Development And Validation Of Guidelines For Clinical Research In Wound Care

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ABSTRACT

PURPOSE: To describe development and validation of a guidance document for stakeholders involved in clinical research in wound care. **DESIGN AND PARTICIPANTS:** A multidisciplinary panel of 11 wound care experts (POWER panel) generated a Preliminary Consensus Document consisting of 17 statements. A modified Delphi approach consisting of 2 web-based surveys was used to reach consensus on the statements and involved over 100 multidisciplinary wound experts. **METHODS:** The POWER panel contacted leadership of organizations with interest in wound care to invite their members to participate in the Delphi process. People interested in participating contacted the POWER panel directly. Only 2 organizations refused participation. Participants rated each of the 17 statements using a 4-point Likert scale. The *a priori* criterion for endorsement of a statement was greater than or equal to 90% of participants responding with "agree" or "strongly agree" to the statement. Statements with less than 90% agreement were reviewed and considered for revision by the POWER panel. **RESULTS:** 119 persons responded to the first Delphi survey (response rate 72%) and produced consensus on 5 of the 17 statements. 12 statements were reviewed, revised and sent to participants in the second Delphi survey. All statements were approved with 90% consensus with two Delphi surveys. **CONCLUSIONS:** The 17 statements provide guidance for the developers and users of new or existing products or devices or interventions, such as assessment techniques, care techniques, mobility/exercise, nutrition, treatment "bundles," or prevention regimens that are being used or will be used in the treatment of wounds, whether acute or chronic.

BACKGROUND

❖Wound care research has been criticized because of methodological issues:

- ✓RCTs can be difficult due to expense, complicated study designs, and endpoint problems.
- ✓Controlled studies are necessary to initially determine efficacy, ***BUT*** may not be generalizable to "*real world*" wound care patients because many have multiple comorbidities or come from highly vulnerable populations that are typically excluded from controlled trials.
- ✓Wounds receive many different treatments from inception to healing thus identifying the comparator group is difficult.

OBJECTIVE

❖To address the problems in wound care research a multidisciplinary Panel on Wound Care Evidence-based Research (POWER panel)™ group was convened to define a set of guidelines in the form of principles to provide direction to all stakeholders involved in clinical research in wound care.

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METHODS

DESIGN AND PARTICIPANTS:

❖11 wound care experts, the POWER panel, generated a Preliminary Consensus Document of 17 statements.

❖ 119 multidisciplinary wound care professionals participated in a modified Delphi approach consisting of 2 web-based surveys to reach consensus on the statements

METHODS:

❖Leadership of 17 organizations with interest in wound care were contacted to invite their members to participate in the Delphi process. Those interested contacted the POWER panel directly (n=173); 2 organizations refused participation

❖Participants rated each statement using a 4-point Likert scale, provided comments, and basic demographic and research background.

❖The *a priori* criterion for endorsement of a statement was ≥90% of participants responding "agree" or "strongly agree" to the statement.

❖Statements with <90% agreement and those that received ≥ 15% affirmative responses to the question, "Does the statement require revision?" were reviewed and considered for revision by the POWER panel.

STATISICAL ANALYSIS:

❖Proportion of panelists endorsing each item was calculated for responses to both questionnaires. Open-ended comments were content analyzed for general themes.

RESULTS

DELPHI ROUND 1

❖119 of 173 initial respondents completed the survey (68% response rate)

❖4 statements were not endorsed (8,9,15,16); 4 did not require revision (6,7,12,17)

❖Comments focused on application of the statements (i.e., use in different situations), objection to specific words or phrases or content (i.e., lack of clarity), or disconnects (i.e., more than one principle embedded in the statement).

DELPHI ROUND 2

❖80 completed the survey (46% response rate).

❖14 statements rated; only statement 9 was not endorsed; 5 statements needed revision(4,5a,8b,9,11)

- Revision largely based on use of specific words or contextual use of the statement.

RESULTS

Table 1: Participant Demographics & Background

Characteristic	N (%)
Gender	
Male	54 (47.8)
Age (y)	
18-25	2 (1.8)
26-35	7 (6.3)
36-45	22 (19.6)
46-55	46 (41.1)
56-65	29 (25.9)
> 65	6 (5.4)
Location (region)	
New England	11 (9.9)
Mid-Atlantic	18 (16.2)
East North Central	14 (12.6)
West North Central	5 (4.5)
South Atlantic	24 (21.6)
East South Central	4 (3.6)
West South Central	16 (14.4)
Mountain	11 (9.9)
Pacific	8 (7.2)
Primary wound-related work setting	
Wound care clinic	27 (23.9)
Other outpatient setting	8 (7.1)
Home health agency	1 (0.9)
Long term care	6 (5.3)
Hospital	21 (18.6)
Long term acute care/subacute facility	3 (2.7)
Academic	18 (15.9)
Industry/manufacturer	16 (14.2)
Other	13 (11.5)
Role	
Administration/management	9 (7.8)
Educator	9 (7.8)
Licensed practical/vocational nurse	1 (0.9)
Physical therapist	5 (4.3)
Physician	31 (27.0)
Podiatrist	19 (16.5)
Registered nurse	11 (9.6)
Researcher/scientist	17 (14.8)
Other	13 (11.3)
Years involved in wound care research	
≤ 2	6 (5.3)
3-5	16 (14.2)
6-10	18 (15.9)
11-20	32 (28.3)
> 20	26 (23.0)
Not in involved in wound care research	15 (13.3)
Years involved in wound care clinical practice	
≤ 2	2 (1.8)
3-5	6 (5.3)
6-10	19 (16.8)
11-20	44 (38.9)
> 20	29 (25.7)
Not in wound care clinical practice	13 (11.5)

DISCUSSION POINTS

❖Statement 4 focused on new products and devices entering the wound care market are derivations of previously marketed products that have known safety and efficacy profiles based upon FDA–evaluated research.

- The panel suggests, therefore, that initial research could be cohort designs (ie, observational studies) to fulfill the requirement of efficacy in products or devices that are modifications of existing products or devices; later trials could use more sophisticated designs.

❖Statement 5 is that most experimental designs focus on a single intervention when distinguishing the experimental from the control group with "usual care."

- However, wounds heal via a series of sequential and overlapping phases, and may have multiple contributory factors. Chronic wounds, therefore, often require multiple interventions or episodes of treatment

- Statement 7 is associated with the issue that wound care studies are often lacking crucial parameters in regard to design, execution, reporting (see below).
- Statement 8 emphasizes that primary endpoints in wound care are often quite diverse and do not always reflect complete wound healing.

Minimum Criteria to be included in Wound Care Studies
include in any research design: Age Gender Social status (as appropriate; e.g., socioeconomic status, education level, married vs. single, rural vs. urban, lives alone or with others) Acuity score (if appropriate and available) Ethnicity/race Comorbid medical conditions (as appropriate). ADLs and functional measures Health habits (e.g., nutritional status, exercise, tobacco, alcohol, and drug abuse) Additional measures as appropriate.
Wound etiology Wound duration (prior to assessment/treatment) Compression (for venous leg ulcers) Offloading (for pressure and diabetic ulcers) Debridement (frequency, types of debridement) Moist wound healing (type of treatment) Vascular assessment (how accomplished) Surface area measurement (e.g. length x width, and method of measurement) Evaluation of tissue depth (how measured; whether measured in size or involvement of tissue) Location of the wound Tissue types Bacteriology as appropriate Use of validated tools Research-based standard wound assessment. Other criteria as appropriate.

Table 2: Final 19 Statements on Wound Research

1. There is a need for a guidance document in the field of wound care research.
2. Wound care researchers, product developers, manufacturers, policy makers, payers, clinicians, and consumers should be educated on wound care research guidelines.
3. All human wound care research conducted in the United States should follow the principles of Good Clinical Practice (GCP) in accordance with FDA regulations.
4. The study design of research conducted in wound care should be matched to its purpose.
5. Wound care clinical research should include evaluation of simultaneous and/or sequential interventions when appropriate.
6. Wound care research should incorporate a multidisciplinary approach whenever possible.
7. Research design should include parameters that are appropriate for the type of the study.
8. Primary endpoints in wound care research need to reflect both the goals of the intervention and clinical practice.
9. Study design should be reviewed.
10. Study design should be open to amendment.
11. Quantitative wound care studies should include a run-in period as part of the initial assessment when it is appropriate.
12. The rationale for inclusion and exclusion criteria in wound care research should match the goals of the study but the generalizability of the results to wound care populations should also be spelled out.
13. Highly vulnerable populations are under-represented in clinical wound care research practice and should be included where feasible.
14. The definitions for intervention(s) provided to the comparator groups in any clinical study, typically defined as "moist wound care" or "usual care," need to be explicit.
15. An appropriate but comprehensive dataset should be included in the research design to describe the participants.
16. An appropriate but comprehensive dataset should be included in the research design for any study that involves wound evaluation.
17. Clinical wound care research should include rates of recurrence where feasible.
18. National or formal wound registries should be developed with real-world data collection.
19. Cooperative groups, composed of multiple researchers working in concert, should be formed in order to facilitate and optimize wound care research.

CONCLUSIONS

The statements provide guidance for developers and users of new or existing products, devices or interventions, such as assessment techniques, care techniques, mobility/exercise, nutrition, treatment "bundles," or prevention regimens that are being used or will be used in the treatment of wounds.