The Current State of Evidence-Based Protocols in Wound Care

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Background: Clinical practice guidelines have blossomed in the last 10 years in medicine as well as wound care. The physician practicing wound care and attempting to use published clinical practice guidelines may, however, have difficulty judging the quality of these guidelines given legitimate concerns that many aspects of clinical practice guidelines are not being properly addressed.

Methods: Guidelines were located using the National Guideline Clearinghouse Web site, PubMed, and the Cochrane database for reviews on diabetic foot ulcers, venous ulcers, and pressure ulcers. The Appraisal of Guidelines for Research and Evaluation instrument was used to evaluate guidelines.

Results: Search engines returned many irrelevant guidelines. Many guidelines would be difficult to evaluate by clinicians not versed in guideline evaluation and were cumbersome in format or were presented more as reference works. Too little attention is focused on such issues as clarity of presentation, consideration of multidisciplinary panels, stakeholder involvement, validity, testing, settings, resources required, cost impact, methods of addressing guideline implementation, and a means of tracking important criteria for feedback once the guideline is in the field. The venous and diabetic ulcer guidelines that were formally evaluated scored poorly in many of these areas despite using relatively sound methods for gathering and evaluating the evidence. Only the developers of one guideline made a commitment for regular update.

Conclusion: Although progress has been made in regard to wound care clinical practice guidelines, much more work will be required before such guidelines are highly accepted by wound care clinicians. (*Plast. Reconstr. Surg.* 127 (Suppl.): 144S, 2011.)

As wound care practice becomes increasingly complicated, involving physicians from many medical and surgical specialties, clinical practice guidelines have become more important as a means of conveying practice information to clinicians and patients based on evidence-based medicine. Clinical practice guidelines can be defined as "systematically developed statements to assist both practitioner and patient decisions in specific circumstances"[1] and thus represent a series of recommendations on a topic that is linked to evidence-based research. The emphasis is on *guideline*; guidelines are never intended to be applied to a given patient with a specific set of comorbidities without judgment or due consideration of the circumstances. This is because the very attempt to standardize care in the belief that the quality of care may be improved[1] can result in potential harm to the patient due to patient heterogeneity and the complexity of decision-making in the context of disease or medical conditions.[2] Other pitfalls commonly encountered in the use of guidelines are the medico-legal consequences of not following a guideline that has been interpreted as a standard of care in a court of law despite its inapplicability to all patients and the potential increase in costs and resource utilization

From Diversified Clinical Services and Strategic Solutions, Inc.
Received for publication June 2, 2010; accepted September 7, 2010.
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DOI: 10.1097/PRS.0b013e31820023dc

Disclosures: *Dr. Warriner is responsible for creating and implementing wound care guidelines for Diversified Clinical Services. Dr. Carter is a paid consultant to Diversified Clinical Services.*

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from a provider's perspective when these have not been considered in the formulation stage of guideline development.[2–4]

Within the clinical practice guideline framework, the methods by which guidelines have been developed and are published vary enormously. Whereas drugs are tested for safety, efficacy, and pharmacokinetic profiles before being released into the marketplace, the majority of clinical practice guidelines are not "test driven" in an appropriate clinical setting before being published.[5] Thus, the attributes of a clinical practice guideline often remain unknown until users have spent some time in the field evaluating them. Although many organizations have published handbooks or articles regarding the overall guideline development process,[6–11] many specialized medical societies and other guideline developers describe the process used in developing the guideline within the individual guideline itself. The selection of individuals for guideline development panels in these latter cases differ considerably, with some organizations using primarily experts and authorities in relevant fields, whereas others use more multidisciplinary panels with representation from a variety of stakeholders, including patients.[12,13]

With this setting in mind, it is unlikely that the average clinician not engaged in systematic wound care research has the background to thoroughly evaluate the dozens of potentially relevant clinical practice guidelines that may be useful to his or her practice. Thus, the goal of this review is to provide some background to practicing clinicians in terms of how to find, evaluate, and implement clinical practice guidelines in wound care.

METHODS

The following strategy was used to locate wound care–related guidelines: (1) search of the National Guideline Clearinghouse on guidelines.gov using the terms "diabetic foot ulcer" and "venous ulcer"; (2) search PubMed using the terms "guideline," "venous ulcer," "diabetic foot ulcer," "and "wound"; and (3) search the Cochrane database for reviews on diabetic foot ulcers and venous ulcers. For clinical practice guidelines, publications had to be peer reviewed either using the peer review system for journals or review by external experts outside of the panel and address physician level practice. We excluded clinical practice guidelines developed by industry and those specifically by or for nurses or other care providers, although articles that addressed the development process by both physicians and nurses were included. Guidelines were accepted for inclusion only if published within the last 5 years.

We used the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument[14] to evaluate these guidelines, a simplified version of which is shown in Table 1. Because some domain items can be difficult to interpret and score, we followed the recommendations of Aass et al.[15] for items 11, 12, 16 to 18, and 21.

RESULTS AND DISCUSSION

Basics of Clinical Practice Guidelines

Implicit in the development of clinical practice guidelines is the understanding that they are based on evidence-based medicine. What is less understood is how strong the level of evidence has to be to make a guideline worthwhile and the role of clinician experience and expert opinion in guideline development.[5]

The goals of any clinical practice guidelines are to (1) promote measurable health care quality, effectiveness, and appropriateness; (2) maintain access to care; (3) and identify the gaps in medical knowledge so that research priorities can be set.[16] Consequently, clinical practice guidelines should not be considered one-time publications but living documents that are periodically reexamined for validity and balance in terms of benefits and possible harms.[17]

Clinical practice guidelines possess many attributes. Foremost is validity, which can be interpreted as the ability of the clinical practice guideline to produce its intended health care outcomes. If health care providers interpret the guidelines very differently, disagree with the recommendations, or patients end up with different outcomes than expected, then the validity of the clinical practice guideline may be in question. This is one good reason why clinical practice guidelines should be reviewed by independent experts, medical specialty boards, patients, health care providers, and other stakeholders for comment before being released.[12,18,19]

Second, using the same methodology and evidence, would another group of experts provide the same set of guidelines? These are the attributes of reliability and reproducibility.[5] In the case of wound care–specific clinical practice guidelines, comparing how guidelines from different groups or societies rate the same interventions for a given wound type and circumstance can assist the physician in assessing reliability and reproducibility. Third is clinical applicability, which can be stated as the clinical settings and populations to which the

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Table 1. The AGREE Instrument*

Domain	Item
Scope and purpose	1. The overall objective(s) of the guideline is (are) specifically described.
	2. The clinical question(s) covered by the guideline is (are) specifically described.
	3. The patients to whom the guideline is meant to apply are specifically described.
Stakeholder involvement	4. The guideline development group includes individuals from all the relevant professional groups.
	5. The patients' views and preferences have been sought.
	6. The target users of the guideline are clearly defined.
	7. The guideline has been piloted among target users.
Rigor of development	8. Systematic methods were used to search for evidence.
	9. The criteria for selecting the evidence are clearly described.
	10. The methods used for formulating the recommendations are clearly described.
	11. The health benefits, side effects, and risks have been considered in formulating the recommendations.
	12. There is an explicit link between the recommendations and the supporting evidence.
	13. The guideline has been externally reviewed by experts prior to its publication.
	14. A procedure for updating the guideline is provided.
Clarity and presentation	15. The recommendations are specific and unambiguous.
	16. The different options for management of the condition are clearly presented.
	17. Key recommendations are easily identifiable.
	18. The guideline is supported with tools for application.
Applicability	19. The potential organizational barriers in applying the recommendations have been discussed.
	20. The potential cost implications of applying the recommendations have been considered.
	21. The guideline presents key review criteria for monitoring and/or audit purposes.
Editorial independence	22. The guideline is editorially independent from the funding body.
	23. Conflicts of interest of guideline development members have been recorded.

*The AGREE instrument consists of 23 items in six domains that use a four-point scale for responses to each item to score the degree to which criteria are fulfilled.

guidelines apply. Fourth, is clinical flexibility, defined as the ability of a guideline to allow judicious interpretation, recognizing that patients often present with unique clinical problems, essentially an "*n* of 1" versus a summation of evidence derived from controlled trials in which patients have more homogenous conditions.[20] Other important attributes include clarity of the guidelines, use of a multidisciplinary process, provision for revisions and updates, and explicit documentation regarding the method used to develop the guidelines, which will be discussed in the following sections.

The Clinical Practice Guideline Development Process

Although there is no universally agreed upon process to develop a guideline, there is agreement that the process should be elaborated upon and documented in some detail before beginning guideline development.[12] In a landmark review conducted by Murphy et al.[21] in 1998, it was found that although selection of particular individuals was likely to have little impact on the decision of a group of sufficient size using defined specialist or professional categories, "specialists tend to favor the interventions with which they are most familiar." This is a form of bias that has been substantiated by studies of experts with clinical expertise related to strong personal opinion, who often demonstrate a disregard of the research evidence and have a less than transparent approach to systematic research.[22–27] Arguments, therefore, have been made for composition in terms of a more multidisciplinary membership, including all stakeholders, such as patient or patient advocates, consumers, epidemiologists, economists, health care providers, as well as experts with very different points of view.[13,28–30]

Conflict of interest among panel participants is another issue that should be dealt with transparently.[31] Financial ties of participants to manufacturers of drugs or medical devices or organizations involved in health care do not invalidate participation, but one randomized controlled study found that the credibility of medical research rated by British Medical Association members in which study participants had competing interests was rated lower, suggesting a cautionary tale in regard to guideline development.[32] As yet, there is no consensus on number of participants for a panel,[13] with one study finding numbers varying 10 to 20.[33] The World Health Organization suggests eight to 12 members, but its own recommendation is often internally ignored.[34] Finally, consideration should be given to appointing a panel leader who can maintain a positive experience, keep the group on track, and ensure that all voices are heard.[13]

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Recent surveys suggest that approximately 40 percent of organizations use formal consensus development methods to develop clinical practice guidelines or health technology assessments.[33,35] Formal methods include the nominal group technique, which was originally developed by Delbecq et al.[36] in the 1970s and involves (1) silent, written generation of responses to a specific question; (2) round robin recording of ideas; (3) serial discussion for clarification; and (4) voting on item importance.[37] The Delphi method, developed by the RAND Corporation in the 1950s is a structured process for collecting and distilling knowledge from a group of experts through a series of questionnaires that can be administered by a variety of different methods, including Web-based interaction.[38] At least two rounds are required, and usually feedback is provided to the participants between rounds so they can see how disparate they are on regard to positions on questions. Formal methods can provide a better process than informal methods,[39] and for this reason, guidelines developed using formal methods may be preferable.

Many methods exist in regard to collecting, assessing the quality and synthesizing the evidence, and creating guidelines from the evidence. A recent review conducted by Carter[20] noted that many organizations worldwide have already adopted the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach, which involves making sequential decisions about the quality of evidence across studies for each important outcome, which outcomes are critical to a decision, the overall evidence across these critical outcomes, the balance between benefits and harms, and the strength of recommendations.[40–42] The quality of evidence is assigned one of four grades: high, moderate, low, and very low. GRADE also suggests using just two recommendation categories: strong and weak.[43] Deciding which study designs to include is a matter of judgment but will depend on the interventions and outcomes being considered and what type of evidence is available; expert opinion should not be used as evidence.[44] In wound care, simply selecting randomized controlled trials as the only eligible study design may cause problems, as many such trials have poor applicability to "real" wound care populations.[45] Moreover, there are other issues with randomized controlled trials in wound care, as well as outcomes in all types of clinical trials, which require careful appraisal.[46] Finally, use of existing, relevant systematic reviews should be made, provided they are recent and are of high quality, as judged by tools such as Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) or Assessment of Multiple Systematic Reviews (AMSTAR).[47–50]

Finding Clinical Practice Guidelines in Wound Care

There are two different ways to find most wound care clinical practice guidelines. The first is to use a Web-based source, such as the National Guideline Clearinghouse in the United States (www.guideline.gov) or the National Institute for Health and Clinical Excellence in the United Kingdom (www.nice.org.uk), and search for specific guidelines with various terms. This does take some effort as searching for "venous ulcer," for example, will return dozens of entries, only a handful of which may be relevant to the searcher.[51] For the National Institute for Health and Clinical Excellence, a query will return both search results and the Institute's guidelines, but for the National Guideline Clearinghouse, search results will only return guidelines produced by various developers, which can include professional societies, special interest groups, and industry. Guidelines listed in the National Guideline Clearinghouse are presented in a summary format with links to full guidelines, which may be freely available on a developer's Web site or available for purchase. The second way is to search for guidelines published in peer-reviewed journals using a database such as PubMed; thus, one might use the search term "venous ulcer guideline." Our experience of searching for venous ulcer guidelines is detailed in Table 2. In general, guidelines retrieved via PubMed were separate publications to those found in the National Guideline Clearinghouse.

Evaluation of Venous Ulcer and Diabetic Foot Ulcer Guidelines

Our search for relevant venous and diabetic foot ulcer guidelines was only meant to be illustrative in terms of evaluation. Our experience mirrored that of Aass et al.[15] in that we found interpretation of some of the items very difficult.

Scoring of clarity and presentation was the most consistent of the six domains, with a mean of 67 percent, whereas stakeholder purpose varied from 17 to 42 percent (Table 3). Rigor of development, which represents the process used to gather and synthesize evidence and the methods used to formulate recommendations and provision for update, ranged from 25 to 54 percent. Although none of the guidelines evaluated was the same as those evaluated by Aass et al.,[15] our scores

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Table 2. Experience Searching for Venous Ulcer Guidelines*

Parameter	NGC	NICE	PubMed
No. of entries returned	40	350 (37 NICE guidance documents)	111
No. of relevant guidelines found	6	NICE guidelines: 1; but guideline was suspended	10
Comments	One developer required payment	Most were references to diabetic ulcers, pressure ulcers, and bowel disease	Payment would be required to read nine of the papers

NGC, National Guideline Clearinghouse; NICE, National Institute for Health and Clinical Excellence.
*The search term was "venous ulcer" for the National Guideline Clearinghouse and Institute for Health and Clinical Excellence, and "venous ulcer guideline" for PubMed.

Table 3. Evaluation of Venous and Diabetic Foot Ulcer Guidelines Using the AGREE Instrument*

Guideline	Scope and Purpose (%)	Stakeholder Involvement (%)	Rigor of Development (%)	Clarity and Presentation (%)	Applicability (%)	Editorial Independence (%)
Venous ulcers						
Bolton et al.[52]	67	42	54	67	33	50
Robson et al.[53]	44	17	46	67	22	0
Diabetic foot ulcers						
Lipsky et al.[54]	67	17	33	67	67	0
Steed et al.[55]	44	17	46	67	22	0
Wraight et al.[56]	22	25	25	67	22	0

AGREE, Appraisal of Guidelines for Research and Evaluation.
*Values for each of the six domains are expressed as standardized domain scores in percentages; on this scale, 0 percent means that the guideline completely failed in regard to domain questions, whereas 100 percent means that a maximum score was attained for the domain. From Murphy MK, Black NA, Lamping DL, et al. Consensus development methods and their use in clinical guideline development. *Health Technol Assess.* 1998;2:i–iv, 1–88.

were lower and may reflect a conservative approach. The AGREE instrument makes no provision for an overall evaluation of guidelines, and Wimpenny and van Zelm also note that appraising a guideline involves more than using AGREE; it takes critical judgment of a guideline's content.[57] Furthermore, there are many instruments available to enhance reporting of clinical practice guidelines that make formats more user-friendly and communicative.[1,58–61]

Our AGREE evaluation experience is likely to be duplicated by clinicians who attempt evaluation of guidelines. In part, this related to the format of the published guidelines, and in some instances, the published format made assessment so difficult that we chose not to evaluate several guidelines. The best format we found was the guidelines published by the Wound Healing Society because they were presented in a standardized way and clearly delineated, and each guideline was directly linked to the evidence is a succinct manner.[53,55] Many guidelines are so lengthy or encumbered with detailed presentation of epidemiology, risk factors, and other aspects that it is hard to easily extract the most important information needed for practice. In a sense, these guidelines read like textbook chapters and in our opinion should not rate highly as guidelines although they are good reference works.

Practical Evaluation of Wound Care Clinical Practice Guidelines

Formal instruments for the evaluation of clinical practice guidelines can be useful for researchers, but for many wound care practitioners without specific training in such methods, they are likely to be distinctly unhelpful. Therefore, this section will concentrate on more practical ways to evaluate guidelines. Table 4 suggests nine steps to consider for the clinician looking at a guideline for the first time.

Applicability (Relevance)

Any guideline should spell out the disease or conditions to which it applies, as well as patient population characteristics. If this is not done, a clinician may inadvertently use the guideline on a patient with possible adverse consequences. For example, compression bandaging for venous ulcers is considered standard treatment but should be exempt for those patients with serious peripheral arterial disease or uncompensated congestive heart failure.[53,62] Only the guidelines published by Robson et al.[53] mention that when mixed venous/arterial disease is present, compression *must* be modified. In addition, these guidelines clearly state "Guidelines have been formulated in eight categories for the treatment of venous ulcers of the lower extremities." In contrast, the publication by Bolton et al.[52] states "the [Association for the

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Table 4. Important Aspects to Consider When First Looking at a Guideline

Aspect	Assessment	Judgment
Applicability (relevance)	Each guideline should spell out the characteristics of the disease/condition and the population to which it applies.	A guideline that does not specify in detail the disease or population characteristics to which it applies may lead to inappropriate use of the guideline.
Clarity	Is each guideline prominently displayed, concise, and easy to understand?	If guidelines are buried in a morass of detail, they are unlikely to be useful.
Clinical details	Each guideline should provide enough clinical detail that a clinician can easily understand what is being proposed without having to "guess" or interpret what is being stated.	Insufficient detail is likely to compromise use of a guideline.
Safety (harms versus benefits)	Does the guideline consider possible adverse events that could result from using the guideline?	If guidelines do not consider important safety issues or harms versus benefits for patients in individual statements or authors have not employed a methodology that considers these issues, users should use guidelines with caution.
	Have author guidelines weighed harms versus benefits in developing their statement of recommendation?	
Validity	Has the guideline been externally reviewed?	Guidelines that have not been externally reviewed may contain serious flaws.
	Has the guideline been tested in a "real world" setting?	Guidelines that have not been properly tested should be regarded as "provisional."
Evidence	Is the evidence linked to the guideline easy to follow, and has it been graded using an appropriate methodology?	When evidence is not linked or properly graded, then guidelines could be seriously flawed.
Recommendations	Is the method by which guideline recommendations have been formulated reasonable and adequately described?	Creating recommendations haphazardly may mean that the guideline content is irrelevant, inappropriate in some situations, or flawed.
Implementation	Has implementation of the guideline been thoroughly considered?	No consideration of implementation may mean that putting a guideline into practice will be difficult or even impossible in the worst case.
Update	Is there provision for regular updates of the guideline—at least every 3 years?	If there is no provision for updates, guidelines may become rapidly obsolete.

Advancement of Wound Care] . . . resolved to develop a content-validated [venous ulcer] guideline based on objective summaries of best available evidence supporting each step of [venous ulcer] care," suggesting it is more of a research-oriented report on venous ulcer guidelines rather than a set of venous ulcer treatment guidelines. This is not a criticism of their work but indicates that a clinician would be better served by the guidelines published by Robson et al.[53] using the report by Bolton et al.[52] as a means to better understand the evidence behind venous ulcer treatment. Another facet may be the setting; a guideline aimed at a long-term care facility, such as a nursing home, may not be appropriate for a clinician with a wound clinic-based practice.

Clarity

Ideally, a guideline should comprise a clear statement, followed by a supporting paragraph in which aspects of the statement are elucidated, including a rating of the evidence, the recommendation strength, and references to the statement. The Infectious Diseases Society of America guidelines[54] for diagnosis and treatment of diabetic foot infections, together with strength of recommendations and quality of evidence rating are clearly delineated in the executive summary at the beginning of the publication, but a reader must examine the entire document to find the supporting references. On the other hand, although the weighty tome published by Frykberg et al.[63] (a clinical practice guideline on diabetic foot disorders) contains some very useful material on the subject, it is a prime example of poor clarity. In contrast, the guideline for assessment, investigation, and management of acute diabetes-related foot complications published by Wraight et al.[56] has some excellent evidence tables and visual algorithms but lacks a concise structure for finding recommendations.

Clinical Details

There must be sufficient clinical detail in each guideline that any clinician reading the document will be able to follow and implement it without

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guessing or trying to interpret what has been said. Most of the time, this detail will be present in the supporting paragraphs of each individual category or statement. In their guidelines for the treatment of diabetic ulcers, Steed et al.[55] provide an excellent example of how this should be done. While more detail can be helpful and many of the guidelines we examined were not lacking for detail, our major criticism of most diabetic wound care–related guidelines was that this detail was not clearly linked to the individual statements. For example, the second statement in the guidelines published by Lipsky et al.[54] relates to attention of local and systemic issues using a multidisciplinary team, which should include an infectious diseases specialist. However, although there are a few nuggets of information on the subject in the text, they are not linked to the statement. Our best advice is that any time one reads a statement and its supporting material within a guideline that raises questions or doubt, do not consider implementing the guideline until those questions are resolved.

Safety (Harms versus Benefits)

One of the most important criteria that the GRADE methodology uses in developing a guideline is harms versus benefits.[40] The methodology used to develop guideline recommendations should incorporate this concept, and specific statements that relate to diagnostic procedures or treatments in which significant harms could occur to a patient should include a brief discussion of them in relation to potential benefits.

What is significant harm? This can be a difficult question to answer because the situation may be contextual. For example, debridement is common practice for many wounds and is usually considered to present minimal risk, but repeated mechanical debridement may in fact impede chronic wound healing.[64] Similarly, autolytic debridement is contraindicated in infected wounds because the infection may progress.[65] Unfortunately, many diabetic wound care–related guidelines can be very uneven in their discussion of discussing harms versus benefits. Thus, the best advice we can give to wound care clinicians is to fully understand the potential harms of any diagnostic procedure or treatment if these are not discussed in any guideline statement; in other words, proceed cautiously.

Validity

Guideline validity in practice means that the statements developed have been reviewed by other experts in the field—essentially an external review that the statements themselves do not contain major flaws. The guidelines that we examined met that requirement. None, however, was tested in "real world" settings. This is a potential problem (see Implementing and Updating Clinical Practice Guidelines section).

Evidence and Recommendations

All guidelines are based on evidence-based medicine and practice. Thus, it is crucial that guideline users be able to review the evidence associated with each statement or recommendation, and see how it was graded. Ideally, tables that refer to each statement or recommendation should have ratings with the methodology used to obtain those ratings clearly described in the text. A particularly good example of this practice was found for the guidelines developed by Wraight et al.[56] Likewise, the methodology underlying the development of recommendations should be properly explained. No guidelines we reviewed used the GRADE methodology to develop recommendations, and many were inadequate in quantifying the rating of the recommendation or describing how the recommendation was developed. Despite its vast wealth of information, the guideline published by Frykberg et al.[63] is entirely deficient in this regard. In summary, wound care guidelines developed to date need to be much improved in describing how recommendations were created and how they should be used in practice.

Implementing and Updating Clinical Practice Guidelines

Implementing and successfully adapting a guideline to local practice may be the most challenging aspect of clinical practice guidelines. Passive dissemination of clinical practice guidelines is unlikely to ensure sufficient adaptation of guidelines,[66] and several studies have noted issues with implementation or adaptation in wound care.[67–72] Poor integration of new guidelines within clinical practices may result from a variety of causes, including little consideration of patients or the professional targets of clinical practice guidelines; the type of setting, as well as its cultural and social characteristics; the organizational and economic environment; and difficulty in remembering procedures, the complexity of carrying them out, or being adequately reimbursed for them.[51,73] Discussion of potential barriers to implementation, cost implications, identification of necessary resources, possible training approaches, piloting the guidelines in a particular setting, and a means of monitoring or auditing key guideline criteria should all take place before the guideline is released (Fig. 1). Finally, provision for update of clinical practice guidelines at least every 3 years must be made.[74]

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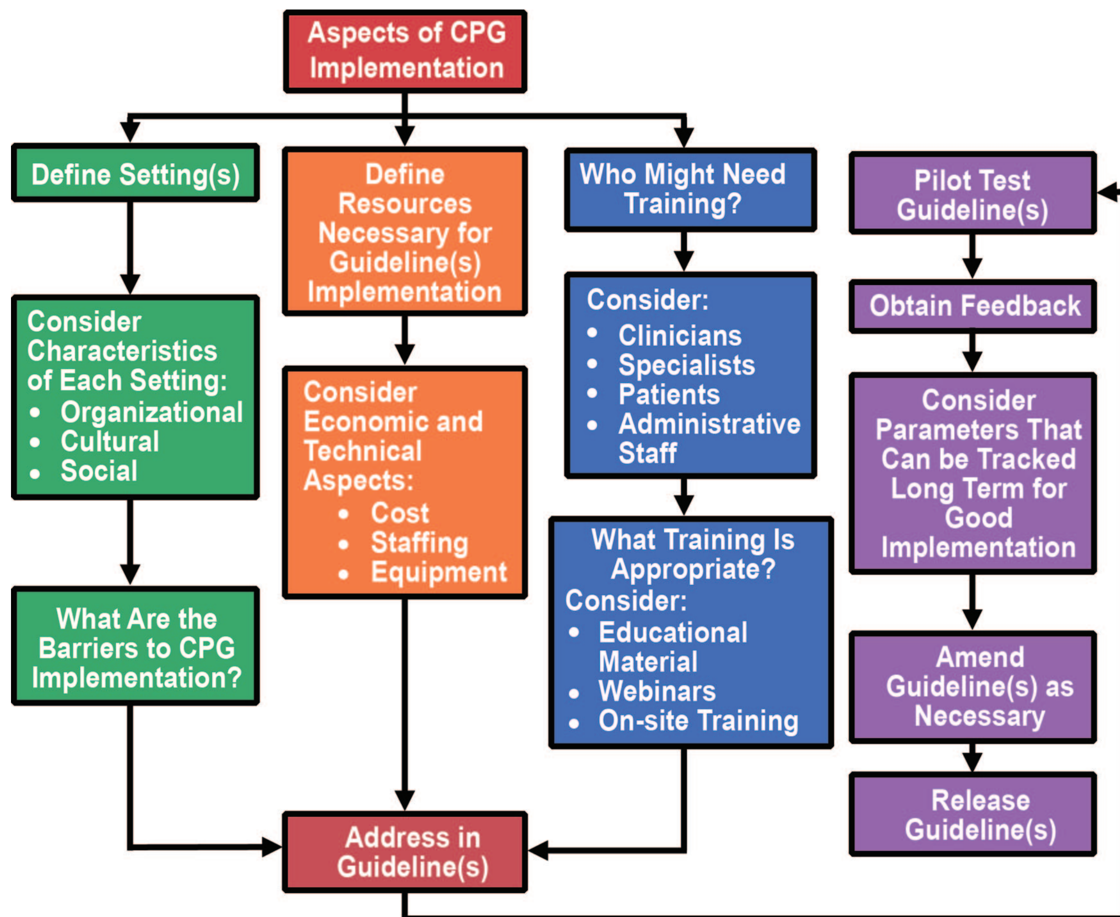

Fig. 1. Discussion of potential barriers to implementation, cost implications, identification of necessary resources, possible training approaches, piloting the guidelines in a particular setting, and a means of monitoring or auditing key guideline criteria should all take place before the guideline is released.

The Future of Wound Care Clinical Practice Guidelines

Much progress has been made in the last 10 years in the development of guidelines in the field of wound care. Even given the limitations discussed in this review, wound care clinical practice guidelines can provide useful information and direction for physicians caring for patients with problem wounds. Much more, however, needs to be done in improving the format of clinical practice guidelines so that they are easier to "digest" for clinicians. In particular, more attention needs to be paid to validity assessment, target groups, patient involvement, the likely settings, cost and resource impact, and the type of education for best implementation.

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ACKNOWLEDGMENT

Funding for this work was provided by Diversified Clinical Services.

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