manufacturers to submit reasonable evidence that a product functions the way it is supposed to—that it can work, does work, and works safely before marketing while protecting manufacturer research and development (R&D) investment.

Conclusion

Clinical practice guidelines must focus on identifying interventions that are both safe and effective. The evidence base that underpins chronic wound care continues to grow and evolve. Nevertheless, for a variety of reasons, evidence in many areas of wound care is lacking, forcing clinicians to rely on tradition and incomplete knowledge of effectiveness when making treatment decisions. Against this background, the FDA is examining several aspects of the premarket notification (510[k]) medical device review program; reducing the number of adverse events from medical products is one of the nationwide objectives for improving the health of all Americans. At the same time, ongoing debate has focused on research design and the role of RCTs and other designs in determining that a product functions the way it is supposed to—that it can work, does work, and works safely before marketing while protecting manufacturer research and development (R&D) investment.

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