Collaboration Encourages Innovation: Setting New Standards in Wound Care With the Wound Care Collaborative Community Expert Panel Consensus Recommendations

Vickie R. Driver, DPM, MS[1]; Howard Walthall, JD, BSE[2]; Alisha Oropallo, MD[3-5]; Marissa J. Carter, PhD, MA[6]; Marjana Tomic-Canic, PhD[7]; Joseph Rolley, MS[8]; and Maribel Henao, DPM, MSPT[9]

Affiliations: [1]Washington State University, Elson S. Floyd College of Medicine, Spokane, WA; [2]ProgenaCare Global, LLC, Marietta, GA; [3]Zucker School of Medicine, Hofstra/Northwell, Uniondale, NY; [4]Feinstein Institutes for Medical Research, Manhasset, NY; [5]Northwell Comprehensive Wound Healing Center and Hyperbarics, North New Hyde Park, NY; [6]Strategic Solutions, Inc., Cody, WY; [7]Wound Healing and Regenerative Medicine Research Program, Dr Phillip Frost Department of Dermatology and Cutaneous Surgery, University of Miami Miller School of Medicine, Miami, FL; [8]JTR Business Consulting, LLC, Doylestown, PA; [9]Organogenesis, Inc, Canton, MA

Disclaimer: The US Food and Drug Administration (FDA) participates as a member of the Wound Care Collaborative Community (WCCC) and participated in the Driving Innovation in Wound Care Summit on May 13, 2024. The FDA did not contribute to the development of the WCCC statements, and the consensus statements should not be construed to represent the FDA's views or policies.

Disclosure: M.T-C. serves on the Flen Health Scientific Advisory Board. Manuscript preparation assistance was provided by Cynthia Cooley-Themm, PhD (HMP Collective).

Manuscript Accepted: December 3, 2024

ABSTRACT

Background. The Wound Care Collaborative Community (WCCC) assesses shortcomings and unmet needs in wound care by partnering with key stakeholders, such as the National Institutes of Health, the US Food and Drug Administration (FDA), industry leaders, and expert health care providers and researchers, to advance the study of wound healing. Through this work, the WCCC has identified a few key barriers to innovation in wound care. The WCCC aims to accelerate the development of science-based, patient-centered solutions and address public policy challenges related to ensuring patients receive early access to innovative treatment options. **Objective.** To develop consensus recommendations that would address current deficiencies in wound care and promote improved innovation and patient access with an expert panel discussion based on both the work conducted within the WCCC and the existing evidence. These recommendations include the voices of the at-large, US-based wound care community. **Methods.** In May 2024, a multi-panel summit with 65 leading voices in clinical practice, academia, industry, and the FDA convened in person in Orlando, Florida. Thirty-two participants with backgrounds in clinical practice, surgery, industry, academia, and research took part in panel discussions. Following the panel meeting, the group corresponded via email and a formal survey process to create consensus recommendations, with the ultimate goal of identifying and overcoming barriers to innovation in wound care. **Results.** A total of 32 experts convened during the 1-day summit, each representing key stakeholders. Five panel discussions took place to discuss the obstacles to innovation, including alternative primary and co-primary endpoints, generating and reporting evidence, real-world evidence in policy decision-making, and the appropriate standard of care in wound management. From these discussions, 12 consensus statements were generated. The statements, their proportion of agreement or disagreement, and summary comments are presented in the order they appeared at the presentation. Overall, greater than or equal to 85% agreement was received on all statements. **Conclusion.** The consensus recommendations promote and encourage a standardized path forward to established, consistent metrics that facilitate innovation and quality assessment, improving patient access to advancements in healing.

Keywords: clinical trial design, real-world evidence, standard of care, wound, wound care, wound healing

Abbreviations: CDER, Center for Drug Evaluation and Research; CDRH, Center for Devices and Radiological Health; FDA, Food and Drug Administration; ICD, *International Classification of Diseases*; NIH, National Institutes of Health; PAR, percent area reduction; PVR, percent volume reduction; RCT, randomized controlled trial; RWD, real-world data; RWE, real-world evidence; SAWC, Symposium on Advanced Wound Care; SOC, standard of care; WCCC, Wound Care Collaborative Community.

The WCCC was established in March of 2021 with the support and encouragement of stakeholders from clinical practice, academia, industry, and the federal government. The overall mission of the WCCC is to assure that patients and health care professionals have access to safe, effective, and high-quality medical devices and drugs to treat chronic wounds. The WCCC works in the pre-competitive space to identify methods, tools, approaches, and appropriate clinical evidence that will enhance understanding and improve evaluation of product safety, quality, and effectiveness. The WCCC is a volunteer group of diverse opinion leaders, experts, health care providers, associations and societies, payors, manufacturers and industry leaders, researchers, and patients in wound care.[1] Overall, the WCCC has over 200 volunteer members, a board of directors, 3 working groups, 7 workstreams, and 2 committees.

The WCCC has identified a lack of innovation in wound care and a lack of patient access to treatment and diagnostic advancements as core obstacles to achieving its mission. Three root causes exacerbate the obstacles: (1) investor hesitancies in commercial investment, research, and development; (2) a lack of understanding of the natural history of the disease state; and (3) insufficiencies in preclinical testing and clinical trial design. Several objectives have been identified for overcoming these barriers.

To this end, the WCCC hosted a panel discussion with 32 key leaders in clinical practice, academics, industry, and the FDA to discuss the gaps and challenges preventing advancements in wound care. The panel discussions aimed to foster the development and availability of innovative and effective wound-healing therapies to drive advancements and outcomes. The proceedings of the Summit discussion were collected, reviewed, and are presented here as expert consensus recommendations. Notably, of the 32 original panelists present during the Summit discussions, 30 voting members contributed to the consensus statements presented here.

METHODS

Panelist selection and meeting

The WCCC Driving Innovation in Wound Care Summit occurred on May 13, 2024, during the SAWC Spring 2024 Pre-Conference in Orlando, Florida. The Summit included a keynote address, opening remarks, 5 panel-based discussions, and several question-and-answer sessions. In preparation for the Summit, several meetings took place in which the WCCC reviewed and selected data from their working groups and workstreams to be presented during these panel discussions. Leaders of these groups served as panel chairs and presented their relevant work before each panel discussion ensued. Panels were comprised of members of the professional wound care community who average more than 21 years of wound care experience, more than 15 years in research, and who have published more than 50 publications (**Table 1**); owing to experience levels, some panelists noted multiple areas of expertise (eg, research and clinical practice).

During the panel discussions, the groups delineated the barriers and strategized methods to overcome them. Panel 1 focused on obstacles to wound care innovation; the 9-person panel included members from the FDA CDRH (n = 1), the FDA CDER (n = 1), clinical practice (n = 2), research (n = 3), and industry (n = 4). Panel 2 explored alternative primary and co-primary endpoints for clinical trials; the 9 panelists included members from the CDRH (n = 1), the CDER (n = 1), clinical practice (n = 4), research (n = 4), and industry (n = 1). Panel 3 assessed methods of generating and reporting evidence; the 10 panelists included members from the CDRH (n = 1), the CDER (n = 1), clinical practice (n = 3), research (n = 3), and industry (n = 3). Panel 4 focused on RWE in FDA and payer decision-making models. The 9 panelists included members from the CDRH (n = 1), clinical practice (n = 5), and industry (n = 3). The 6-member final panel worked to define an SOC in wound management and included representatives from the CDRH (n = 1), clinical practice (n = 3), research (n = 1), and industry (n = 1).

Consensus statement formation

Each statement—crafted by a medical writer with input from the Summit chair and a review by all of the panelists—captures the important elements from each panel discussion. An anonymous survey of 12 declarative "agree" or "disagree" statements, with a section for comments included with each statement, was distributed electronically to the panelists. The responses and comments of 30 voting panelists were recorded. The survey results are presented as a fractional proportion and a percentage of agreement or disagreement. Comments that emerged from the survey are also presented (**Table 2**).

RESULTS

Panel 1: Addressing barriers to wound care

Consensus statement 1: Investor hesitancy resulting from poorly executed clinical trials, poor clinical trial design, and/or insufficient endpoints hinders innovation in wound care.

Panel 1 examined the causes underlying the lack of progress and advancement in wound care. In this session, the 9 panelists shared their expertise, including from the CDRH (n = 1), the CDER (n = 1), clinical practice (n = 2), research (n = 3), and industry (n = 4). Highlighting the lack of innovation in wound care, the panel noted that only 1 recombinant human platelet-derived growth factor product has been approved to treat chronic ulcers since 1997, and no small molecule drugs have been approved.[2] Investor hesitancy was offered as a contributing factor to the lack of progress. The panel maintained that investors have doubts about clinical trial endpoints and design, preventing their support for new ideas. Panelists agreed that a standardized consensus for primary endpoints, quality measures, metrics, and SOC is vital to properly calibrating wound care research and ensuring that results are measured with the same criteria.

Consensus statement 2: Improved and efficient methods of RWD collection (eg, an industry-wide registry) could help define accurate

Table 1. Summary of Experience Represented by the Panelists

PANELIST	SPECIALTY/BACKGROUND	YEARS IN THE PROFESSIONAL WOUND CARE COMMUNITY	YEARS IN RESEARCH	APPROXIMATE NUMBER OF PUBLICATIONS
1	Family medicine, undersea and hyperbaric medicine	35	30	80
2	Strategic evidence, diagnostic imaging, reimbursement, medical affairs	10	20	40
3	Economics	16	10	4
4	Wound care, hyperbaric medicine, family medicine	13	10	17
5	Plastic and reconstructive surgery, FDA drug regulation	10	N/A	12
6	Market access, reimbursement, business development	38	N/A	1
7	Business and commercialization	40	N/A	N/A
8	Vascular surgery, general surgery, wound care	15	13	70
9	Research and development, wound care, orthopedics	11	17	30
10	Family medicine, medical devices	12	4	2
11	Regenerative medicine, tissue engineering, research and development, clinical development, medical affairs	15	20	41
12	Biomedical science of skin substitutes and wound healing	30	30	48
13	Wound care, vascular surgery	30	20	150
14	Market access, new product development, market adoption	10	N/A	N/A
15	Regulatory	20	13	5
16	Vascular surgery, general surgery	24	24	94
17	Clinical research, surgery	11	20	10
18	Podiatric medicine and surgery, physical therapy	13	N/A	N/A
19	Plastic surgery, wound care	30	30	100
20	Wound care research, FDA approval of new devices and clinical assessment, reimbursement	44	8	16
21	Regulatory science	13	5	2
22	Industry, product development	12	12	3
23	Clinical evidence, product development, professional education, health economics	25	10	5
24	Clinical trial design and analysis, health economics modeling, systematic reviewing, epidemiology, infectious disease	20	20	150
25	Wound care, hyperbaric medicine, infectious disease	24	30	36
26	Wound care, software, data analytics	10	10	200
27	Nephrology	20	10	20
28	Podiatric surgery, wound care researcher, professor	30	27	200
29	Regenerative medicine research, preclinical testing, clinical trials	25	30	170
30	Business, wound care	37	N/A	N/A
Mean	-	**21.4**	**15.1**	**51.9**
Median	-	**20**	**13**	**20**

Abbreviations: FDA, Food and Drug Administration; N/A, not available.

Table 2. Summary of Consensus Statements and Panelist Feedback

NUMBER	CONSENSUS STATEMENT	NUMBER (%)		COMMENTS
		YES (n=30)	NO (n=30)	
PANEL 1				
1	Investor hesitancy resulting from poorly executed clinical trials, poor clinical trial design, and/or insufficient endpoints hinders innovation in wound care.	28 (93)	2 (7)	- Investors hesitate from lack of clarity on evidence requirements, performance thresholds, and consistency in the interpretation of results. Poor trials result when these are not clear. - Crowded space, very little differentiation between products.
2	Improved and efficient methods of RWD collection (eg, industry-wide registry) could help define accurate patient populations for clinical trial selection and improve the likelihood of success.	30 (100)	0 (0)	
PANEL 2				
3	Complete wound closure remains the gold standard in primary endpoints for clinical trial design.	28 (93)	2 (7)	- This is an artificial endpoint based on a comprehensive algorithm of care. Unfortunately, if one is doing clinical trials looking at specific wound therapies, simply improving the wound or getting the wound ready for the next step should be adequate. - Strong evidence from reported literature supports multiple clinical outcomes that should be considered as primary (but are currently not), such as QoL, pain, reduction of amputation, reduction of wound size, etc.

Continued on next page

patient populations for clinical trial selection and improve the likelihood of success.

Industry experts on the panel noted that investors are often more interested in the commercial side of products, where success is measured by revenue rather than patient-centered outcomes. However, the panelists emphasized the importance of patient-centered care and identifying why individual patients are not healing (ie, Is it the cells? The scaffolding? The matrix? Cellular senescence?). Having such information could positively impact patient selection in clinical trials. Panelists suggested that defining subtypes and collecting data through clinical trials and natural history can distinguish responders and non-responders based on mechanisms of action, which can then be used to facilitate higher opportunities for success. Panelists also suggested that understanding the underlying mechanisms can drive translational research and the innovation of systemic products like those seen in inflammatory dermatological conditions. The WCCC team is conducting research in RWE and developing a natural history project to work toward this goal.

Ultimately, RWE is thoroughly heterogeneous. At the same time, clinical trial populations are designed to be as homogenous as possible in terms of inclusion/exclusion criteria (although the FDA encourages sponsors to ensure study populations are representative of the diversity of the US population).[3-6] Balancing these 2 sides is difficult when the field uses different metrics and endpoints for RWD. Basket-based trials were suggested, which allow RWD to generate an initial hypothesis that then leads to randomized controlled trials.

Panel 2: Alternative primary and co-primary endpoints

Consensus statement 3: Complete wound closure remains the gold standard in primary endpoints for clinical trial design.

The 9 members of Panel 2 shared their insights from the CDRH (n = 1), the CDER (n = 1), clinical practice (n =

Continued from previous page

Table 2. Summary of Consensus Statements and Panelist Feedback

NUMBER	CONSENSUS STATEMENT	NUMBER (%)		COMMENTS
		YES (n=30)	NO (n=30)	
4	If complete wound closure is unattainable, clinical trials can be carefully designed to incorporate alternative endpoints, targeting both a meaningful degree of wound area reduction and a clinically meaningful outcome for patients.	29 (96)	1 (4)	- I agree with the whole statement, with a caveat at the end that states: "Alternative endpoints must have sufficient evidence to demonstrate clinical meaningfulness and should be agreed upon early in development with the FDA (eg, they may be able to be developed in the proof-of-concept phase 2 trials and should be formally agreed upon prior to initiation of phase 3 trials). Complete wound closure should always be included as a safety endpoint to ensure the product does not delay ultimate wound healing."
5	Innovative tools, devices, products, or diagnostics must accurately and reproducibly measure primary endpoints and provide reliable consistency across study results.	29 (96)	1 (4)	- The only thing I would add to this statement is that all solutions must accurately and reproducibly measure their intended use. This may or may not include primary endpoints.
PANEL 3				
6	The wound care community has a significant need for updated clinical trial reporting guidelines.	30 (100)	0 (0)	
7	Established clinical trial reporting guidelines should be communicated with national and international journals, associations, and conferences for successful adoption. When the entire community agrees to use the same standard, the guidelines will carry the most weight in calibrating published studies.	29 (96)	1 (4)	- I totally agree with the first part of this statement; however, while I believe that standards would be overwhelmingly beneficial, this community of numerous organizations and stakeholders has rarely driven consensus. My recommendation would be to not wait for consensus but to push the consensus on those entities through data and fact. - Wound care research is published in various journals across different specialties, making it challenging to disseminate
PANEL 4				
8	Accurate and updated ICD-10 codes for wound care are urgently needed.	28 (96)	2 (4)	- An important challenge in wound care practice and research is the diverse backgrounds and training of clinicians, which can lead to inconsistent classifications of chronic wounds.
9	Standardized, universal data entry metrics are needed to help calibrate results between RWE and RCTs.	30 (100)	0 (0)	

Continued on next page

Continued from previous page

Table 2. Summary of Consensus Statements and Panelist Feedback

NUMBER	CONSENSUS STATEMENT	NUMBER (%)		COMMENTS
		YES (n=30)	NO (n=30)	
PANEL 5				
10	As the FDA does not regulate SOC or the practice of medicine, professional practice organizations must define their own SOC.	27 (90)	3 (10)	- I agree that SOC would be ideal; however, not everyone has access to SOC technologies or can utilize these solutions due to various limitations. As such, an SOC may have to be adopted by the setting or medical professionals. - The FDA may have input on SOC as used in FDA-registered clinical trials. - The control groups in RCTs define SOC. Societies clarify or give summaries based on the studies.
11	The SOC should be specific and granular, with reasonable parameters to eliminate trial inconsistencies while allowing flexibility for patient-specific needs.	30 (100)	0 (0)	
12	The entire Wound Healing Collaborative Community and its stakeholders must be held accountable for consistently implementing the established SOC.	26 (87)	4 (13)	- WCCC can be responsible for establishing/defining SOC, but it would be impossible to police its execution in studies and clinical practice. If this statement refers to the wound community as a whole and not specifically to WCCC, then I would agree with the statement - We can influence, but implementation needs to take place with the help of the government, clinical guidelines, and individual hospital systems. - Implementation must be achieved through education, with competencies assessed by board examinations. - It is much more than the WCCC. The wound care field is fragmented by multiple competing societies. and not all have joined the WCCC. The field as a whole needs to work together to establish a reasonable SOC that may differ for different types of wounds.

Abbreviations: FDA, Food and Drug Administration; ICD, *International Classification of Diseases*; QoL, quality of life; RCT, randomized controlled trial; RWD, real-world data; RWE, real-world evidence; SOC, standard of care; WCCC, Wound Care Collaborative Community.

4), research (n = 4), and industry (n = 1) on alternative primary and co-primary endpoints for clinical trials. The panel recognized that the common primary endpoint in clinical trials, complete wound closure, is a very high bar for drug, biologic, or device developers to achieve, prolonging the time it takes for products to be available to patients. Yet complete wound closure is consistently lauded as the most clinically meaningful outcome.

Consensus statement 4: If complete wound closure is unattainable, clinical trial designs

can be carefully designed to incorporate alternative endpoints, targeting both a meaningful degree of wound area reduction and a clinically meaningful outcome for patients.

There is extensive evidence that strongly supports the utilization of additional primary endpoints in wound healing clinical trials.[7-9] In addition, co-primary endpoints have been suggested as alternatives to complete wound closure. The FDA may consider co-primary endpoints if such endpoints are clinically meaningful and can be reliably measured in clinical trials using validated tools.[10] For example, a patient experiences a greater than or equal to 50% wound area reduction in combination with a clinically meaningful patient-reported outcome, such as a reduction in pain or infection. The panel discussion emphasized that co-primary endpoints must be measured accurately, and the score change—referring to measurements for a chosen endpoint, scale, or tool—should be predefined and meaningful. Panelists suggest that implementing standardized data registries across the field may be helpful. Alternatively, clinical trial designs could utilize composite or multi-component endpoints, although interpreting the calculated score with these alternative endpoints can be challenging. These designs require significant and strategic planning, as well as early engagement by FDA sponsors to agreed-upon endpoints. Because of the potential for new data on the underlying mechanisms that delay wound care—mentioned in consensus statement 2—new possibilities may emerge as promising candidates for alternative endpoints in a carefully planned trial. Lastly, a clinical trial design must demonstrate a safety endpoint to show that the study treatment is at least equal to or better than the SOC.

Consensus statement 5: Innovative tools, devices, products, or diagnostics must accurately and reproducibly measure primary endpoints and provide reliable consistency across study results.

Within the WCCC, the Tools Working Group identifies validated tools and methods for measuring meaningful clinical endpoints in wound research to develop a core outcome set. The group aims to promote tool advancements that accurately and reproducibly support new primary and secondary endpoints through validated measures. One initial objective has been to evaluate information on methods and devices that support PAR and PVR as primary endpoints in wound healing clinical trials. The group identified that simple length and width measurements frequently overestimate the wound area by more than 44%. Current tools cannot accurately measure the volume of irregular wounds with significant depth, undermining, and tunneling. Digital imaging can reduce variability and record progress over time in an automated process, though much variability remains. Differences were found in using laser 3D photography, the pixel-to-centimeter scale, reference markers, skew correction, color segmentation, calibration, quality measures, clarity focus, and the ability to edit and create trajectory graphs. Product assessments also need to be "fit-for-purpose" in that the level of validation associated with a tool is sufficient to support its context of use.

The WCCC team conducted research focusing on wound care from the patient's point of view.[9] For patients, success is not simply about the wound-healing process; it is also about being able to lead a normal life while the wound heals. Patients uniformly prioritize infection reductions, decreased amputation rates, less social isolation, and improved quality of life, such as performing daily activities independently.[9] It is essential to have the right tools and metrics in place to measure progress in these areas.

Panel 3: Generating and reporting evidence

Consensus statement 6: The wound care community has a significant need for updated clinical trial reporting guidelines.

Panel 3 included experts from the CDRH (n = 1), the CDER (n = 1), clinical practice (n = 3), research (n = 3), and industry (n = 3). They addressed the barriers that prevent standardized reporting in human clinical trials, identified the obstacles to implementing guidelines for reporting of preclinical animal and human testing, and outlined specific steps toward implementing preclinical guidelines among stakeholders.[11] The group provided commentary that clinical trial design and reporting should be comprehensive and representative of the general population on which potential treatments are intended to be used. They also shared advice for developing clinical trial reporting guidelines for wound care that captures vital variables and identifies desired wound outcomes. The WCCC team is conducting research in this area for both preclinical and clinical trial designs. The panel emphasized that clinical trial reporting guidelines must be realistic, timely, flexible, not exceedingly burdensome (eg, requiring a 10-year trial), and sufficient to meet the industry's compliance requirements. It must also be updated frequently to include novel technologies and devices.

Consensus statement 7: Established clinical trial reporting guidelines should be communicated with national and international journals, associations, and conferences for successful adoption. When the entire community agrees to use the same standard, the guidelines will carry the most weight in calibrating published studies.

The aim is to enforce consistent, standardized clinical trial guidelines on a global scale.[11] It is essential to consider initiatives to motivate individual stakeholders. The uniform application of guidelines ensures the quality of the research and facilitates accurate interpretation of results across all studies.

Panel 4: Real-world evidence in FDA and payer decision-making

Consensus statement 8: Accurate and updated ICD-10 codes for wound care are urgently needed.

Panel 4 sought to understand the role of RWE in FDA and payer decision-making.

The WCCC group intends to develop a set of standardized approaches to RWE and wound research in medical policy decision-making. The 9 panelists in this session shared their expertise from the CDRH (n = 1), clinical practice (n = 5), and industry (n = 3). Discussions identified a crucial unmet need for updated ICD-10 codes that accurately describe different wound types.[12] Without accurate codes, studies that report RWE will be inconsistent.

Consensus statement 9: Standardized, universal data entry metrics are needed to help calibrate results between RWE and RCTs.

The panelists discussed how results from real-world trials conducted in hospitals often differ from the results of RCTs.[3-6] They all agree that there is a place for both RCTs and RWE in wound research. For instance, RCTs are necessary for crucial initial labeling. Meanwhile, RWE can be used as a control arm to expand indications for other types of related wounds, validate RCT findings, establish objective performance criteria, enhance post-market requirements, and provide preliminary findings to indicate where RCTs should be conducted.

The challenge in wound care is to find common ground and pursue both RCTs and RWE.[3-6] Collecting data toward this end is also challenging, as data systems do not always collect helpful, research-ready data. Agreeing on standardized metrics for real-world data entry and moving towards a pay-for-performance model can make data more easily collectible.

Panel 5: Defining standard of care in wound care

Consensus statement 10: As the FDA does not regulate SOC or the practice of medicine, professional practice organizations must define their own SOC.

Panel 5 addressed the critical need for a universal SOC in wound care. WCCC volunteer members have strategized on how the SOC can be incorporated into future clinical trials and have projects underway. The 6 panelists in this session shared their expertise from the CDRH (n = 1), clinical practice (n = 3), research (n = 1), and industry (n = 1). They acknowledged that the lack of consensus on an SOC for managing wounds affects all wound care patients. Using a Delphi method to establish consensus opinions on the foundational elements that constitute a solid SOC in clinical trials will allow for refinement of future trial designs for new wound technologies. With the results, the group intends to communicate the findings with key players like the FDA.

Consensus statement 11: The SOC should be specific and granular, with reasonable parameters to eliminate trial inconsistencies while allowing flexibility for patient-specific needs.

According to the panel, the SOC should be as specific and granular as possible, as treatment styles and methods can vary significantly across providers. This will require training/cross-training to ensure consistent levels of health care delivery. Furthermore, the design of this SOC will likely be akin to a spectrum stratified by various patient populations rather than as single, immutable points. This design will benefit clinicians and patients, allowing them to target the most appropriate care. This will also enable the industry to innovate products targeted toward a particular patient population. An official SOC will enable companies to design proper trials to commercialize their technologies effectively, promoting innovation in wound care.

Consensus statement 12: The entire Wound Healing Collaborative Community and its stakeholders must be held accountable for consistently implementing the established SOC.

The panelists agree that once an appropriate SOC is established, the entire wound healing community must commit to its adoption and to promoting the same quality of science across the board. Mechanisms should be in place to hold the entire community accountable. For example, wound care centers would not be able to enroll patients in trials without applying the unified SOC.

DISCUSSION

The summit panelists' collective expertise provides a thorough and diverse representation of the wound care community. Leading voices from the FDA, NIH, industry, health care settings, and research institutions collaborated to discuss the current landscape in wound care and its critical areas for improvement. The 5 panel discussions explored current obstacles, clinical trial reform—including alternative primary and co-primary endpoints—reporting guidelines, the role of RWE in decision-making models, and appropriate SOC. The consensus statements developed here and the continued work of the WCCC offer a strategic pathway forward in the advancement of wound care.

LIMITATIONS

The recommendations from the summit represent the individual experiences of its participants rather than empirical evidence or clinical studies. As a result, the recommendations are influenced by panelist bias, training, discipline, and interpretation of their experiences.

CONCLUSION

The summit panelists represent a diverse group of stakeholders in the wound care community. Their discussions identified the need to develop standards, including those to be used in preclinical and clinical trial design, SOC, and modernized, streamlined processes that will ultimately reduce shortcomings in clinical research. This collaboration can help drive funding and innovation to promote new systems that will provide meaningful change for patients. Much work remains, but the continuing progress being made by the WCCC and its stakeholders, including the collaboration and conversations that occurred during this summit, is an essential step forward.

REFERENCES

1. Driver VR, Gould LJ, Dotson P. When an opportunity knocked, the wound care community responded. *Wound Manag Prevention*. 2021;67(6):6.
2. Chen M, Chang C, Levian B, Woodley DT, Li W. Why are there so few FDA-approved

therapeutics for wound healing? *Int J Mol Sci*. 2023;24(20):15109. doi:10.3390/ijms242015109
3. Bowrin K, Briere JB, Levy P, Toumi M, Millier A. Use of real-world evidence in meta-analyses and cost-effectiveness models. *J Med Econ*. 2020;23(10):1053-1060. doi:10.1080/13696998.2020.1792917
4. Blonde L, Khunti K, Harris SB, Meizinger C, Skolnik NS. Interpretation and impact of real-world clinical data for the practicing clinician. *Adv Ther*. 2018;35(11):1763-1774. doi:10.1007/s12325-018-0805-y
5. Klonoff DC. The expanding role of real-world evidence trials in health care decision making. *J Diabetes Sci Technol*. 2020;14(1):174-179. doi:10.1177/1932296819832653
6. Miksad RA, Abernethy AP. Harnessing the power of real-world evidence (RWE): a checklist to ensure regulatory-grade data quality. *Clin Pharmacol Ther*. 2018;103(2):202-205. doi:10.1002/cpt.946
7. Driver VR, Gould LJ, Dotson P, et al. Identification and content validation of wound therapy clinical endpoints relevant to clinical practice and patient values for FDA approval. Part 1. Survey of the wound care community. *Wound Repair Regen*. 2017;25(3):454-465. doi:10.1111/wrr.12533
8. Driver VR, Gould LJ, Dotson P, Allen LL, Carter MJ, Bolton LL. Evidence supporting wound care end points relevant to clinical practice and patients' lives. Part 2. Literature survey. *Wound Repair Regen*. 2019;27(1):80-89. doi:10.1111/wrr.12676
9. Gould LJ, Liu J, Wan R, Carter MJ, Dotson M, Driver VR. Evidence supporting wound care end points relevant to clinical practice and patients' lives. Part 3: the patient survey. *Wound Repair Regen*. 2021;29(1):60-69. doi:10.1111/wrr.12872
10. US Department of Health and Human Services. Food and Drug Administration, Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER). Multiple Endpoints in Clinical Trials: Guidance for Industry. October 2022.
11. Brölmann FE, Eskes AM, Sumpio BE, et al. Fundamentals of randomized clinical trials in wound care: reporting standards. *Wound Repair Regen*. 2013;21(5):641-647. doi:10.1111/wrr.12087
12. Cartwright D. Pathway to acquire new ICD-10 codes pertinent to new wound care technology. *Adv Wound Care (New Rochelle)*. 2018;7(11):354-357. doi:10.1089/wound.2018.0823

Acknowledgments: The Wound Care Collaborative Community (WCCC) would like to thank all panel members in attendance for their valuable participation at the Summit: William Li, MD; Yu-Chieh Chiu, PhD; Dev Verma, MD; Bill Ennis, DO; Peggy Dotson, RN, BS; John Azeke, PhD; Caroline Fife, MD; Lucian Vlad, MD; William H. Tettelbach, MD; John C. Lantis II, MD; Emma Wright, PhD, BSc; Michael Steadman; John Harper, PhD; Katie Mowry, PhD; Lisa Gould, MD, PhD; Cristina Taylor, MSHS PA; Shabnam Vaezzadeh, MD, MPA; Randy Schwartz; Amy Law, MBA; Monique Rennie, PhD; Dheerendra Kommala, MD; Matt Pine; Kira Rupprecht, MBA; Beate Hanson, MD, MPH; Yi Arnold, PhD, MBA; and Tim Jacobson, CFA. Cynthia J. Chang, PhD participates in the WCCC as an FDA liaison.

WCCC Appointments: V.R.D. serves as Chair, Board of Directors, WCCC. H.W. serves as Chair, WCCC Gaps Working Group. A.O. serves as Chair, WCCC Tools Working Group. M.J.C. serves as Chair, Clinical Trial Standards and Reporting Workstream. M.T-C. serves as Chair, WCCC Pre-Clinical Trial Standards and Reporting Workstream. J.R. serves as Chair, WCCC Real-World Evidence Working Group. M.H. serves as Chair, WCCC Real-World Evidence Group Standard of Care Workstream.

Recommended Citation: Driver VR, Walthall H, Oropallo A, et al. Collaboration encourages innovation: setting new standards in wound care with the Wound Care Collaborative Community expert panel consensus recommendations. *Wounds*. 2024;36(12):410-418. doi:10.25270/wnds/24186