



Guidelines for the best care of chronic wounds

Martin C. Robson, MD, FACS¹; Adrian Barbul, MD, FACS²

1. University of South Florida, Tampa, FL and

2. Sinai Hospital/Johns Hopkins Medical Institutions, Baltimore, MD

Uniformity of quality of the care rendered to patients with wounds has been a paramount desire of clinicians, government regulators, and third-party payers. Whether it was for the best patient care, minimum standards to be met, or reimbursable therapies, guidelines for treatment have been sought. One of the goals of the founders of the Wound Healing Society (WHS) in 1991 was to establish guidelines for wound treatment.

One of the first tasks of the WHS Board of Directors following the first annual meeting in Galveston, Texas, was to appoint a committee to develop treatment guidelines. This committee, under the direction of Gerald S. Lazarus, MD, realized that uniform care guidelines could not be developed because there was no uniformity in the definitions of wounds, wound healing, or wound attributes. The committee developed the necessary definitions and after holding several public hearings, published the "Definitions and Guidelines for Assessment of Wounds and Evaluation of Healing" in 1994.¹

This publication defined a chronic wound as one that has failed to proceed through an orderly and timely reparative process to produce anatomic and functional integrity or that has proceeded through the repair process without establishing a sustained anatomic and functional result.¹ Simply stated, wounds may be classified as those that can repair themselves or can be repaired in an orderly and timely process (acute wounds) and those that do not (chronic wounds). Because of continued interest by the WHS and a desire by the United States Food and Drug Administration (FDA), a Government Affairs Committee chaired by Richard A. F. Clark, MD, worked in conjunction with the FDA to establish guidelines for the conduct of clinical trials in wound healing.²

In 2003, the Wound Healing Foundation (WHF) distributed a Request for Application (RFA) for a grant to develop for the best treatment of chronic wounds. The WHS, with Adrian Barbul, MD, as Principal Investigator, was the successful applicant and became the grantee.

The chronic wounds chosen for treatment guideline development were venous, diabetic, arterial, and pressure ulcers. Separate panels were appointed to develop the respective guidelines. Each panel was composed of academicians, private practice physicians, podiatrists, nurse clinicians, research nurses, industrial scientists, and epidemiologists representing most scientific, medical, and nursing societies/associations that have wound care as a major scope of interest.

The charge to each panel was to develop guidelines for the best wound treatment as supported by evidence from the literature. To formulate these evidence-based guidelines, a common methodology was agreed upon by all four panels. Previous guidelines, meta-analyses, PubMed, MEDLINE, EMBASE, The Cochrane Database of Systematic Reviews, recent review articles of treatment of the ulcer under consideration, and the Medicare/CMS con-

sensus of usual treatment of chronic wounds were all reviewed for evidence. Guidelines were formulated, underlying principle(s) enumerated, and evidence references listed and coded. The code abbreviations for evidence citations were as follows:

STAT	statistical analysis, meta-analysis, consensus statement by commissioned panel of experts
RCT	randomized clinical trial
LIT REV	literature review
CLIN S	clinical case series
RETRO S	retrospective series review
EXP	experimental laboratory or animal study
TECH	technique or methodology description
PATH S	pathological series review

There were major differences between the approach to evidence citations agreed to by the panels and past approaches to evidence-based guidelines. Most past approaches relied only on publications regarding clinical human studies. Laboratory or animal studies were not cited. In these current guidelines, well-controlled animal studies that present proof of principle, especially when a clinical series corroborated the laboratory results, have been cited. It is also clear that principles that have been validated for one type of chronic wound often are applicable to other chronic wounds.

Because of these variations, a different system was used to grade the evidence weight supporting a given guideline. The strength of evidence supporting a guideline is listed as Level I, Level II, or Level III. The guideline evidence levels are:

- **Level I:** Meta-analysis of multiple randomized clinical trials (RCTs) or at least two RCTs supporting the intervention of the guideline. Another route would be multiple laboratory or animal experiments with at least two significant clinical series supporting the laboratory results.
- **Level II:** Less than Level I, but at least one RCT and at least significant clinical series or expert opinion papers with literature reviews supporting the intervention. Experimental evidence that is quite convincing, but not yet supported by adequate human experience, is included.
- **Level III:** Suggestive data of proof-of-principle, but lacking sufficient evidence such as meta-analysis, RCT, or multiple clinical series.

FDA	United States Food and Drug Administration
RCT	Randomized clinical trials
WHF	Wound Healing Foundation
WHS	Wound Healing Society

- *NB*: The recommendation in the guideline can be positive or negative at the proposed level.

Each of the specific ulcer guidelines is designed as a stand-alone document. Therefore, there is intentional repetition of some treatment principles and guidelines among the various ulcer documents. It is clear that certain guidelines such as wound bed preparation, infection control, or dressings are common for all chronic ulcer types. These guidelines are summarized in the General Common Guidelines for the Care of Chronic Wounds section.

Once the guidelines for each ulcer type had been drafted, a Delphi process was used to gain consensus among the various panel members. The draft documents were presented at two public hearings sponsored by the WHS, WHF, and the National Institutes of Health, a plenary session of the WHS at its annual meeting in Scottsdale, Arizona, and reviewed by the Boards of Directors of the WHS and the WHF. Following this peer-review process, the draft documents were modified prior to presentation here. It became clear during this three-year process that the guidelines as presented are the best evidence-based guidelines that can gain consensus at the time of publication.

Because the evidence is constantly being updated through ongoing contributions to the literature, all of the panel members and the Boards of Directors of the WHS and WHF realize that the guidelines must be dynamic. Cognizant of this fact, the WHS has established a standing committee under the chairmanship of Martin C. Robson, MD, to monitor additions and/or changes in evidence and to recommend revisions to these guidelines as necessary.

It also became clear that these guidelines for treatment of chronic wounds are not standards of care. To become standards, they will have to stand the test of time, and be embraced by multiple diverse groups interested in the care delivered to patients with chronic wounds.

Finally, in the various public presentations of the draft guidelines, many opinions as to proper wound care were voiced. Many of these suggestions appeared to be quite successful when used by the advocate for the specific therapy. However, the treatment had not been tested in a clinical trial, did not have multiple advocates, and/or did not have animal or laboratory results to prove the principle. Many of these ideas may well spur the research necessary to develop the evidence for a new or modified guideline. These suggestions for innovative care were an added benefit to the whole process of treatment guideline development.

The panel members responsible for the development of the guidelines welcome further discourse on treatments that have not been cited and hope that this process will be an incentive for further research and contributions to the wound care literature.

REFERENCES

1. Lazarus GS, Cooper DM, Knighton DR, Margolis DJ, Pecoraro RE, Rodeheaver G, Robson MC. Definitions and guidelines for the assessment of wounds and evaluation of healing. *Arch Dermatol* 1994; 130: 489–93.
2. FDA Wound Healing Clinical Focus Group. Guidelines for industry: chronic cutaneous ulcer and burn wounds—developing products for treatment. *Wound Rep Reg* 2001; 9: 258–68.