WCCC

WOUND CARE COLLABORATIVE COMMUNITY

Driving Innovation in Wound Care Summit

SAWC Spring WHS | WOUNDS

Summit Opening: Coming Together as a Community

May 2, 2025 **Begins at 8:00AM**

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WOUND CARE COLLABORATIVE COMMUNITY

Driving Innovation in Wound Care Summit

SAWC Spring WHS | WOUNDS

Summit Opening: Coming Together as a Community

Vickie R Driver, DPM, MS
Chair, Wound Care Collaborative Community
Professor, Washington State Univ. School of Medicine

May 2, 2025

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Driving Innovation in Wound Care Summit

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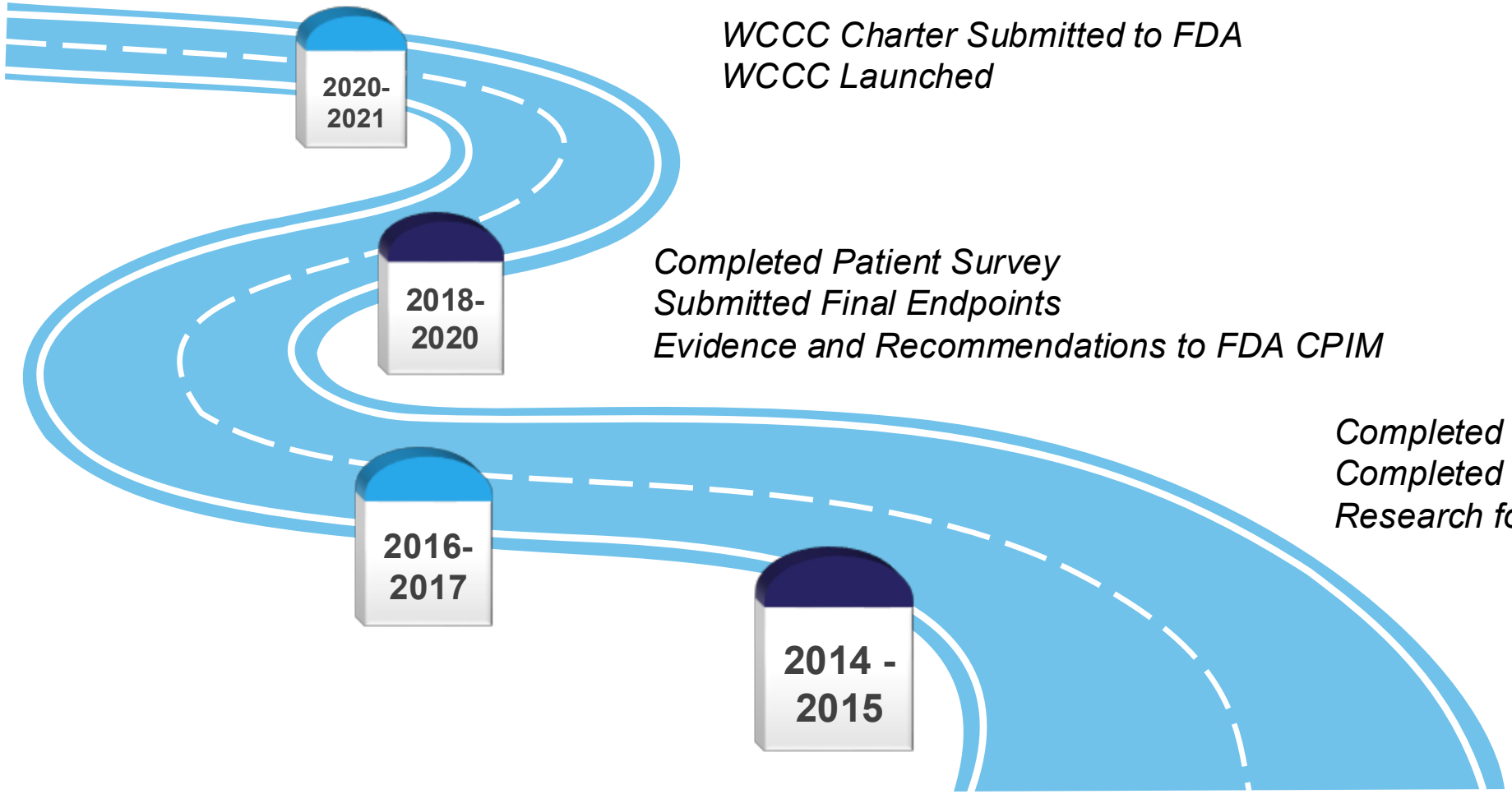
Driving Innovation in Wound Care Summit

WCCC – In the beginning…

- Years of successfully working with the FDA and the WC community on defining meaningful & patient centric endpoints (WEF-CEP initiative)~ 7 years
- Following this extensive research effort, three publications[1,2,3] and a community outreach program… the FDA asked us to consider developing a Wound Care Collaborative Community-

1. 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. Wound Rep Regen 2017;25 (3):454–465.
2. Driver VR, Gould LJ, Dotson P, Allen LL, Carter MJ, Bolton LL. Evidence Supporting Wound Care Endpoints Relevant to Clinical Practice and Patients' Lives. Part 2. Wound Rep *Regen 2019;27(1):80-89.*
3. Gould LJ, Liu J, Wan R, Carter MJ, Dotson M, Wan R, Driver VR. Evidence supporting wound care end points relevant to clinical practice and patients' lives. Part 3: The Patient Survey. Wound Rep Regen 2020;1-10.

WCCC How We Got Here



WCCC Charter Submitted to FDA
WCCC Launched

Completed Patient Survey
Submitted Final Endpoints
Evidence and Recommendations to FDA CPIM

Completed Clinician Survey
Completed Evidence
Research for 15 Endpoints

Engaged with FDA
Launched WEF-CEP
Developed Clinician Survey

What is a Collaborative Community?

A Community Of Continuing Forum – Including The Private And Public Sector To Achieve Common Objectives

Developed when:

- Challenges are ill-defined or there is no consensus
- Incremental or unilateral efforts to address the challenge have been ineffective
- Partners seek to optimize efforts, including preventing duplication of efforts

Collaborative Communities

MDIC
MEDICAL DEVICE INNOVATION CONSORTIUM

WCCC
WOUND CARE COLLABORATIVE COMMUNITY

FNIH 25
Foundation for the National Institutes of Health

NEST
Coordinating Center
An initiative of MDIC

CCOI

Collaborative Community on Ophthalmic Imaging

Pathology Innovation Collaborative Community
Picc
The Alliance for Digital Pathology

Heart Valve COLLABORATORY

STRIPE
STANDARDIZING LABORATORY PRACTICES IN PHARMACOGENOMICS

RESCUE Collaborative Community

MedTechColor

Xavier Artificial Intelligence (AI) World Consortium

DATACC
Digital Health Measurement Collaborative Community

International Liquid Biopsy Standardization Alliance (ILSA)

United Effort to Confront Barriers

- At the request of the FDA started a Collaborative Community-2021
- Investigated what a CC should be
- Agreed that new diagnostics and treatments were severely lacking at the bedside
- Developed WGs to explore most critical inhibiting factors of innovation in WC
- Recruited top notch content experts
- Focus on improving research methods and process, then clinical practice
- Constant SWAT analysis

Uphill battle well recognized

Removing Barriers Requires Evidence Intended To Predictably "Move The Needle"

- Build a bridge towards the ultimate vision of driving innovation
- Understand key barriers
- Work groups focused on inhibiting barriers
- Find the gaps and work to close them - improve the quality of research, the quality-of-care standards and new innovations to our patients
- Work as a community for productive outputs
- Be nimble and adapt to change

WCCC Vision

To transform wound care by breaking down barriers that will ensure patients and health care providers benefit from modern treatments and technologies for healing wounds.

Wound Care Collaborative Community

The W Triple C (WCCC)

- Non-profit 501c with a BOD and work group leaders
- Volunteer- work groups with content experts
- Structured platform and timelines to gain results
- Closely partnered with FDA, CMS, NIH
- Dedicated to developing and publishing the evidence

2025 WCCC Executive Leadership Team

Vickie R. Driver, DPM, MS, FACFAS

Chair

Alisha Oropallo, MD

Vice Chair

Robert Snyder, DPM, MBA

Secretary

Joseph Rolley, MSIA

Treasurer

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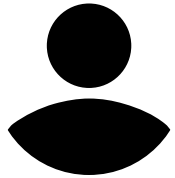
PhD, BSc

Work Group Leadership

GAPS WORK GROUP CHAIR

Howard Walthall
BSE, JD



GAPS WORK GROUP VICE CHAIR

OPEN

GAPS WORK GROUP OFFICER LIAISON

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DPM, MS, FACFAS

REAL-WORLD EVIDENCE WORK GROUP CHAIR

Lucian Vlad
MD

REAL-WORLD EVIDENCE WORK GROUP VICE CHAIR

Caroline Fife
MD

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TOOLS WORK GROUP

Holly Franzen-Korzendorfer
PT, PhD, CWS, FACCWS

TOOLS WORK GROUP VICE CHAIR

Francis James

TOOLS WORK GROUP OFFICER LIAISON

Alisha Oropallo
MD

Work Stream Leadership

CLINICAL TRIAL STANDARDS & REPORTING (GAPS)

Dr. Marissa Carter

CLINICAL TRIAL STANDARDS (RWE)

Maribel Henao

DPM

DRESSINGS STANDARDS (GAPS)

Sarah Griffiths Langbord

FACS, FSVS, FABWMS

NATURAL HISTORY PROJECT – (RWE)

Caroline Fife

MD

Committee Leadership

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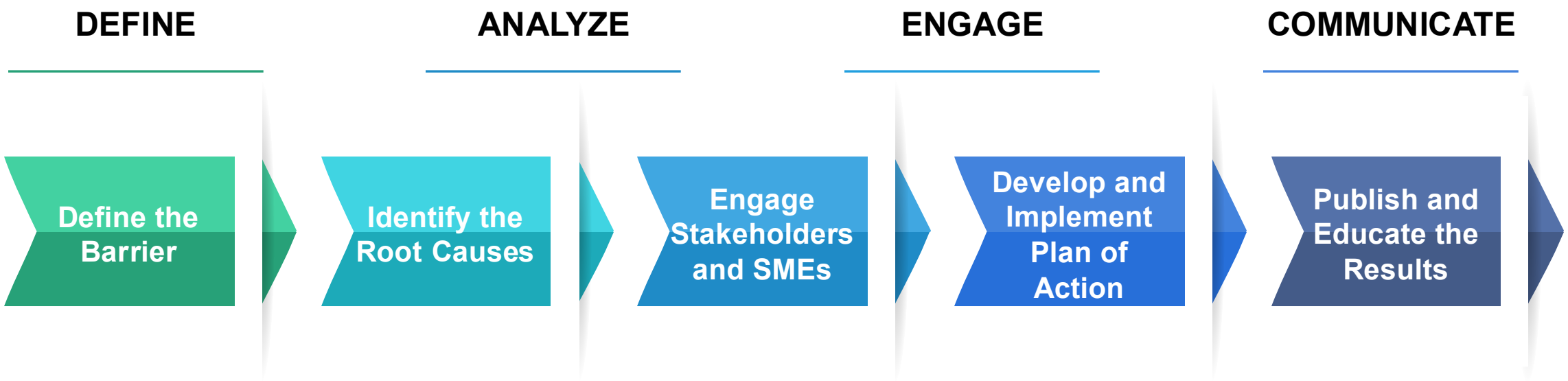
WCCC Identifies and Addresses the Root Causes of Access Barriers



Collaborators (list not comprehensive)

WCCC's Work is Spread Across Three Work Groups, 9 Work Streams and 2 Committees

Gaps Work Group

Chair: *Howard Walthall, JD*

Goal: Identification of gaps in current wound healing versus the desired pace of innovating real-world advanced diagnostics and treatments for patients including

- regulatory,
- clinical trials,
- clinical practice
- preclinical.

RWE Work Group

Chair: *Lucian Vlad, MD*

Vice-Chair: *Caroline Fife, MD*

Goal: Development of a standardized approach to use real-world data in wound research and the role it plays in:

- FDA approvals and
- public and commercial payer coverage decisions.

Tools Work Group

Chair: *Holly Franzen-Korzendorfer, PT, PhD, CWS, FACCWS*

Vice Chair: *Francis James*

Goal: Identification of validated tools and methods for measuring meaningful clinical endpoints in wound research to develop a Core Outcome Set. Educate and help develop and validate tools for research and clinical practice.

Multiple Projects to Drive Innovation and Access

Improvement in how randomized clinical trials are designed, conducted, and evaluated to improve the quality of the evidence supporting innovative technologies and reduce health inequities

Evaluation of existing real-world databases for their suitability for wound research and fit-for-purpose for regulatory and coverage decisions.

In-depth analysis of real-world data contained within a Qualified Clinical Data Registry to identify what real-world patients look like versus the patients and wound types selected for clinical trials; working with FDA to close the gap.

Improvement of the **peer-review processes employed by scientific journals** evaluating wound care research to raise the bar of what constitutes quality clinical wound research.

Advocating for inclusion in FDA's "Guidance for Industry Chronic Cutaneous Ulcer and Burn Wounds — Developing Products for Treatment" additional validated and measurable clinical outcomes as primary endpoints

Validation of available technologies for more accurate wound diagnoses and measurements

Encouraging the **use of "Big Data"** to better predict whether a product is going to work or not.

Identification of specific steps towards the **implementation of pre-clinical and clinical guidelines with researchers, industry and FDA for use in designing wound healing research studies**

While WCCC is an FDA-recognized collaborative community, our mission goes beyond FDA engagements

February 20, 2024

Dr. Jeff Shuren and Dr. Peter Marks
c/o Dockets Management Staff
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852-1740

Re: Document number GUI00500012
Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices
Draft Guidance for Industry and Food and Drug Administration Staff

Submitted electronically at https://www.regulations.gov

Dear Drs. Shuren and Marks,

The Wound Care Collaborative Community (WCCC) would like to express its support and concerns regarding the draft Guidance Real-World Data: Assessing Registries to Support Regulatory Decision-Making for Drug and Biological Products Guidance for Industry.

WCCC is a 501(c)3 non-profit, FDA-recognized collaborative community of over 150 wound care experts focused on improving the availability and accessibility of best practice care for people suffering with wounds. Our volunteer experts contribute their experience in clinical research, patient care, and development of devices, biologics, and drugs for patients with wounds. Participating members represent a wide range of healthcare practitioners, clinical societies, and associations in the fields of medicine, geriatrics, dermatology, podiatry, vascular, cardiovascular, plastic surgery, physical therapy, nursing, and research, as well as industry distributors, manufacturers, and product developers in both the US and international markets. More information about our community can be found at: http://www.woundcarecc.org/.

We value the attention the FDA is placing on the use of Real-World Data (RWD) and Real-World Evidence (RWE) as a basis for regulatory decision making. We believe FDA's openness to clarifying its approach to RWE in regulatory decision making and willingness to work with study sponsors as they develop real-world evidence that FDA regards as fit-for-purpose will encourage and accelerate the development of high-quality RWD/RWE. While we certainly understand the significant role that randomized controlled studies play in regulatory safety and efficacy decision making, we also believe there is also a significant role for real-world evidence which has not been fully considered to date. This stems mostly from a lack of clarity on what is and is not suitable for RWD and RWE for regulatory decisions. While the emphasis on RCTs as the primary source of acceptable evidence, the generalizability of RCT findings to real-world patients is often limited due to narrow inclusion and broad exclusion criteria among other artificial study conditions. Moreover, for wound studies, the only acceptable clinical endpoint by evidence assessors has primarily been total wound closure despite published

WCCC communicates and works with all government policymakers or contractors that impact patient access to wound care innovations.

While our focus is on wound care treatments, many of the problems we address also impact access to technologies in other disease areas.

Wound Care Collaborative Community…By the Numbers

289

Total Members incl. FDA & CMS

All Volunteers

62

Medical Professionals

100

Industry Members

3

Working Groups

10

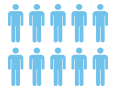
Active Projects

9

Publications

4 papers planned for 2025

7



Comment Letters to Policymakers

4

Years Since Formation

WCCC website: [Home Page - Wound Care Collaborative Community]

Challenges in Developing Innovative Products for Non-Healing Chronic Wounds

Developers' Challenges Bringing Innovation to Market

Regulatory Hurdles	Financial Strain	Market Competition	Intellectual Property Protection	Manufacturing & Supply Chain	Team Building & Expertise	Physician & Patient Adoption	Insurance Reimbursement
FDA approval & compliance Ongoing compliance	High capital needs for R&D, clinical trials, and regulatory approvals Cash flow issues Commercial launch costs	Established competitors Pricing pressures	Patent issues Patent expenses Life cycle management Competitor 'me-too's'	Production scalability Supplier relationships	Lack of experienced leadership Hiring challenges	Clinical validation Patient education	Coding, coverage and payment Payer relationships

2024 WCCC Expert Panel Consensus Recommendations

Define the Barrier

CONSENSUS STATEMENTS

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[3,4]; Marissa J. Carter, PhD, MA[5]; Marjana Tomic-Canic, PhD[6]; Joseph Rolley, MS[7]; and Maribel Henao, DPM, MSPT[8]

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 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."

WCCC WOUND CARE COLLABORATIVE COMMUNITY

LinkedIn

Comments Most relevant

Dev Verma, MD (He/Him) • 1st 2h •••
Plastic & Reconstructive Surgeon | FDA Medi...

Fantastic work and much needed clear consensus recommendations from key stakeholders!

In my personal opinion this article should be cited and referenced often, and its recommendations implemented, by anyone interested in product development for wound care and in obtaining product approval through regulatory agencies.

Patients are in need of innovative products, and this paper provides clear recommendations on how to make that path to development smoother and a real possibility.

Like | Reply

#1: Investor Hesitancies in Commercial Investment, Research and Development

- High risk, low probabilities and reliability of clinical trials
  - High rate of trial failure, trial design, SOC, multidisciplinary, EPs not reachable, lack validated tools for EPs, 2006 FDA guidance not updated
- Commercial viability - reimbursement landscape changes
- RWD - not properly collected/utilized to define population
- The regulatory and reimbursement system penalizes innovation and rewards me-too products
  - Innovators that navigate the complexity and barriers face me-too copies that leverage the innovator products as 510(k) predicates with the same reimbursement as the innovator

#1: Investor Hesitancies in Commercial Investment, Research and Development

- Research and publications defining meaningful & patient centric endpoints
  - WEF-CEP initiative – collaborate with the FDA
- Develop a standardized approach to RWD in wound research and the role it plays in FDA approvals and public and commercial payer coverage decisions
- Identify a minimal set of treatment standards for use in comparative clinical trials – higher quality evidence for regulatory decision making
- Initiatives to modernize systems and streamline processes to reduce the burden of confusion and ineffectiveness of clinical research in wound care that drives investors away

#2: Understanding the Natural History of Disease

- Lack of standards and translation of pre-clinical models to human clinical trials
- Much of scientific and clinical data is focused on low complexity patients with superficial wounds
- No standardized approach to use RWD in wound research.
- Used alone or in conjunction with data gathered from RCTs, RWD can help researchers gain insights into how diagnostics and therapies are performing in the real-world
- Most current therapies do not understand target pathways and mechanism of product

#2: Understanding the Natural History of Disease

- Develop a Natural History Project focused on harnessing real-world data to differentiate real-world chronic wound patients versus those studied in RCTs
- Develop a Fit-For-Purpose Project to best meet FDA RWE guidelines for expanded labeling and ensuring RWD meets FDA's criteria of fit-for-purpose, high quality, relevance and reliability

#3: Insufficiencies in Preclinical Testing and Clinical Trial Design

- No agreed clinical trial standards across sites and trials - need prescriptive measures – protocol violations
- Lack of meaningful clinical endpoints
- Standardized and validated measurement and diagnostic tools not understood, or agreed upon for support of EPs
- Enrollment based on limited parameters and patient population- slow enrollment and not RW
- Lack of trained clinical trial sites and SOC practice standards
- No agreement on reasonable comparator

#3: Insufficiencies in Preclinical Testing and Clinical Trial Design

- Develop pre-clinical and clinical trial reporting guidance – Minimum Core Dataset
- Develop clinical trial development standards/guidelines
- Develop clinical SOC best practices for clinical trials
- Identify barriers to utilization of new endpoints
- Identify valid tools that accurately and reproducibly support new primary and secondary endpoints, validated through the WEF-CEP initiative and publish findings
- Identify a minimal set of treatment standards for use in comparative clinical trials

WCCC Publications and Education Programs

Publish and Educate the Results

Published papers:

- *Comprehensive Landscape Analysis for Usable Real-World Wound Care Data* (Authors: Lucian G. Vlad, MD; Joseph Rolley, BS, MSIA; Shabnam Vaezzadeh, MD, MPA; Lisa Gould, MD, PhD; Caroline E. Fife, MD,6; Vickie R. Driver, DPM, MS; Anokhi J. Kapasi, PhD, BS; John C. Lantis II, MD; Sharmila A. Kamani, BA; and Burak K. Pakkal, MD, MBA)
- *The Wound Reporting in Animal and Human Preclinical Studies (WRAHPS) Guidelines* (Authors: Nkemcho Ojeh PhD, Nicole M. Vecin MD, MPH, Irena Pastar PhD, Susan W. Volk VMD, PhD, Traci Wilgus PhD, Sarah Griffiths PhD, Allison N. Ramey-Ward PhD, Vickie R. Driver DPM, MS, Luisa A. DiPietro DDS, PhD, Lisa J. Gould MD, PhD, Marjana Tomic-Canic PhD)
- *Collaboration Encourages Innovation: Setting New Standards in Wound Care With the Wound Care Collaborative Community Expert Panel Consensus Recommendations* (Authors: Vickie Driver, DPM, MS, Howard Walthall, JD, BSE, Alisha Oropallo, MD, Marissa Carter, Ph.D., Marjana Tomic-Canic, Ph.D., Joseph Rolley, BS, MSIA, Maribel Henao, DPM, MSPT)

Submitted for publication:

- *Reporting of Clinical Trials* (Authors: Marissa Carter PhD, Alisha Oropallo MD, Windy Cole DPM, Edmond Lee MBA, Vickie R Driver DPM, Rhonda Sullivan PhD, Howard Walthall JD, Robert Snyder DPM, Christine Bongards, PhD)
- *An Overview and Survey of FDA-registered Wound Imaging Devices Capable of Determining Percent Area/Volume Reduction* (Authors: Holly Korzendorfer, Peggy Dotson, Francis James, Windy Cole, Alisha Oropallo)
- *The Importance of Color Accuracy in Wound Assessment* (Authors: Frances James, Peggy Dotson, Alisha Oropallo, Vickie Driver, Monique Rennie, Ben Favret, Jason Woodworth)
- *NIR Literature Review: Advancing Chronic Wound Care with Near-infrared Spectroscopy Imaging: Clinical Applications, Measurement Parameters, and Insights into Healing Dynamics* (To be submitted Spring 2025)

To be Submitted Q4, 2025:

- Three papers from the Natural History Project

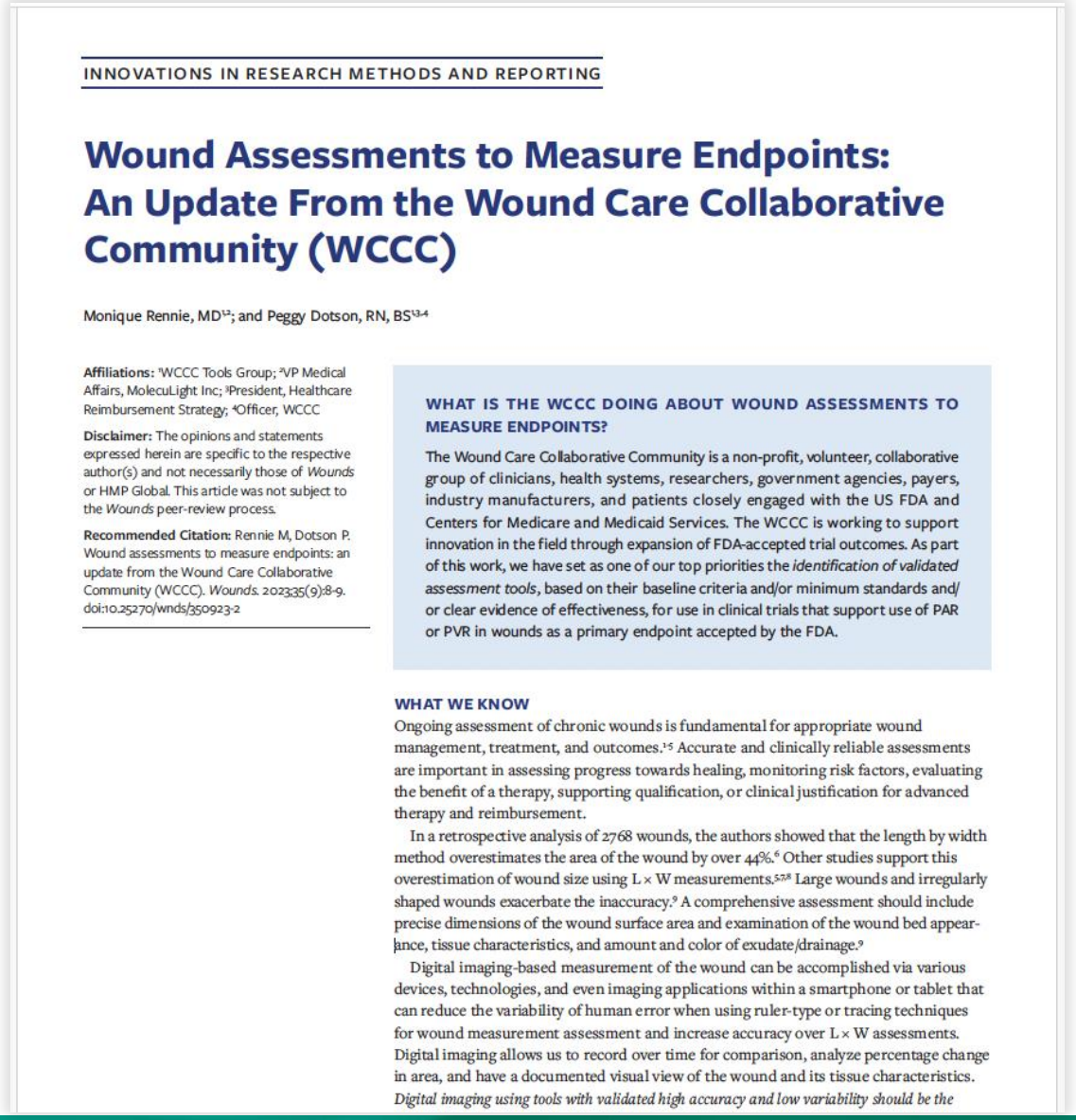
SAWC Poster:

- *Standardizing Medical Photo Acquisition to Improve Image Quality (*Contributors: Francis James, Ben Favret, Peggy Dotson, Holly Korzendorfer, Alisha Oropallo, Windy Cole, Scott Laraus)

Educational Programs:

- Planned for rollout in late 2025

WCCC Tools WG, Wounds, September 2023 | vol. 35, no. 9



INNOVATIONS IN RESEARCH METHODS AND REPORTING

Wound Assessments to Measure Endpoints: An Update From the Wound Care Collaborative Community (WCCC)

Monique Rennie, MD[1,2]; and Peggy Dotson, RN, BS[3,4]

Affiliations: [1]WCCC Tools Group; [2]VP Medical Affairs, MolecuLight Inc; [3]President, Healthcare Reimbursement Strategy; [4]Officer, WCCC

Recommended Citation: Rennie M, Dotson P. Wound assessments to measure endpoints: an update from the Wound Care Collaborative Community (WCCC). *Wounds*. 202335(9):8-9. doi:10.25270/wnds/350923-2

WHAT IS THE WCCC DOING ABOUT WOUND ASSESSMENTS TO MEASURE ENDPOINTS?

The Wound Care Collaborative Community is a non-profit, volunteer, collaborative group of clinicians, health systems, researchers, government agencies, payers, industry manufacturers, and patients closely engaged with the US FDA and Centers for Medicare and Medicaid Services. The WCCC is working to support innovation in the field through expansion of FDA-accepted trial outcomes. As part of this work, we have set as one of our top priorities the *identification of validated assessment tools*, based on their baseline criteria and/or minimum standards and/or clear evidence of effectiveness, for use in clinical trials that support use of PAR or PVR in wounds as a primary endpoint accepted by the FDA.

WHAT WE KNOW

Ongoing assessment of chronic wounds is fundamental for appropriate wound management, treatment, and outcomes.[1-5] Accurate and clinically reliable assessments are important in assessing progress towards healing, monitoring risk factors, evaluating the benefit of a therapy, supporting qualification, or clinical justification for advanced therapy and reimbursement.

In a retrospective analysis of 2768 wounds, the authors showed that the length by width method overestimates the area of the wound by over 44%.[6] Other studies support this overestimation of wound size using L × W measurements.[5,7,8] Large wounds and irregularly shaped wounds exacerbate the inaccuracy.[9] A comprehensive assessment should include precise dimensions of the wound surface area and examination of the wound bed appearance, tissue characteristics, and amount and color of exudate/drainage.[9]

Digital imaging-based measurement of the wound can be accomplished via various devices, technologies, and even imaging applications within a smartphone or tablet that can reduce the variability of human error when using ruler-type or tracing techniques for wound measurement assessment and increase accuracy over L × W assessments. Digital imaging allows us to record over time for comparison, analyze percentage change in area, and have a documented visual view of the wound and its tissue characteristics. *Digital imaging using tools with validated high accuracy and low variability should be the*

WCCC WOUND CARE COLLABORATIVE COMMUNITY

Coming Together as a Community

- The FDA and CMS have a renewed interest in advancing product development for non-healing chronic wounds, have identified barriers to product development, and are planning on **taking specific actions to help address** these barriers in collaboration with external stakeholders.
- The WCCC is taking advantage of the collaborative opportunities offered by FDA and CMS to serve as a **valuable resource** dedicated to identifying the causes and effects of barriers to innovation and then employing an evidence-based approach towards obtaining resolutions.

U.S. FOOD & DRUG ADMINISTRATION

CDRH

Enhancing Patient-Centered Efforts

Michelle Tarver, MD, PhD

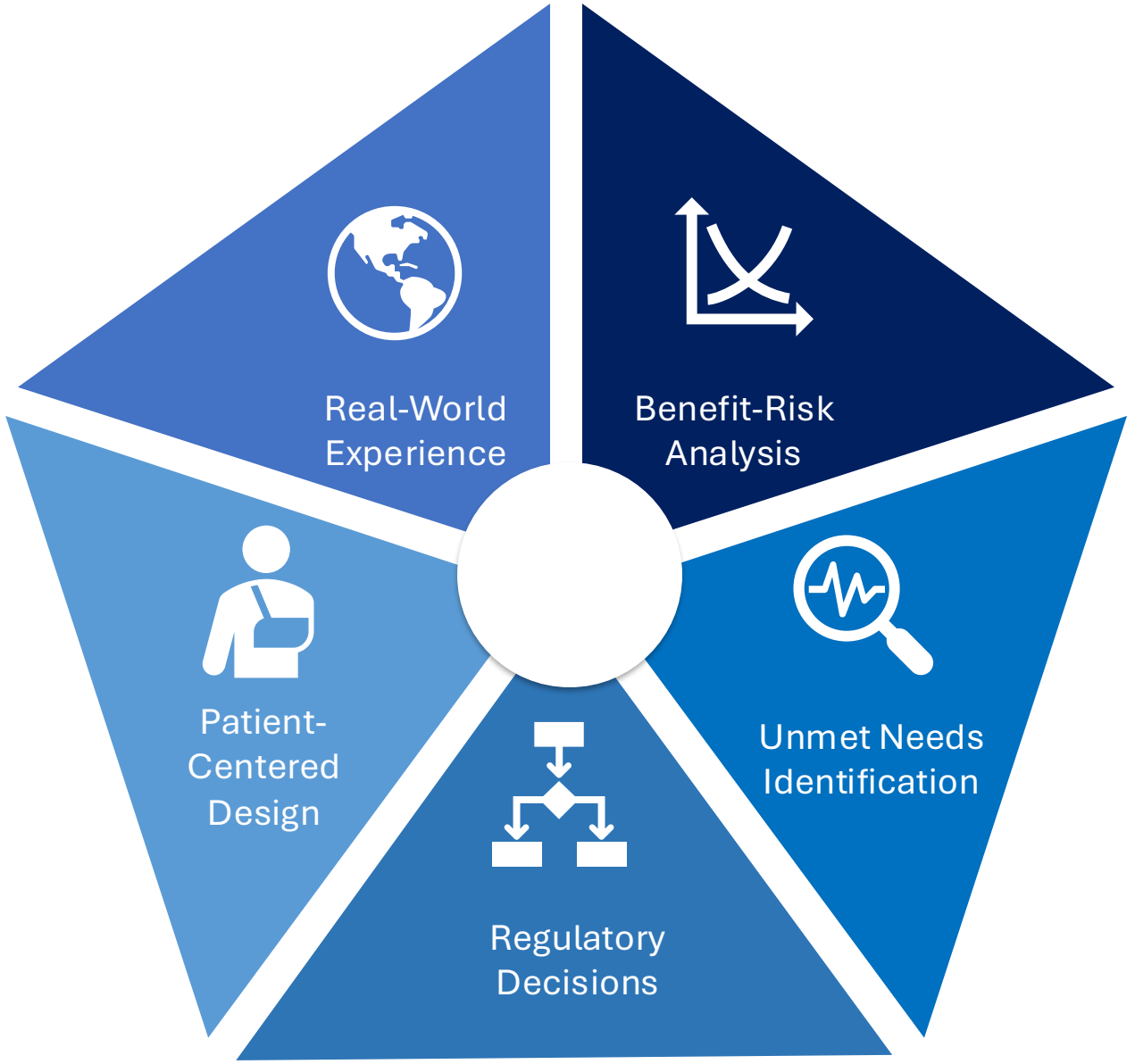
Director, Center for Devices and Radiological Health
US Food and Drug Administration
Department of Health and Human Services
May 2, 2025

Patients are at the heart of what we do

CDRH Vision

Patients in the U.S. have high-quality, safe, and effective medical devices of public health importance first in the world

The value of the patient voice



Collaborative communities benefit from patient perspectives

FDA currently participates in 17 Collaborative Communities

Impact of collaborative communities

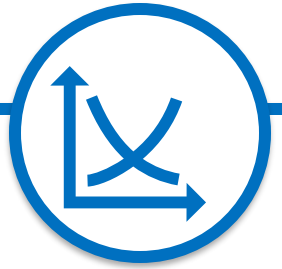
- Tool development
- Discussion papers
- Best practice documents
- Templates & frameworks to support innovation
- Research projects to advance science
- Peer-reviewed manuscripts
- Improved relationships

Methods to measure the patient's experience

Clinical Outcome Assessments

Measures that reflect how a patient feels & functions

e.g., PROs



Patient Preference Information

Captures how patients value benefits and risks

e.g., survey-based methods

Patient-Generated Health Data

Health related data recorded by patients

e.g., wearables

Fostering reliability and validity

Patient-Focused Device Guidances

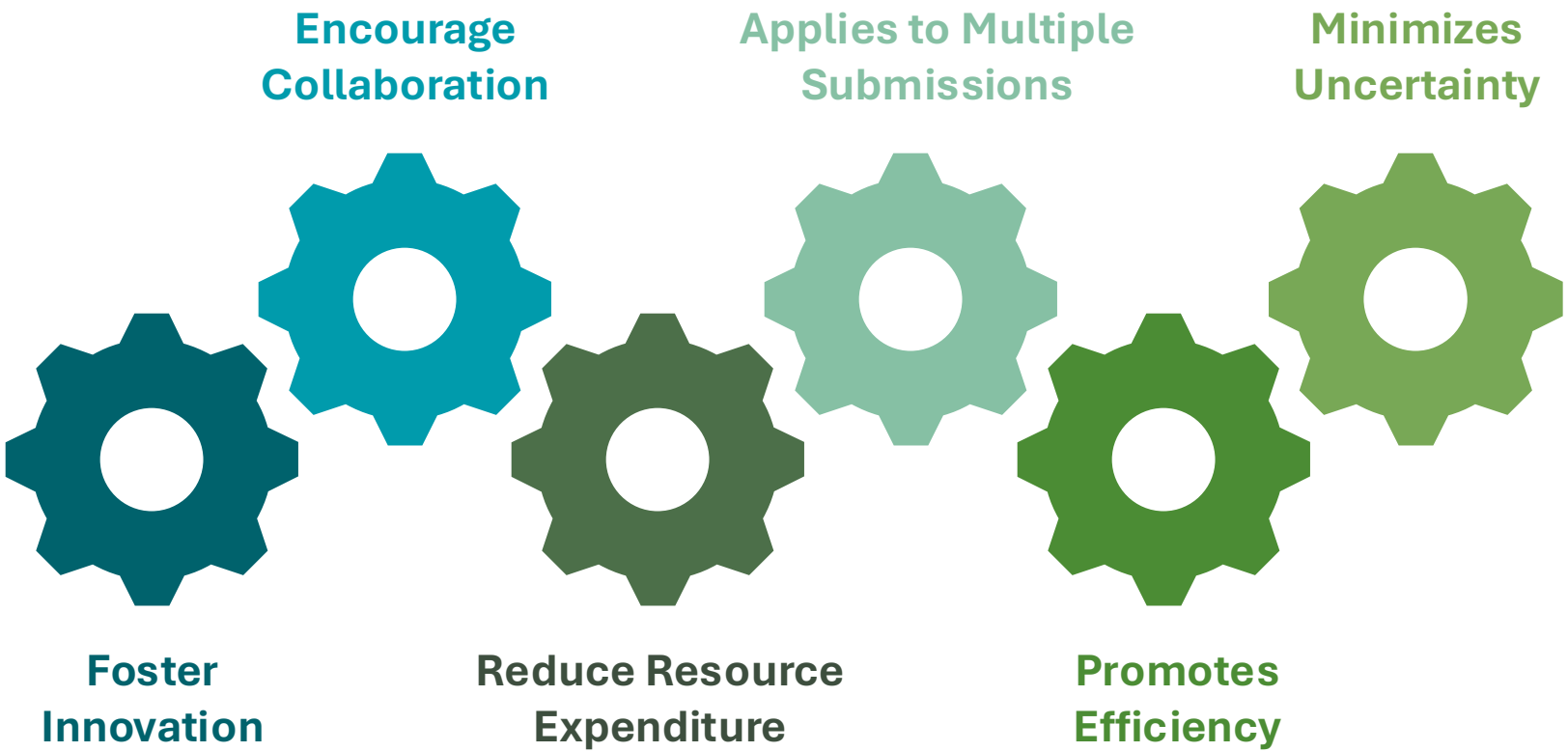
Patient Engagement in the Design and Conduct of Medical Device Clinical Studies

Incorporating Voluntary Patient Preference Information over the Total Product Life Cycle

Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation

CDRH qualifies tools that measure patient experience

The Medical Device Development Tool (MDDT) Program promotes efficient medical device development through the qualification of tools



WOUND–Q as a new Clinical Outcome Assessment MDDT

FDA U.S. FOOD & DRUG ADMINISTRATION

Center for Devices and Radiological Health

SHARE

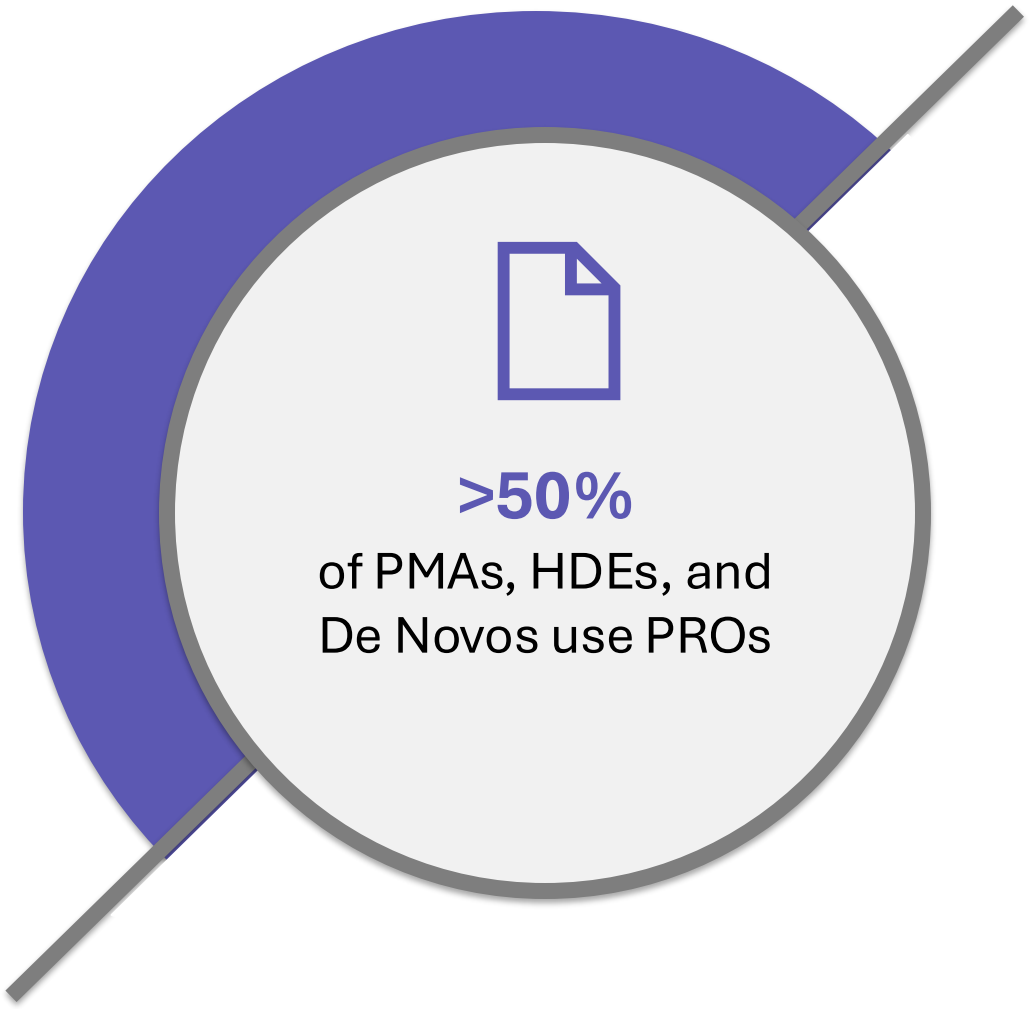
FDA qualifies WOUND-Q instrument as a new MDDT

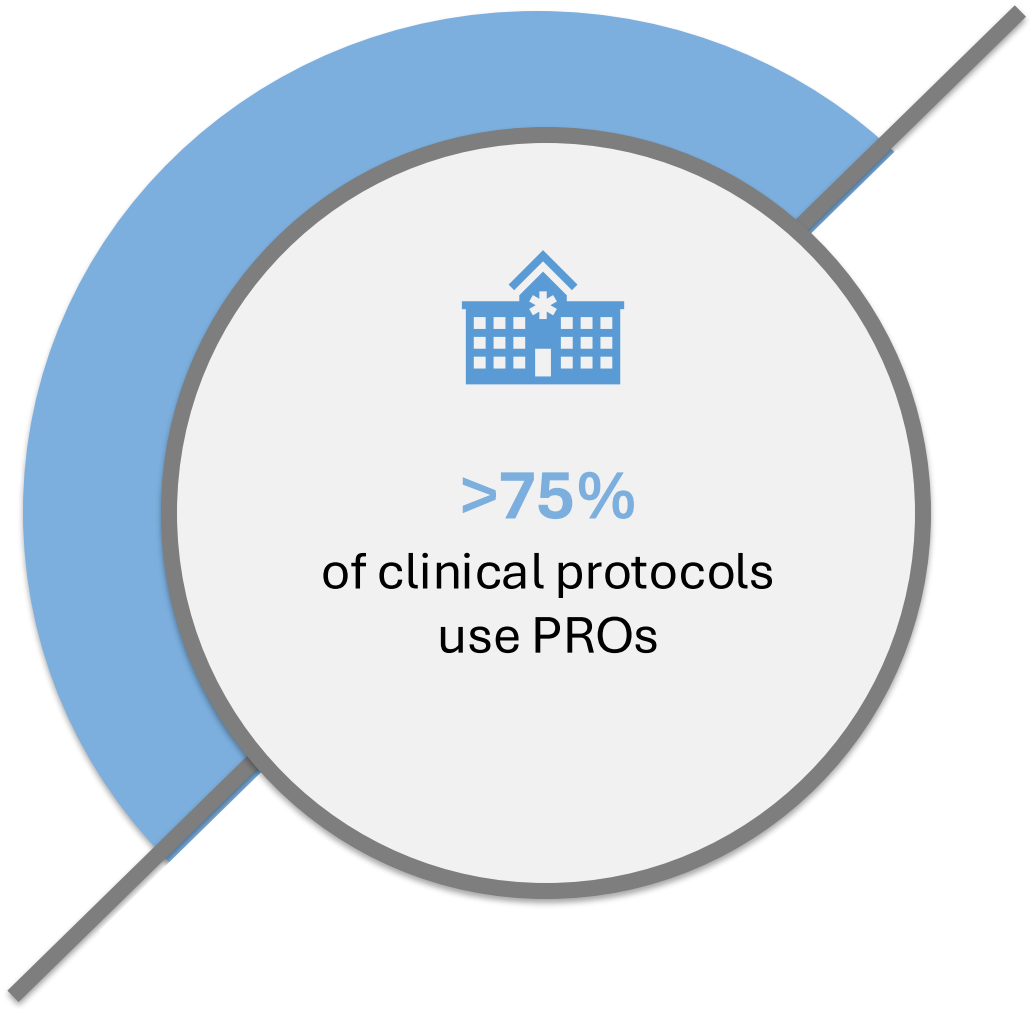
The FDA is announcing qualification of the WOUND-Q instrument through the Medical Device Development Tools (MDDT) program. WOUND-Q is a new patient-reported outcome instrument, to measure outcomes in individuals with nonhealing chronic wounds in any area of the body.

The qualified WOUND-Q instrument:

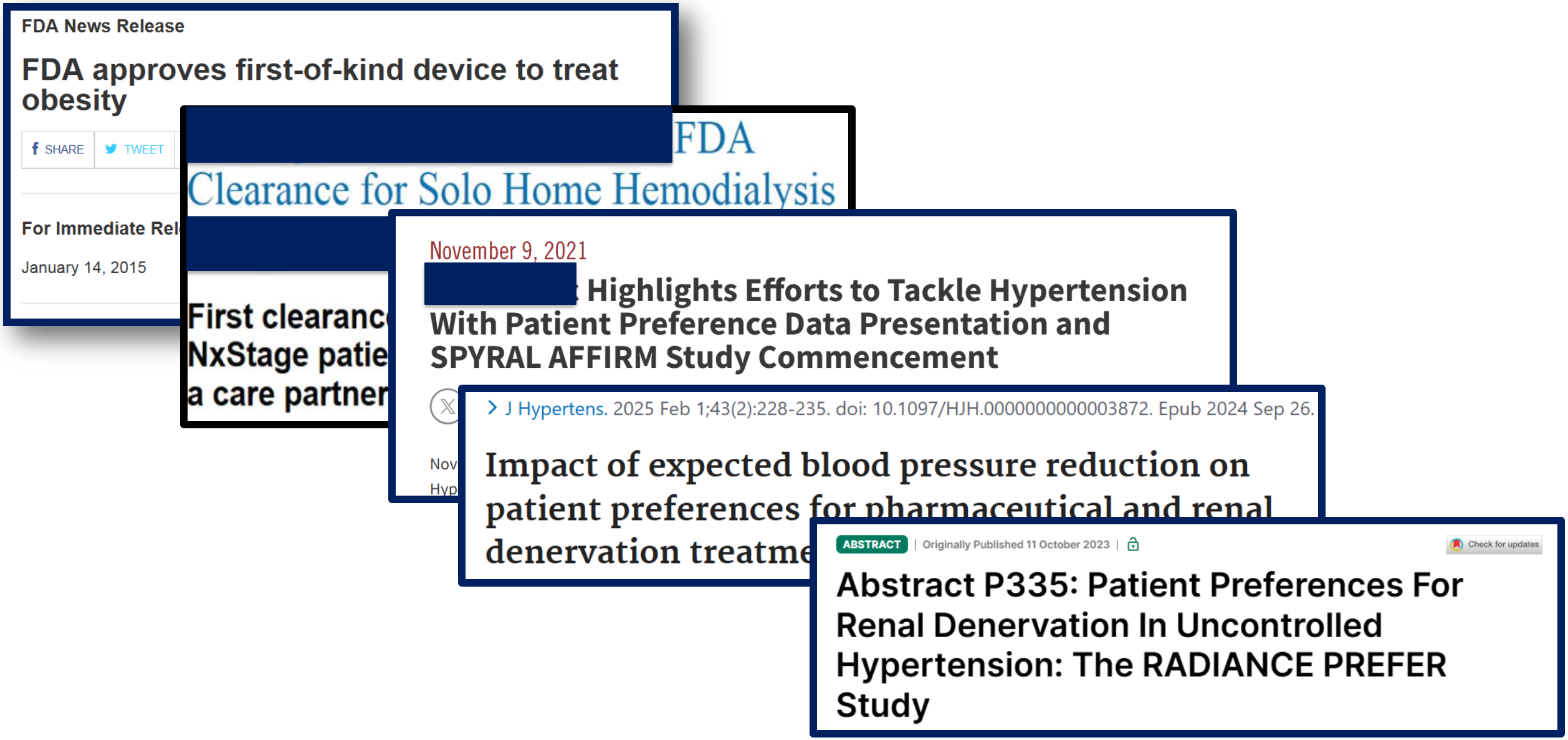
- Can measure outcomes important to individuals with nonhealing chronic wounds (lasting three months or longer) for medical device development.
- Is a set of seven separate scales to assess aspects of wound characteristics and impact on health-related quality of life.

More than 50% of submissions use PROs





Dozens of industry-sponsored regulatory PPI studies completed or in pipeline



Patient generated health data enables an understanding of patient behavior

Patient-generated health data collected from digital health technologies allows us to understand patient behavior in the context of their daily lives

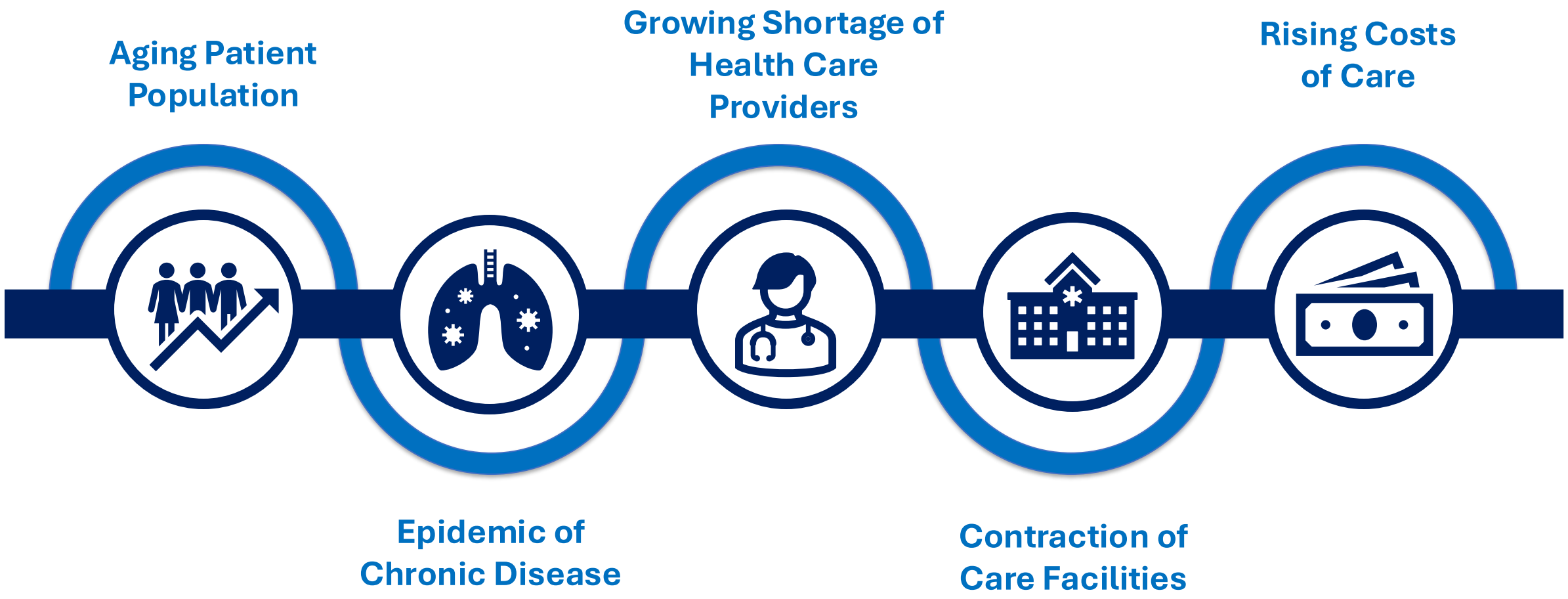
WORKSHOP | VIRTUAL

Co-sponsored Public Workshop – Using Patient-Generated Health Data in Medical Device Development: Case Examples of Implementation Throughout the Total Product Life Cycle

JUNE 26 - 27, 2024

[Co-sponsored Public Workshop - Using Patient-Generated Health Data in Medical Device Development: Case Examples of Implementation Throughout the Total Product Life Cycle - 06/26/2024 | FDA]

Health Care Today: Challenges



CDRH's new person-centered initiative

Home as a Health Care Hub Initiative

Reimagine device use in the home environment as an integral part of the health care system, with the goal of advancing access to better health outcomes for all people in the U.S.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ADMINISTRATION

WCCC is continually seeking new experts to join and support its efforts.

Join us:

www.woundcarecc.org
info@woundcarecc.org
407.337.9222

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Driving Innovation
in Wound Care Summit

SAWC Spring
WHS

WOUNDS
A Compendium of Clinical Research and Practice

Natural History Project (Real-World Evidence)

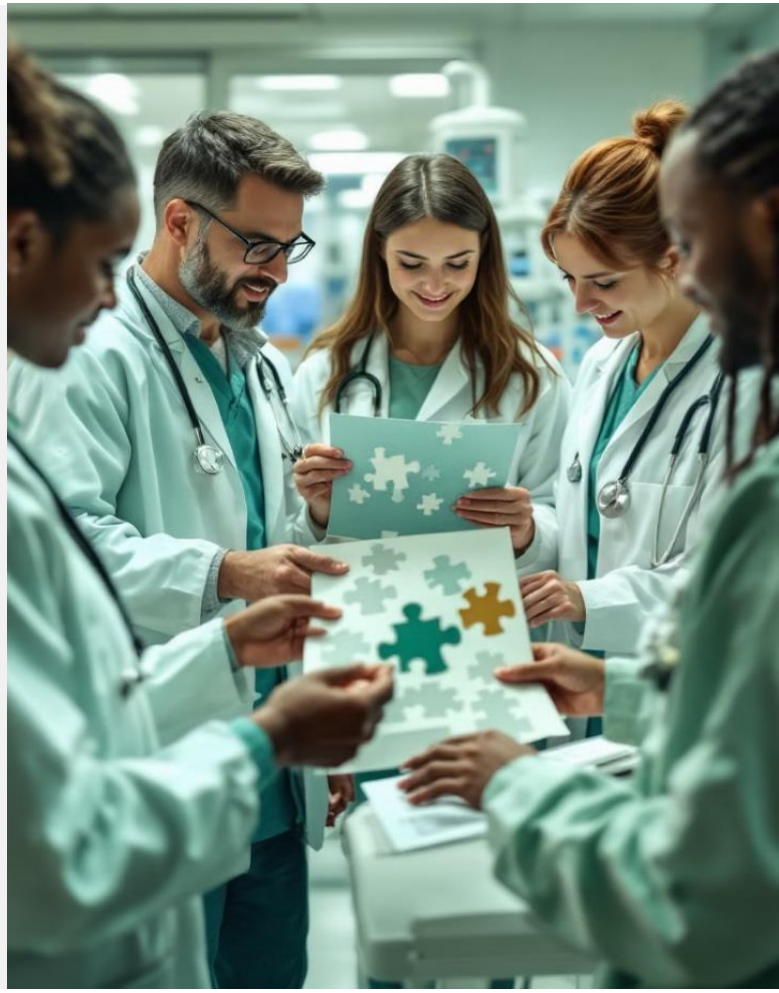
Lucian Vlad, MD
Atrium Health Wake Forest Baptist Wound Care

Caroline Fife, MD
Intellicure LLC

May 2, 2025 9:00 – 9:30 AM

The Fragmented Landscape of Wound Care

- No unified organization represents all wound care practitioners
- Specialists come from different medical backgrounds with varying training
- Industry drives education more than academia or patient needs



Wound Care Organizations Overview

- Multiple organizations with overlapping missions create confusion
- No single entity addresses comprehensive needs of the field
- Practitioners struggle to identify the most relevant organizations

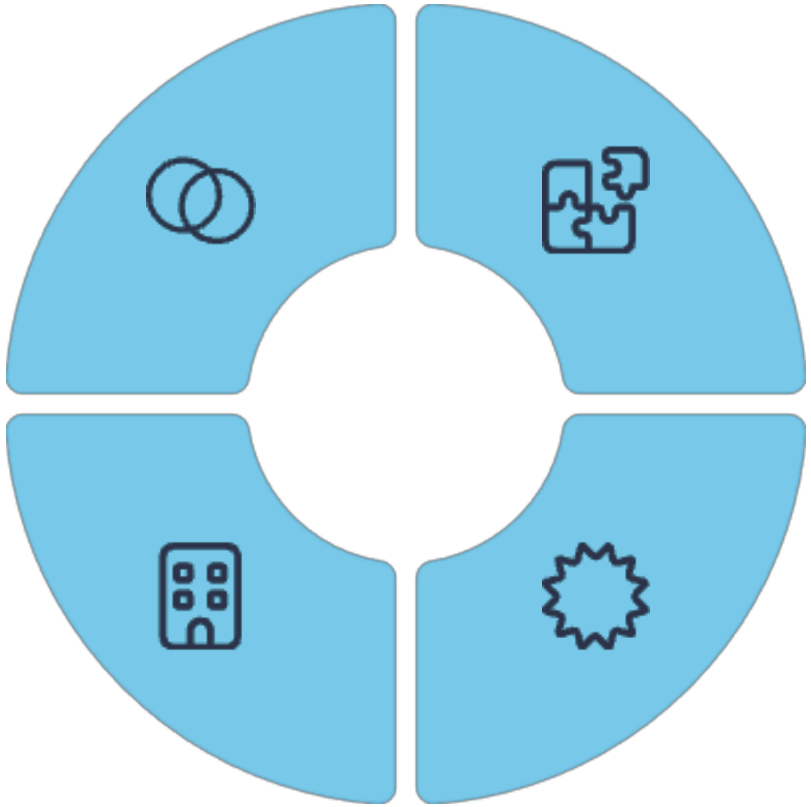
Current Organizational Challenges

Redundant Functions

Organizations duplicate efforts and resources

Specialty Silos

Each specialty focuses on narrow interests



Commercial Influence

Industry is driving education over evidence-based practice

Credential Confusion

Practitioners are uncertain of which certifications to pursue

Wound Care Collaborative Community

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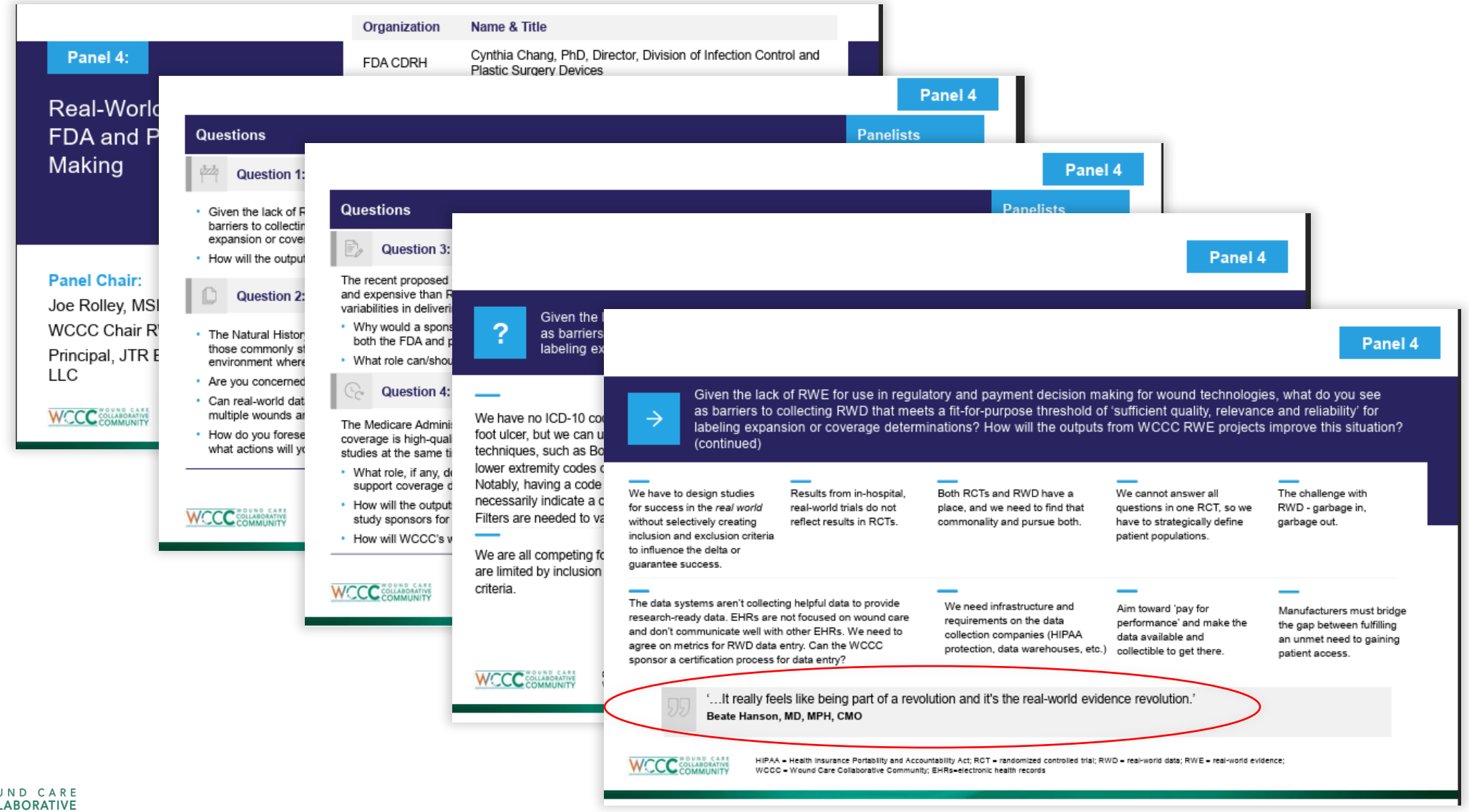
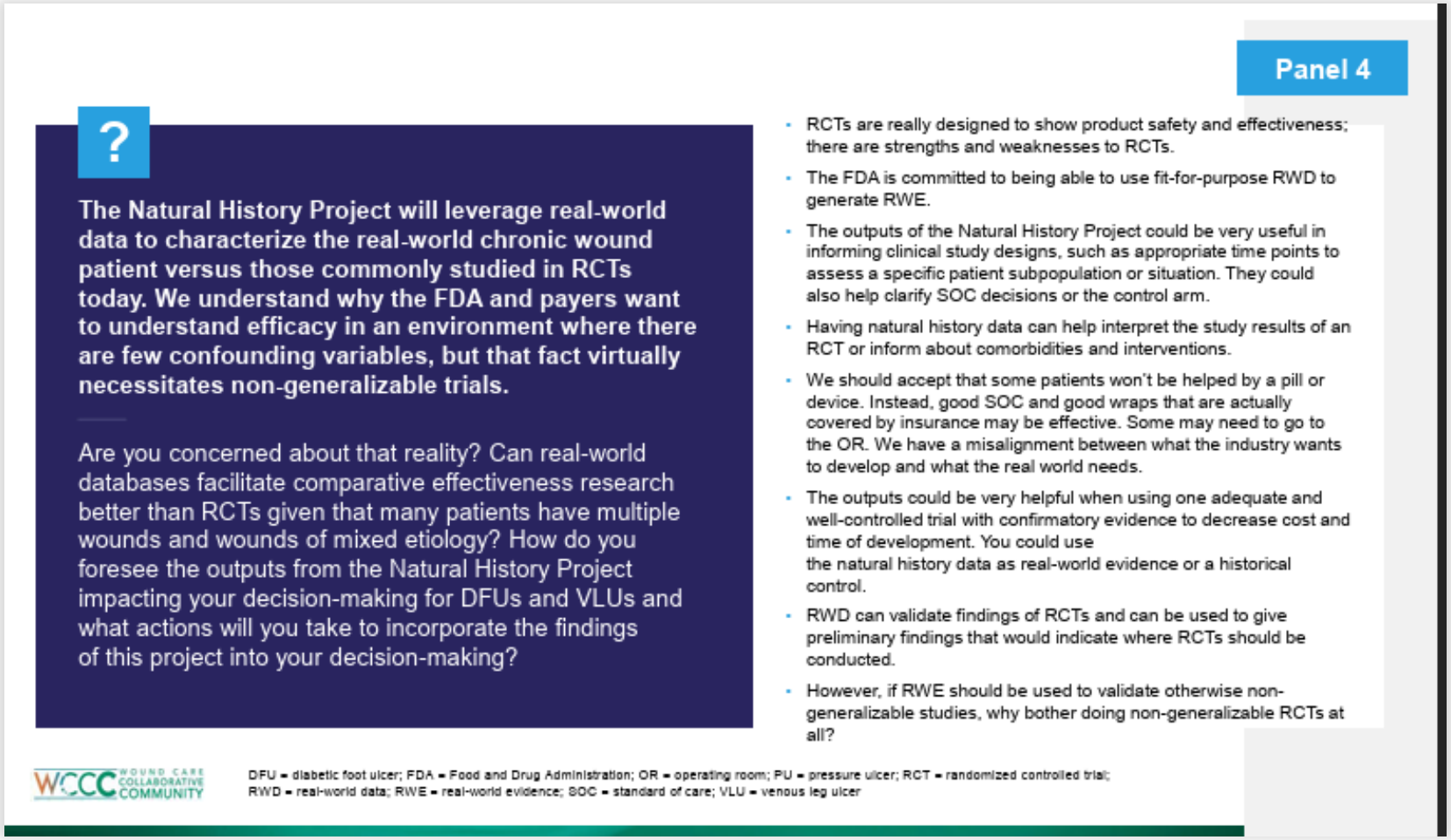
Real World Evidence Workstream

ACTIVE PROJECTS	
Natural History Project Update	C. Fife
SOC Project Update	M. Henao
ICD-10 DFU Project	D. Cartwright; R. Alper

Executive Summary – 2024 Summit



Executive Summary – 2024 Summit



Panel 4

?

The Natural History Project will leverage real-world data to characterize the real-world chronic wound patient versus those commonly studied in RCTs today. We understand why the FDA and payers want to understand efficacy in an environment where there are few confounding variables, but that fact virtually necessitates non-generalizable trials.

Are you concerned about that reality? Can real-world databases facilitate comparative effectiveness research better than RCTs given that many patients have multiple wounds and wounds of mixed etiology? How do you foresee the outputs from the Natural History Project impacting your decision-making for DFUs and VLUs and what actions will you take to incorporate the findings of this project into your decision-making?

- RCTs are really designed to show product safety and effectiveness; there are strengths and weaknesses to RCTs.
- The FDA is committed to being able to use fit-for-purpose RWD to generate RWE.
- The outputs of the Natural History Project could be very useful in informing clinical study designs, such as appropriate time points to assess a specific patient subpopulation or situation. They could also help clarify SOC decisions or the control arm.
- Having natural history data can help interpret the study results of an RCT or inform about comorbidities and interventions.
- We should accept that some patients won't be helped by a pill or device. Instead, good SOC and good wraps that are actually covered by insurance may be effective. Some may need to go to the OR. We have a misalignment between what the industry wants to develop and what the real world needs.
- The outputs could be very helpful when using one adequate and well-controlled trial with confirmatory evidence to decrease cost and time of development. You could use the natural history data as real-world evidence or a historical control.
- RWD can validate findings of RCTs and can be used to give preliminary findings that would indicate where RCTs should be conducted.
- However, if RWE should be used to validate otherwise non-generalizable studies, why bother doing non-generalizable RCTs at all?

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DFU = diabetic foot ulcer; FDA = Food and Drug Administration; OR = operating room; PU = pressure ulcer; RCT = randomized controlled trial; RWD = real-world data; RWE = real-world evidence; SOC = standard of care; VLU = venous leg ulcer

REAL-WORLD EVIDENCE

Comprehensive Landscape Analysis for Usable Real-World Wound Care Data

Lucian G. Vlad, MD[1]; Joseph Rolley, BS, MSIA[2]; Shabnam Vaezzadeh, MD, MPA[3]; Lisa Gould, MD, PhD[4]; Caroline E. Fife, MD[5,6]; Vickie R. Driver, DPM, MS[7]; Anokhi J. Kapasi, PhD, BS[8]; John C. Lantis II, MD[9]; Sharmila A. Kamani, BA[8]; and Burak K. Pakkal, MD, MBA[3]

Affiliations: [1]Wake Forest University School of Medicine, Winston-Salem, NC; [2]JTR Business Consulting, LLC, Doylestown, PA; [3]Exquisite Biomedical Consulting, LTD, Vancouver, BC; [4]South Shore Health, South Weymouth, MA; [5]Baylor College of Medicine, Houston, TX; [6]Intellicure, The Woodlands, TX; [7]Washington State University, Elson S. Floyd College of Medicine, Spokane, WA; [8]B.R.I.D.G.E. TO DATA®, DGI, LLC, Fairfax, VA; [9]Icahn School of Medicine at Mount Sinai, New York, NY

Contributions: All authors contributed equally to this work.

Ethical Approval: This project was exempt from institutional review board approval; it does not contain any patient personal health information.

Disclosure: The authors disclose no financial or other conflicts of interest. V.R.D. is Chair of Wound Care Collaborative Community (WCCC). L.G. is Vice Chair of WCCC. C.E.F. is the Executive Director of the USWR. All remaining authors are volunteer members of WCCC.

Correspondence: Lucian G. Vlad, MD; Atrium Health Wake Forest Baptist, Plastic & Reconstructive Surgery - Wound Care and Hyperbaric Center, 1 Medical Ctr. Blvd, Winston-Salem, NC 27157; lvlad@wakehealth.edu

Manuscript Accepted: September 3, 2024

Recommended Citation: Vlad LG, Rolley J, Vaezzadeh S, et al. Comprehensive landscape analysis for usable real-world wound care data. *Wounds*. 2024;36(9):3##-3##. doi:10.25270/wnds/24076

Keywords: chronic wounds, databases, fit for purpose, real-world data, registry, wound outcomes

ABSTRACT

Background. The Wound Care Collaborative Community (WCCC) aims to assess current usable real-world data (RWD) sources to determine which real-world databases (DBs) are suitable and usable for studying the natural history of chronic wounds. Randomized controlled trials (RCTs) do not fully reflect the complexity of chronic wound patients. Using RWD, establishment of a scientifically grounded "road map" for RCTs is needed to better navigate the real-world complexity of the patients with chronic wounds. The long-term objectives include identifying patients ineligible to receive evidence-based advanced treatment and diagnostic options, reducing patient suffering, and providing decision support for regulatory bodies, payers, and clinicians. **Objective.** To identify available and usable RWD on US chronic wound care patients, as an early step toward the WCCC's objectives. **Methods.** Using B.R.I.D.G.E. TO DATA® methodology, the WCCC conducted a comprehensive RWD landscape analysis and systematically screened 34 potential sources for chronic wounds. Multiple data elements helped determine suitability and usability. **Results.** Four clinical US DBs have "high potential" for elucidating the natural history of chronic wounds; a fifth met the WCCC criteria but has data access restrictions. **Conclusion.** Identifying suitable, usable real-world DBs for research is complex. Only 1 DB was found that is fit for purpose and matches the goals to study the natural history of patients with chronic wounds.

According to a 2023 published analysis of 2014-2019 Medicare claims data, 16.4% of Medicare beneficiaries (10.5 million people) were affected by chronic wounds in that period, the annual cost of which was conservatively estimated at $22.5 billion but may have been in excess of $67 billion[1]; this is a significant economic impact.[2] RCTs, which occupy the apex of the evidence pyramid, are designed to demonstrate the efficacy of a treatment under ideal conditions. These studies look at a particular wound type for a single treatment period, usually 12 to 16 weeks, and a narrowly defined population with many comorbid conditions excluded. RCTs provide limited insights into the natural history of specific wound types, their incidence in the general population, the number of concomitant wounds per patient, locations of care, wound outcome, frequency or number of recurrences, and the association of comorbid conditions with failure to heal.[3-5] This information can be obtained from RWD.[3-7] RWD are vital for identifying gaps in evidence-based clinical practice, disparities in care, unmet therapeutic needs, and promising signals that a medical treatment may be of benefit to a broader population than was explored in RCTs.

The FDA is placing increasing value on RWE in regulatory decision-making, and this has increased the demand for RWD in the field of wound care.[8] To date, analysis of large, structured data sets in this field have been limited to administrative data. Although interoperability standards facilitate the exchange of already structured health care in-

Abbreviations: DB, database; DFU, diabetic foot ulcer; EHR, electronic health record; FDA, US Food and Drug Administration; RCT, randomized controlled trial; RWD, real-world data; RWE, real-world evidence; VLU, venous leg ulcer; WCCC, Wound Care Collaborative Community.

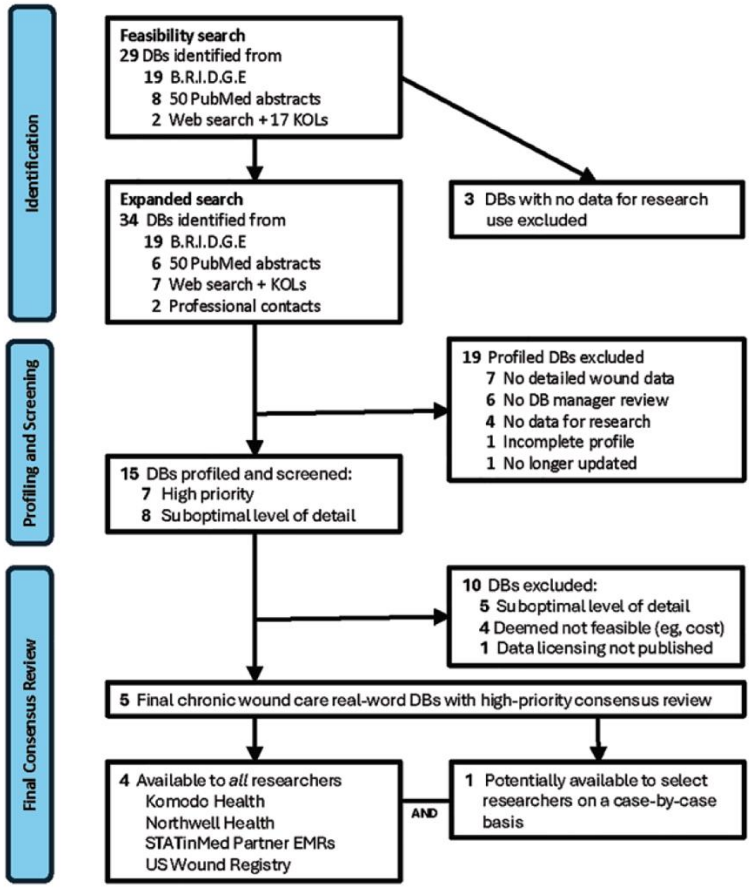
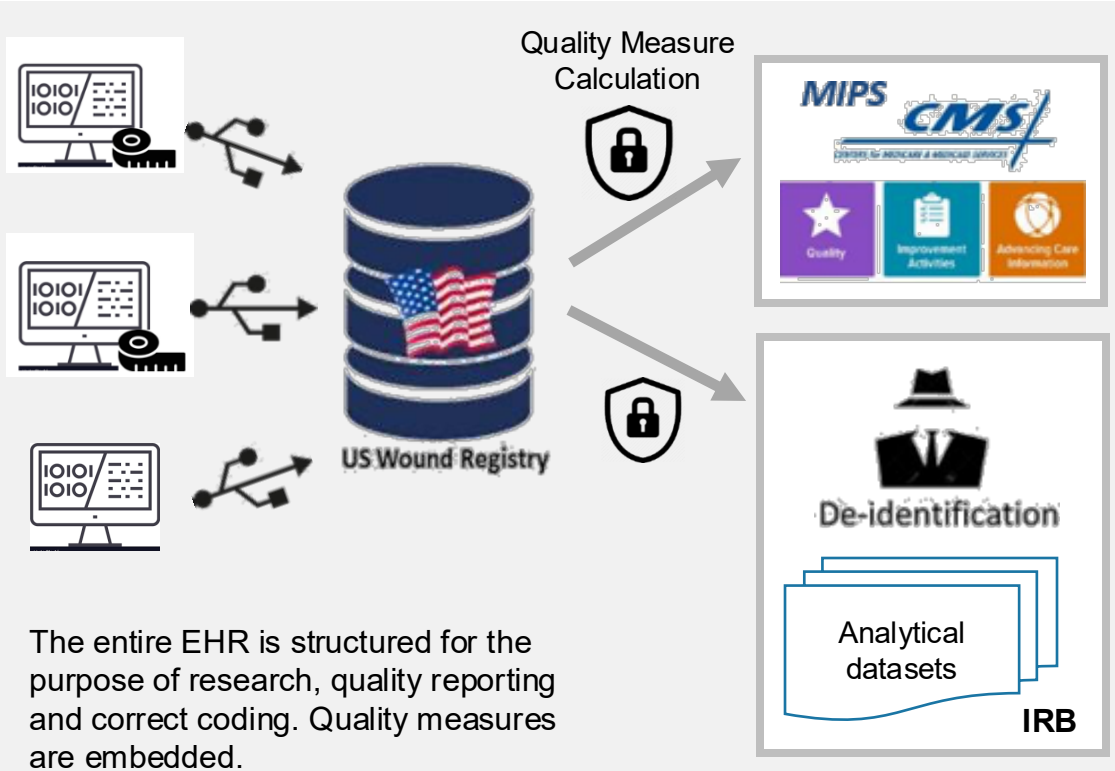


Figure. PRISMA flow diagram of identification and selection of real-world DBs with chronic wound care data in US populations.
Abbreviations: B.R.I.D.G.E., B.R.I.D.G.E. TO DATA (DGI, LLC); DB, database; EMR, electronic medical record; KOL, key opinion leader.

US Wound Registry: Derived From Data Transmitted Electronically Directly From Electronic Health Records (EHR)



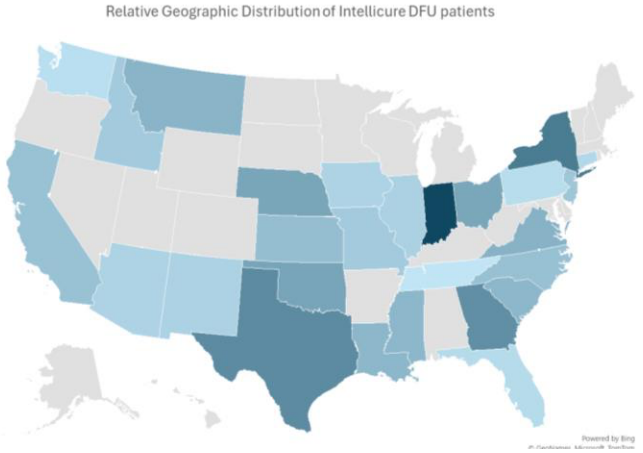
The entire EHR is structured for the purpose of research, quality reporting and correct coding. Quality measures are embedded.

- Data are structured inside the EHR collected at the point of care (the entire EHR is structured); this is the legal medical record
- No patient or wound selection bias
- No secondary data entry, no post hoc vetting of outcomes
- Quality measures provide a way to measure standard of care
- Data currently from 32 states

Goals: Describe the severity, treatment, and outcome of diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) and the prevalence rate of comorbid conditions among patients with these ulcers

Identify the difference between real-world patients + ulcers and subjects + ulcers enrolled in most DFU prospective clinical trials

Start: 1/1/2021 End:12/31/2022
Patients: 51,708
Wounds/Ulcers: 160,341
Visits: 616,341
Providers: 527
Clinics/Practices: 149



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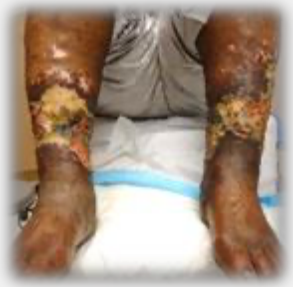
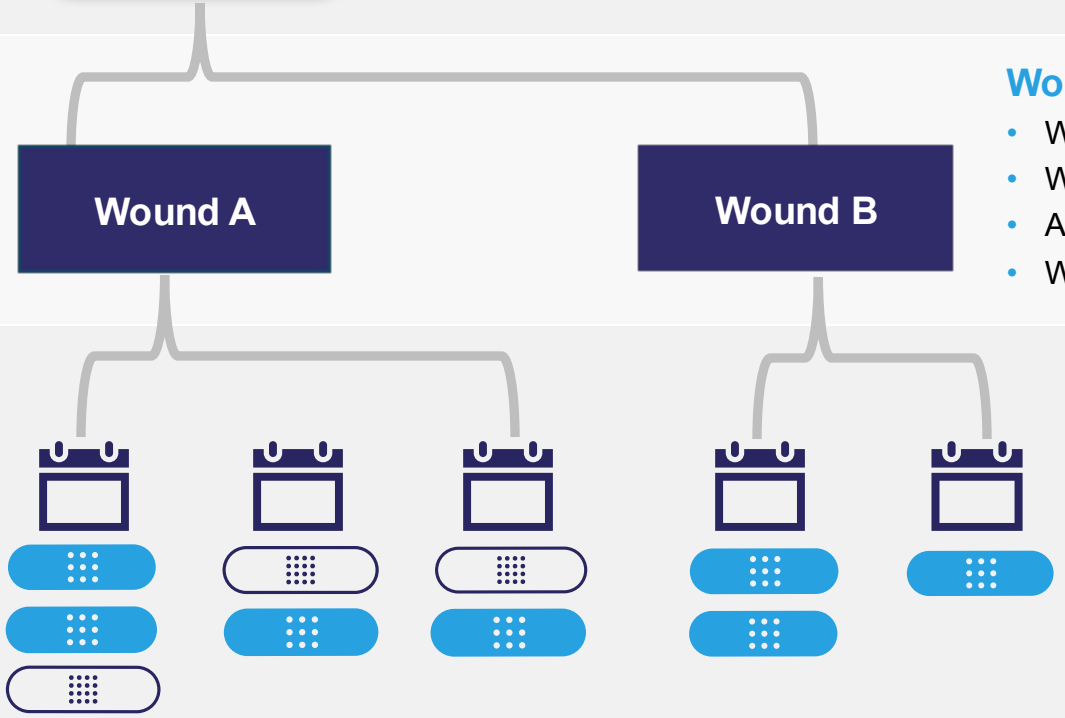
Patient, Wound, Wound-Visit Level Data



Patient data

- Medications
- Comorbid conditions
- Vitals
- Total number wounds per patient
- Patient time in service

The average patient has > 2 wounds (often of different types)

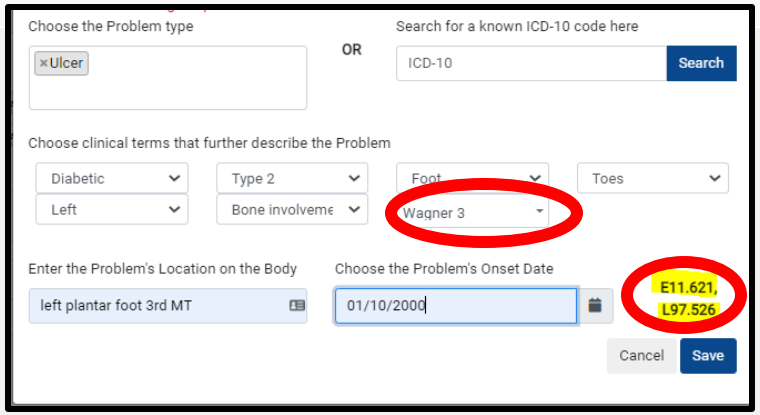


Wound data

- Wound duration (“wound age”)
- Wound time in service
- All treatments/dressings over treatment course
- Wound outcome

Wound-visit data

- Today’s measurements
- Today’s characteristics
- Today’s treatments



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Dataset

DFUs (16.2% of dataset)

- **Patients: 10,966**
- **DFUs: 26,042**
- DFU-visits: 200,678
- Median age: 63.5 years
- Males: 70%
- 41% developed a new DFU while in treatment for the initial DFU
- Concomitant DFUs:
  - 1.7 mean; 1 median
- Concomitant wounds/ulcers (any type):
  - 2.7 mean; 2.0 median

VLUs (21.4% of dataset)

- **Patients: 11,197**
- **VLUs: 30,790**
- VLU-visits: 210,302
- Median age: 71.2 years
- Males: 54%
- 41.3% developed a new VLU while in treatment for the initial VLU
- Concomitant VLUs:
  - 1.8 mean; 1 median
- Concomitant wounds/ulcers (any type):
  - 2.5 mean; 2.0 median

Comorbid Diseases in Real-World Patients With DFUs and VLUs

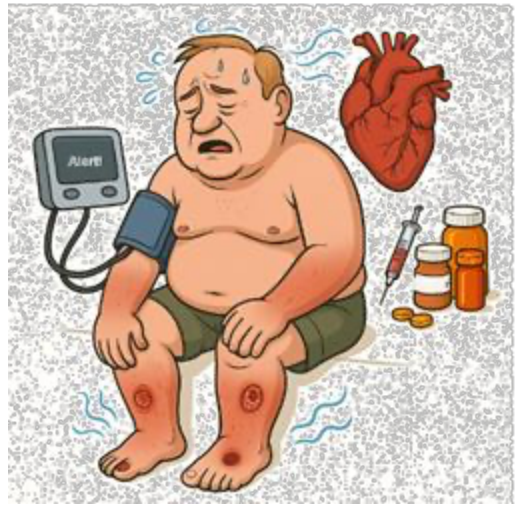
Patients With DFUs

Rank	Comorbidity	% of DFU patients
1	Diabetes	10,966 (100.0)
2	Hypertension	7,964 (72.6)
3	Obesity	6,469 (59.0)
4	Edema	4,059 (37.0)
5	Peripheral Arterial Disease	3,817 (34.8)
6	Osteomyelitis	2,837 (25.9)
7	Hyperlipidemia	5,323 (48.5)
8	Venous Insufficiency	2,130 (19.4)
9	Cellulitis	1,839 (16.8)
10	Autoimmune Disease	1,762 (16.1)
11	Neuropathy	1,762 (16.1)

Patients With VLUs

Rank	Comorbidity	% of VLU patients
1	Edema	8,757 (78.2)
2	Venous Insufficiency	7,367 (65.8)
3	Hypertension	7,159 (63.9)
4	Obesity	7,150 (63.0)
5	Diabetes	4,850 (43.3)
6	Lymphedema	2,702 (24.1)
7	Cellulitis	2,252 (20.1)
8	Peripheral Arterial Disease	2,471 (22.1)
9	Hyperlipidemia	3,972 (35.5)
10	Congestive Heart Failure	1,535 (13.7)
11	Autoimmune Disease	1,533 (13.7)

- Of the top 30 medications taken by patients with DFUs, 80% were in the top 30 taken by patients with VLUs.
- 43% of patients with VLUs have diabetes.
- Autoimmune disease is present in 16% of patients with DFUs and 13.7% of patients with VLUs.



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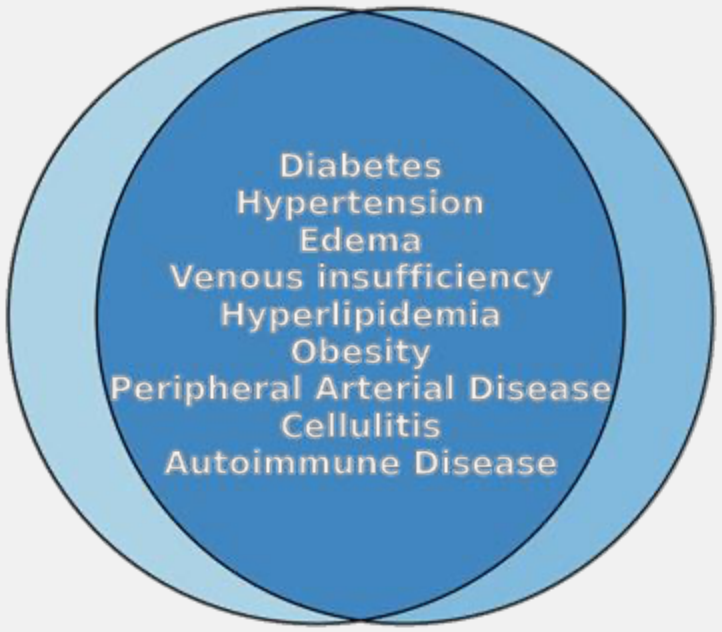
Overlap of Comorbid Conditions in Patients With DFUs and VLUs

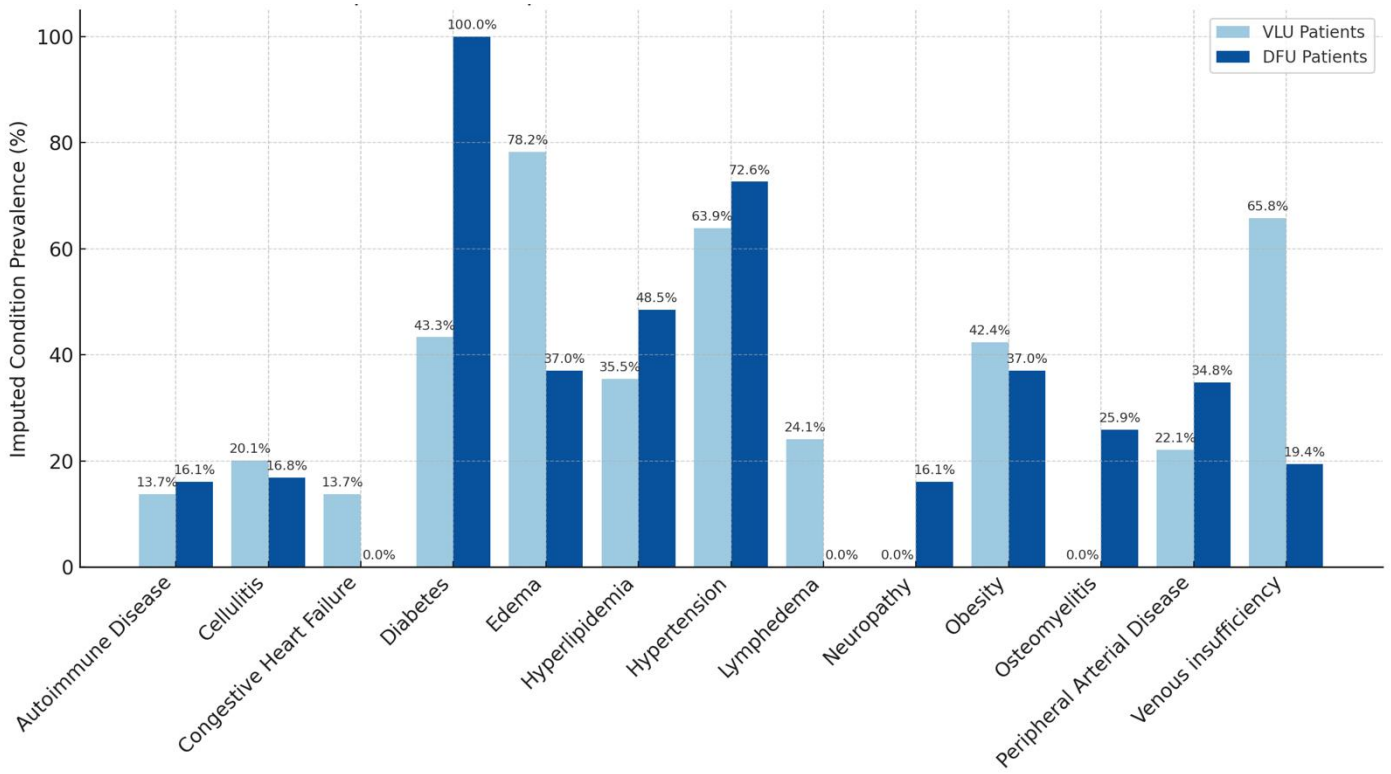


Congestive Heart Failure
Lymphedema

Patients with VLUs

Neuropathy
Osteomyelitis

Patients with DFUs



These do not appear to be different patient populations.

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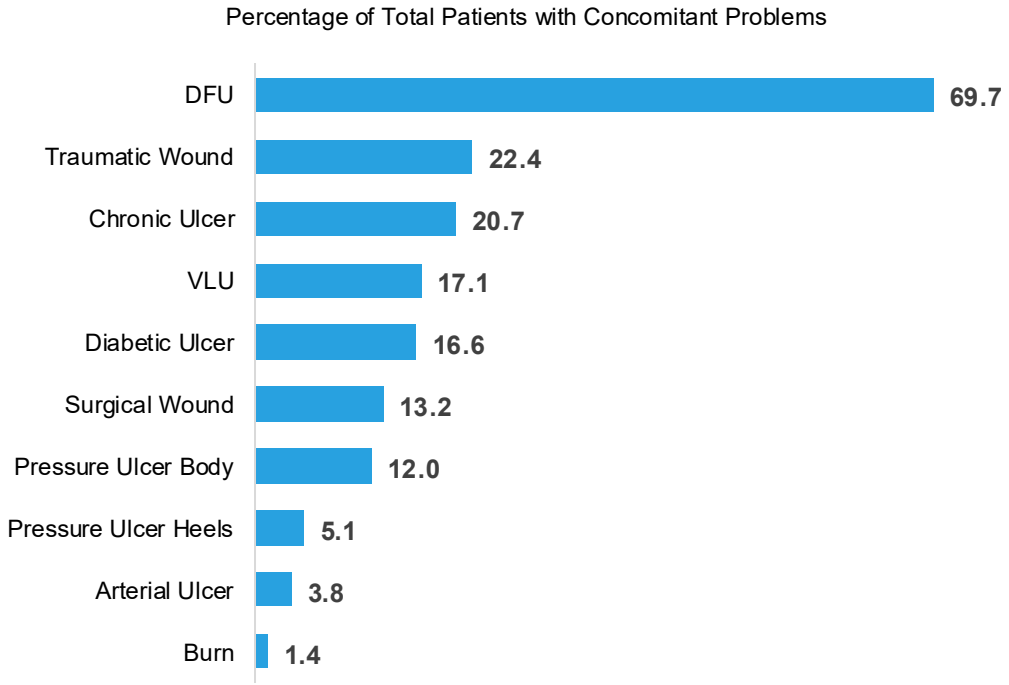
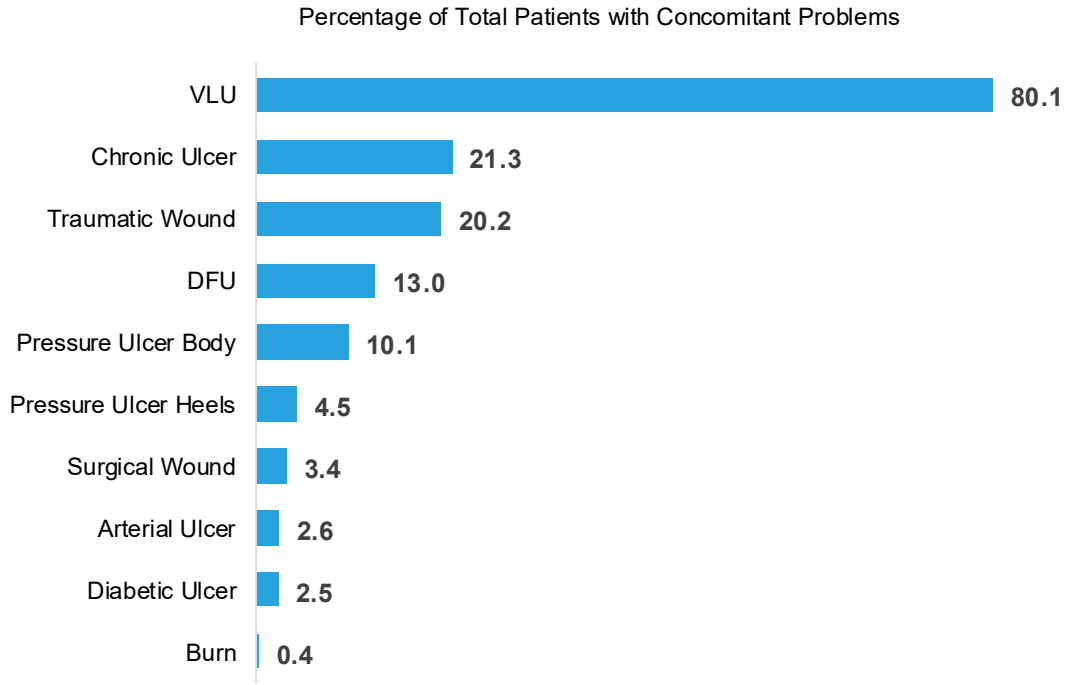
Overlap of Wound/Ulcer Types

Wound and Ulcers in Patient With DFUs

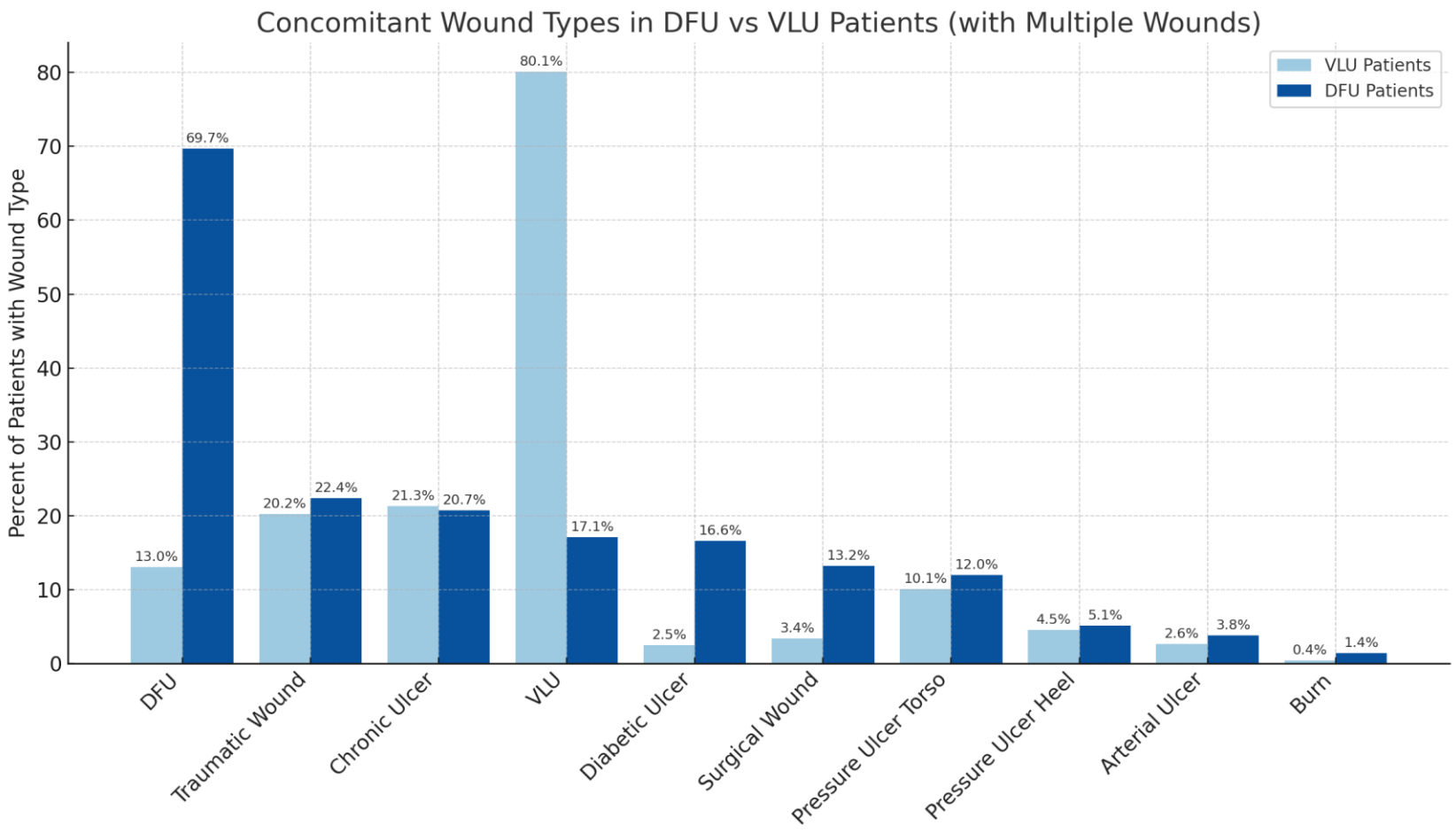


Wound and Ulcers in Patients With VLUs



WOUND CARE COLLABORATIVE COMMUNITY

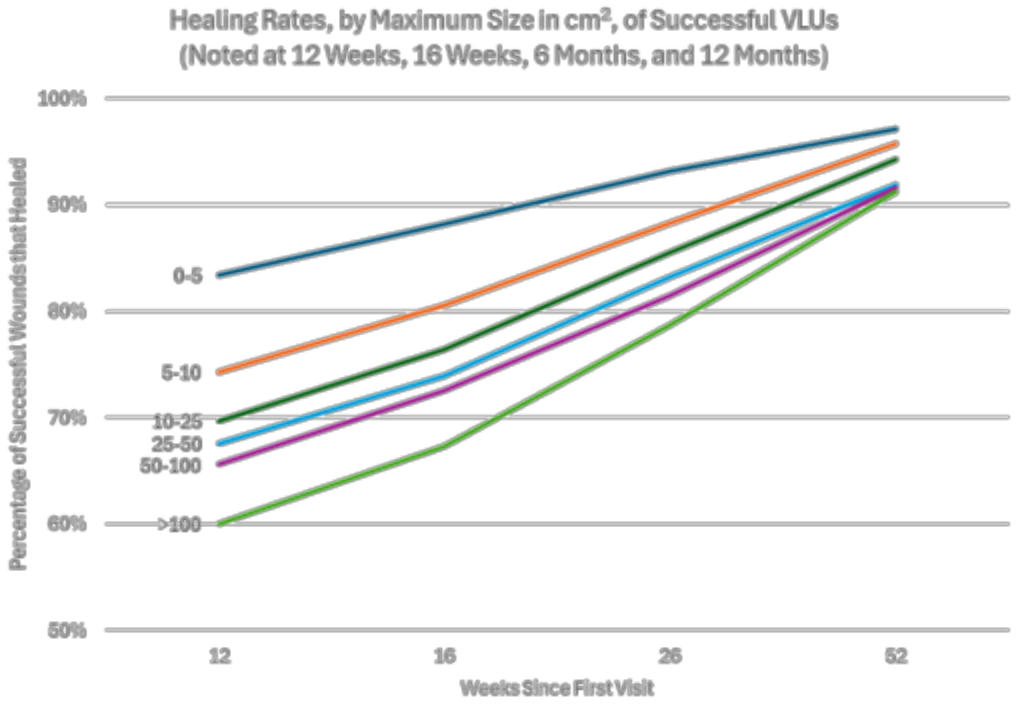
Overlap of Wound/Ulcer Types

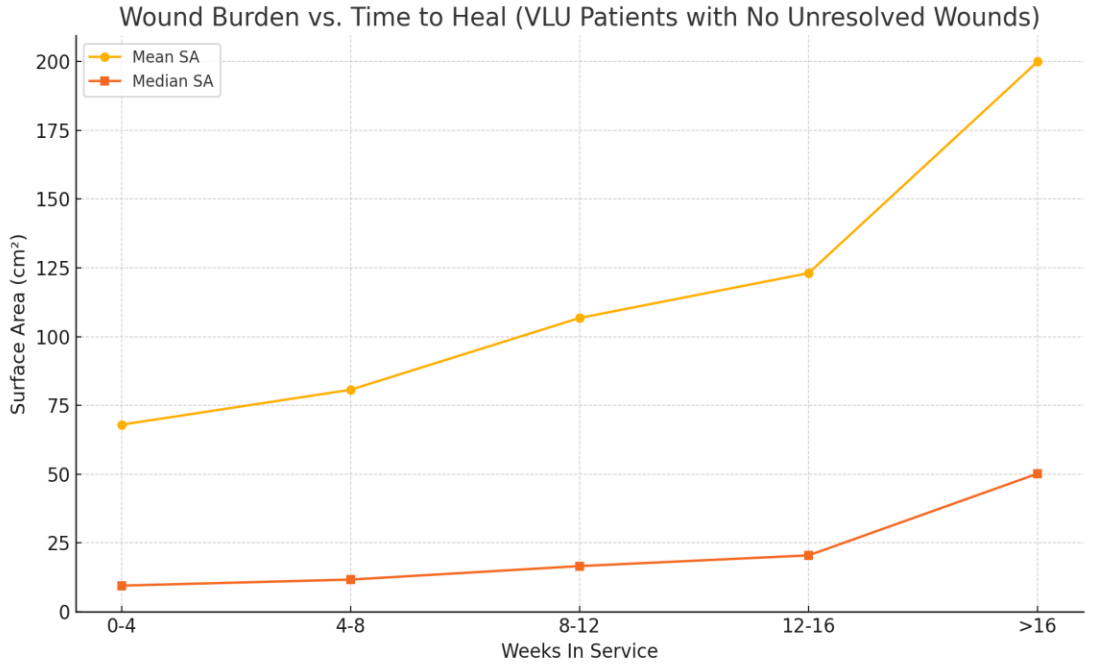


- 13% of patients with a DFU have a VLU
- 17% of patients with a VLU have a DFU
- Among those with diabetes, 41.6% had a venous ulcer
- Prevalence of chronic ulcers, pressure ulcers, arterial ulcers, and traumatic wounds is surprisingly similar between the 2 patient groups

WOUND CARE COLLABORATIVE COMMUNITY

VLU Time to Heal and Time in Service is Determined by Ulcer Size and Total Burden



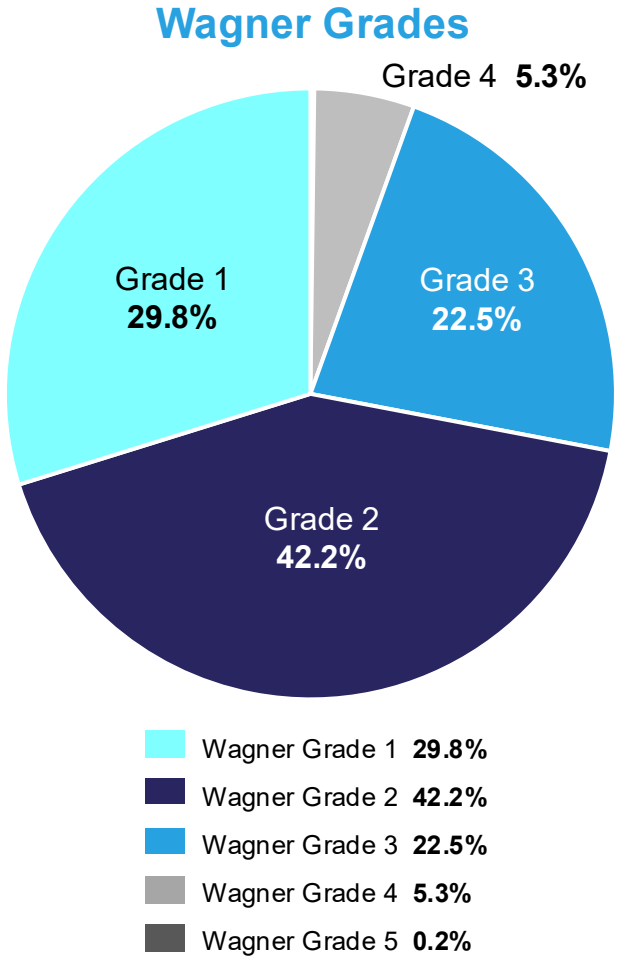


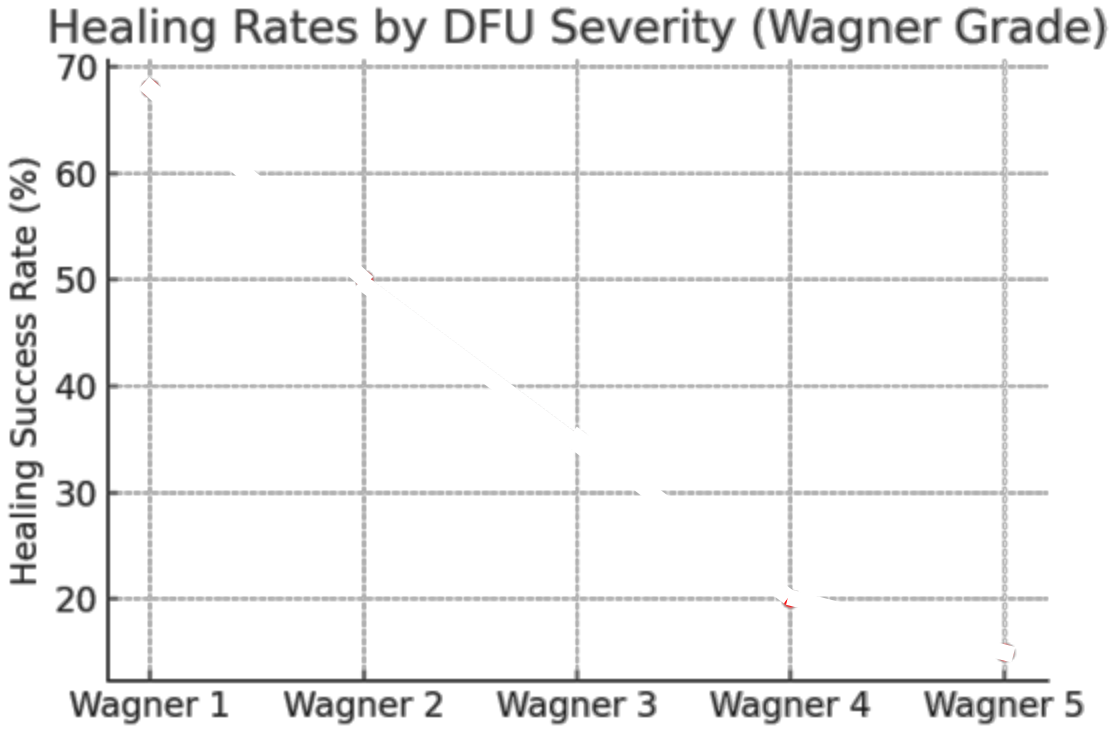
In VLUs that heal, >90% heal in 12 months. Median size of an ulcer that heals in 16 weeks is 7.5 cm².

The number of weeks that a patient with aVLU stays in service is determined by the total surface area of all wounds and ulcers.

WOUND CARE COLLABORATIVE COMMUNITY

DFUs: Severity/Wagner Grade and Healing Rate (at any time)

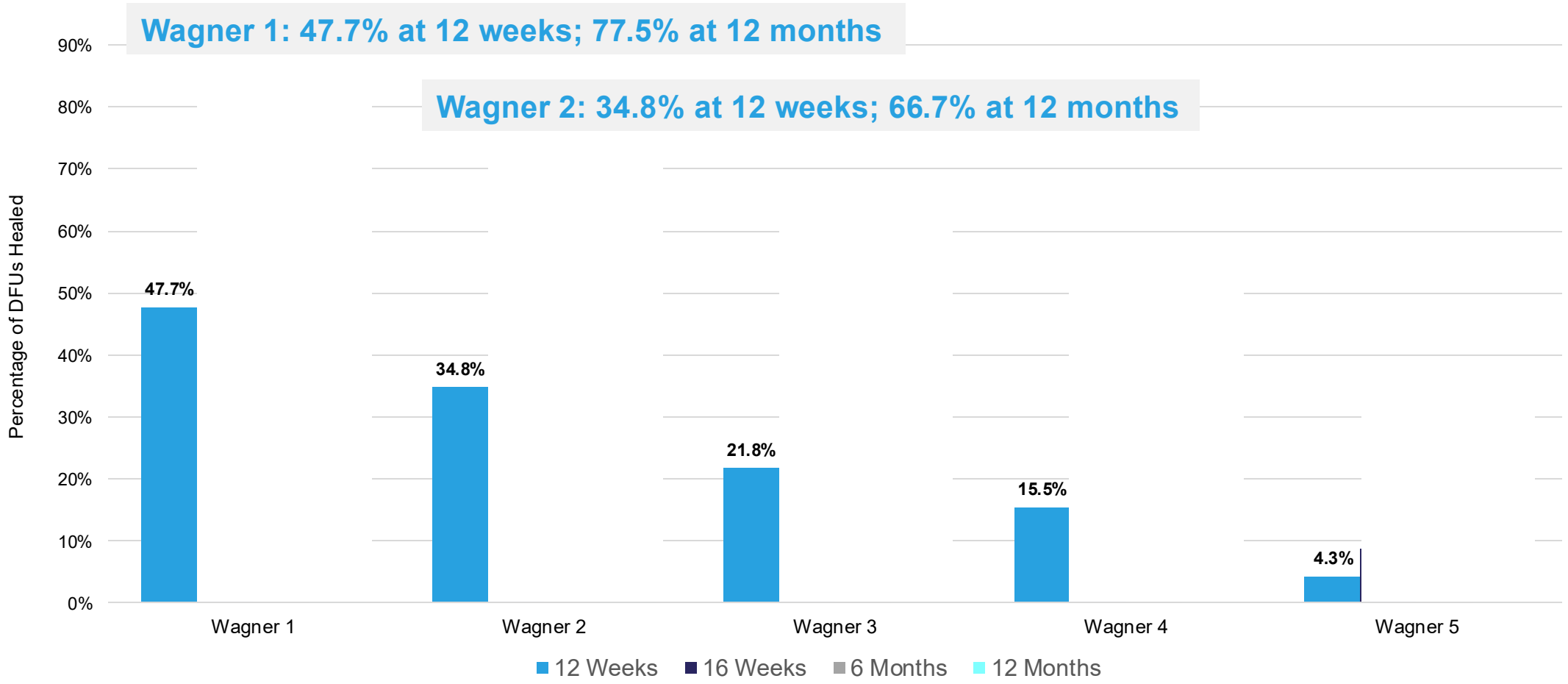




Healing rate of Wagner 2 is only ~50% even with long follow-up times. Is this because of the ulcer or the patient?

WOUND CARE COLLABORATIVE COMMUNITY

DFU Healing Rate Over Time by Wagner Grade



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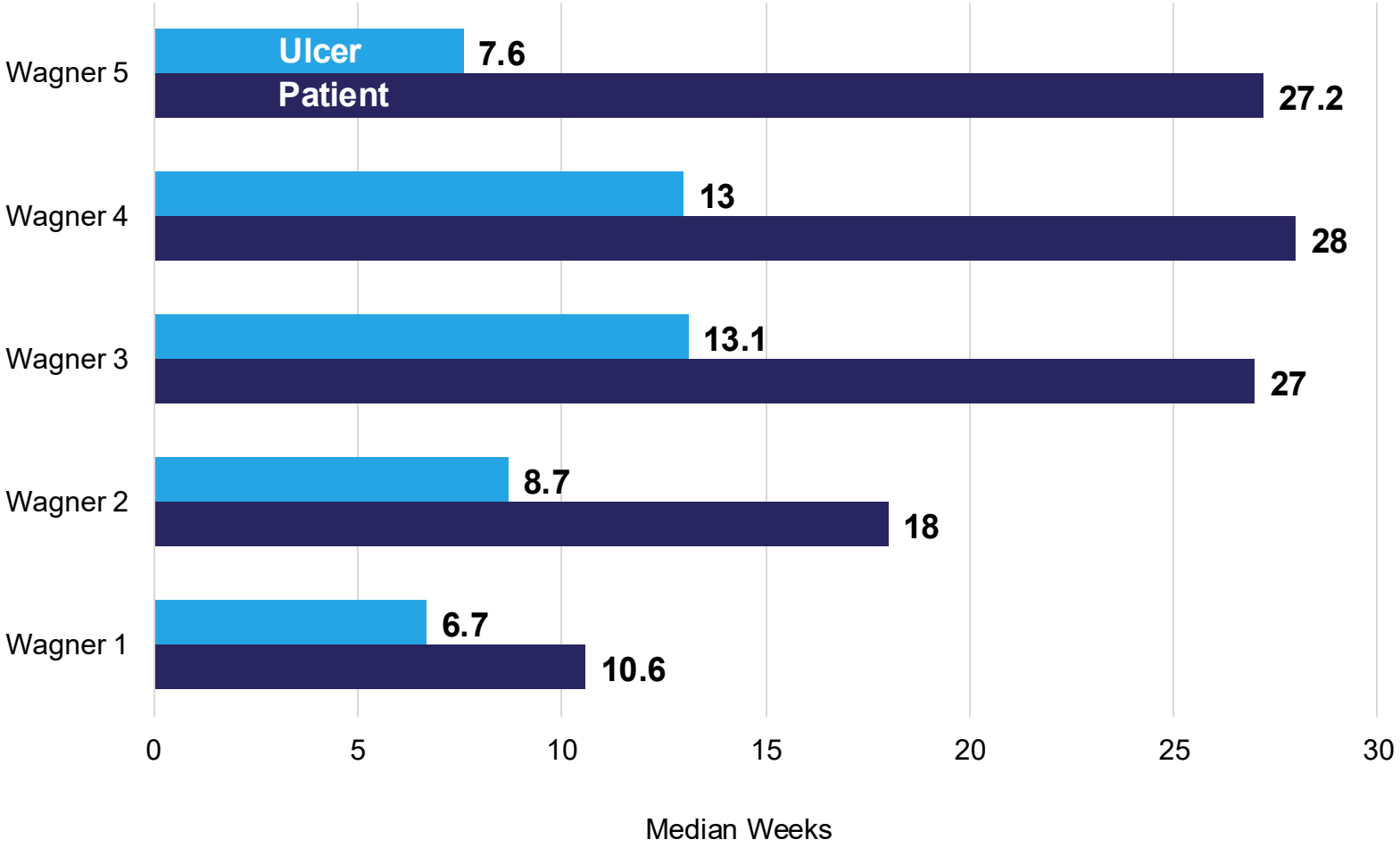
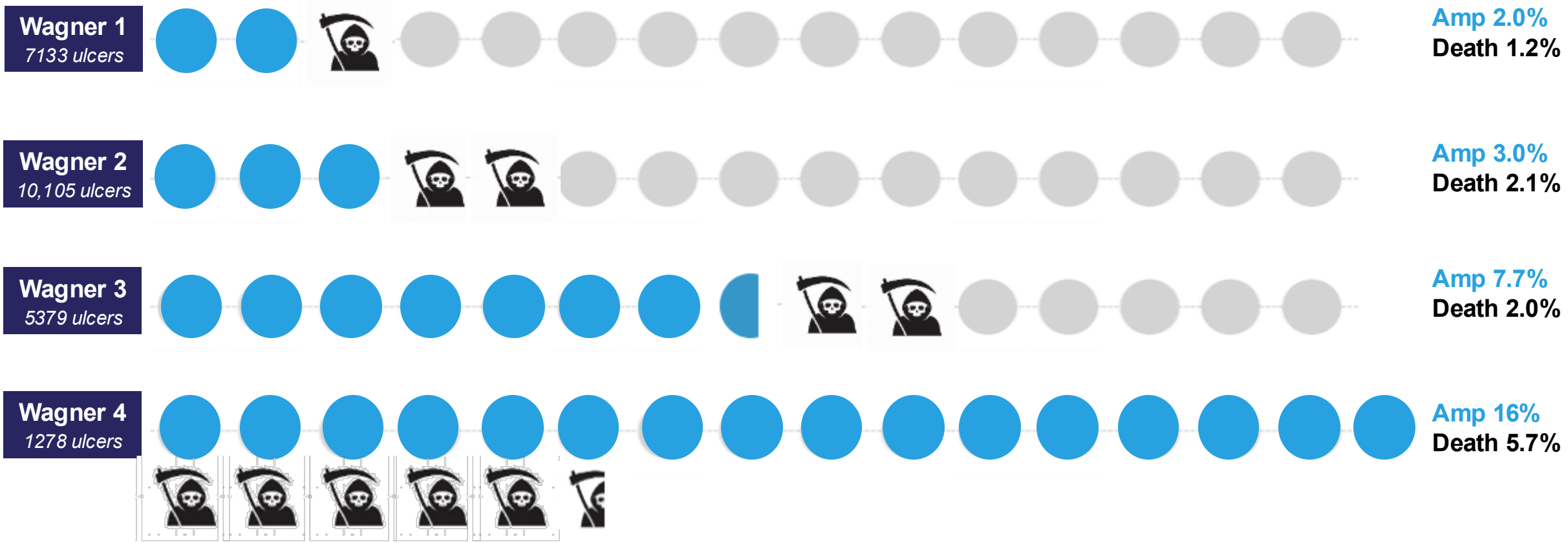
Median DFU Time in Treatment vs Patient Time in Treatment by Wagner Grade



The clinical course of a DFU does not reflect the patient's experience of care.

Is there a way to focus on the patient and not an individual ulcer?

Major Amputation and Death by Wagner Grade (while in treatment)



Conclusions of the Natural History Project

- Patients with DFUs and VLUs have similar major comorbid conditions including autoimmune disease.
- Patients with DFUs and VLUs have more than 1 ulcer with surprising overlap of wound types.
- Real-world data call into question the paradigm of distinct patient/ulcer types.
- >90% of DFUs/patients with DFUs would be excluded from most DFU randomized controlled trials (RCTs).
- Payer coverage policy based on RCTs may have poor relevance to real-world patients.
- Real-world DFU and VLU healing times are long and healing rates are disappointing.
- In patients with DFUs, major amputation and death rates *while in treatment* are surprisingly high.
- The patient's experience of care is determined by the total wound burden and not the outcome of a single wound/ulcer.

Recommendations

- Poor generalizability of most DFU trials deserves scrutiny by FDA.
- RCTs of Wagner 1 DFUs are focused on the least prevalent, most likely to heal DFUs with the lowest risk of complications.
- Additional analysis is needed to understand whether ulcer outcomes are determined by diagnosed wound “type” or by patient comorbid conditions and ulcer number and severity (ie, are these ulcer types distinct entities?).
- Improvements are needed in ICD-10 coding for DFUs and VLUs.

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Driving Innovation in Wound Care Summit

SAWC Spring WHS | WOUNDS

Diagnostics: Tools for Wound Healing

Holly Korzendorfer, PT, PhD, CWS, FACCWS
Marist University / TWG Chair

Francis James
SOC, Founder & Chief Product Officer for TRUE-See / TWG Vice Chair

May 2, 2025 **9:30 – 9:50 AM**

Achieving Innovation—the Mission of WCCC

2025 Tools Working Group (TWG) achievements to support better access to treatments & technologies:

- Identified reliable tools to measure percent area reduction as a primary endpoint
- Developed a standardized method to evaluate tools, applicable for other technologies for endpoints
- Published findings; sharing lessons learned
- Defined next steps
- Collaborated with wound care clinicians, industry experts, researchers, academia, and government to make a difference

How We Got Here

15 Evidence-Based Endpoints:

- Time to heal
- Percent area reduction
- Reduced infection
- Reduced pain
- Reduced recurrence
- Increased physical function/ambulation
- Amputation reduction
- Reduced analgesia use
- Reduced depression
- Reduced social isolation
- Percent volume reduction
- Reduced odor
- Cost effectiveness
- Reduced cost of treatment
- Reduced bioburden

6 Primary Endpoints

- Percent area reduction (PAR)
- Reduced infection
- Reduced pain/analgesia use
- Increased function & ambulation
- Quality of life
- Cost effectiveness

Moving Forward: Innovation

The process of creating and implementing new ideas, methods, and solutions that improve efficiency, effectiveness, or address unmet needs

Three types of innovation:

- Organizational
- Methodology
- Solutions

- Our role in answering the call from Summit “Quantum Leaps” that improve patient care and remove barriers to investment

Tools Work Group Innovations

Improve patient care and remove barriers that inhibit it by validating the new FDA primary endpoints

1. **Organizational Innovation:**
   Collaboration of industry and clinical experts
2. **Methodology Innovation:**
   Standardized method to evaluate tools for endpoints
3. **Solutions Innovation:**
   Identify barriers and lessons learned to develop next steps for resolving barriers

Accepted Means to Evaluate Partial or Significant Healing in Trials/Clinical Practice

- Wound measurements
- Wound images
- Comparison of percent change in size over time
- Assessing changes of tissue state – color, exudate, necrosis, integrity
- Bioburden assessment
- Circulation
- Wound depth assessment, tunneling, undermining

New Endpoint: Percent Area Reduction (PAR)

Supports PAR:

- Wound measurements
- Comparison of percent change in size over time
- Wound images
- Assessing changes of tissue state – color, exudate, necrosis, integrity

Supports Future Endpoints:

- Bioburden assessment
- Circulation
- Wound depth assessment – tunneling, undermining

Tool Identification Process

Search: Advertised for Wound Imaging

- WoundSource
- Wound Reference
- Websites
- TWG experiences

Search: Medical Device Databases

- Publicly available
- FDA Establishment Registration and Device Listing
- Global Unique Device Identification Database (GUDID)

Inclusion Criteria

- Registered medical devices with FXN product code
  - FXN = Tape, Camera, Surgical
- Currently marketed by FDA-registered establishments
- Capable of length and width wound measurements

Survey Development

- Measurement and auto calculation abilities
- Trustworthiness of measurements
- Wound tissue characteristics assessment abilities
- Photo editing and adjustment capabilities
- Photo review and PAR/ percent volume reduction (PVR) tracking
- Convenience/ usability

Methodology

- Replication of search process
- Customization of survey skeleton for near-infrared (NIR) and fluorescence

Methodology: Identify Appropriate PAR/PVR Tools

Conducted research: on marketed tools capable of measuring PAR and/or PVR in the United States

- Reviewed data from publicly available databases

Identified medical devices: with FXN (Tape, Camera, Surgical) product code classification marketed by FDA-listed establishments capable of measuring/calculating PAR/PVR

Assessed features: associated with wound imaging devices

Methodology: Identify Appropriate PAR/PVR Tools

Identified issues: for evaluating tools to measure PAR and/or PVR

- Some devices rely on a mobile software application downloaded to a smartphone
  - Not all mobile applications are registered with the FDA as medical devices
  - Reliability is an issue
- Lack of imaging standard or objective means for measurement accuracy, color calibration, skew adjustment, and image security
- Device variations in features and methodologies for image capture
  - Makes comparisons from one device to another difficult

Established inclusion/exclusion criteria: for evaluating devices

Developed questionnaire: to survey manufacturers meeting criteria

- Collected in 4th quarter of 2023 and 2nd quarter of 2024

Survey Results

13 FDA-registered establishments with **14** wound imaging devices

10 establishments completed the TWG Survey

Comparative quantitative tables developed

- Allow FDA and clinicians to select most accurate measurement tools for PAR in trials and clinical practice

Data Tables For Tools that Measure PAR and/or PVR

Table 2: Measurement Abilities (automatic)
Table 3: Accuracy
Table 4: External Markers
Table 5: Wound Tissue Character and Assessment Ability
Table 6: Photo Review and PAR/PVR Tracking
Table 7: Convenience and Useability

Supporting Data: Publications/Posters

Publication (educational) 2024 – PAR/PVR Measurements

- Oropallo A, Dotson P, Brindle T, Driver VR, Gould L. Need for percent area reduction and percent volume reduction measurements in diagnostic wound imaging: a statement from the Wound Care Collaborative Community—part 1. *Wounds*. 2024;36(2):A3-A6. doi:10.25270/wnds/360224-2

Survey Results

- "An Overview and Survey of FDA-registered Wound Imaging Devices Capable of Determining Percent Area/Volume Reduction"
    - Manuscript forthcoming in *Wounds* (May 2025 publication)

Publications/Posters

Overview Article

- Educate clinicians on the complexity of imaging, potential for color distortion, and features required to ensure more accurate interpretation of image/tissue for decision making *"The Importance of Color Accuracy in Wound Assessment"*
  - Manuscript submitted to *Wounds*, Jan 2025; resubmitted April 2025

Poster

- Source capture optimization & alignment guides (SCOAG) to operationalize a standardization process during photo acquisition to improve clinical utility *"Standardizing Medical Photo Acquisition to Improve Image Quality"*
  - Accepted for SAWC Spring 2025

Lessons Learned

To evaluate a ‘tool’ inclusion/exclusion criteria must be established

- Review publicly available data
- Identify Product Code classification (FDA) for devices listed by registered manufacturers
- Review FDA product filings for these devices
- Interview clinicians, manufacturers, researchers
- Understand what features or processes are important for use/accuracy of the devices
- Develop core questions to survey industry based on identified capabilities of the tool
- Confirm data collected with manufacturers before initiating a survey

Imaging tools require color control (calibration)

- Core to ensuring accuracy for interpretation by algorithms/humans

TWG In-Line With the Mission of the WCCC

Created a methodology for evaluating tools applicable for assessing other tools/technologies for measuring other endpoints

Developed unbiased method to provide clinicians and FDA data in selecting an appropriate tool for measuring PAR

Fulfilled FDA request to identify valid tools for measuring PAR to support its use as a primary endpoint

What is Next For Tools Work Group?

Evaluate tools for other validated endpoints

- Reduced infection
- Reduced bioburden
- Reduced pain
- Reduced recurrence
- Improved tissue quality/oxygenation/ quality healing

Technology Reviews

- Near Infrared Spectroscopy *(underway)* (circulation, support of PAR/PVR partial healing)
- Fluorescence Technology *(underway)* (bioburden and infection detection/measurement)
- Color Calibration Methods *(to be scheduled)* (improve imaging accuracy and move to a ‘standard’)

Technology Reviews Underway Supporting Endpoints

Near Infrared Spectroscopy Technology

- **Part 1:** Educational publication on NIR
  "Advancing Chronic Wound Care with Near-infrared Spectroscopy Imaging: Clinical Applications, Measurement Parameters, and Insights into Healing Dynamics"
  - Submitted to *Wounds,* April 2025
- **Part 2:** Results of Survey NIR devices

Fluorescence Technology

- Literature review and survey plan underway

Technology Reviews to be Initiated

Imaging color consistency, integrity, and calibration of color

- Foundation for decision-making and critical comparisons in clinical trials and practice
- Critical to delivering effective remote care and accurately training AI tools

Further Output:

- Develop photo acquisition standards (identified need)
- Develop imaging color validation standards (identified need)

What is Needed for the Near Future?

Develop Standard for Imaging Color Validation?
Key contributing factors for Imaging in Wound Care

1. Standardized methods for photo capture
2. Standard methods of color accuracy
3. Standard methods of ensuring image integrity

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SAWC Spring WHS | WOUNDS A Compendium of Clinical Research and Practice

Improving Clinical Trial Design and Reporting

Marissa J. Carter, PhD, MA
Strategic Solutions, Inc
Marjana Tomic-Canic, PhD
University of Miami Miller School of Medicine

May 2, 2025 **9:50 AM – 10:15 AM**

Reporting of Clinical Trials: Committee Members

Committee members (part of Gaps Group):

Marissa Carter, PhD (Chair)

Alisha Oropallo, MD

Windy Cole, DPM

Edmond Lee, MBA

Vickie R. Driver, DPM

Rhonda Sullivan, PhD

Howard Walthall, JD

Robert Snyder, DPM

Support from Christine Bongards, PhD, and Solventum

Background

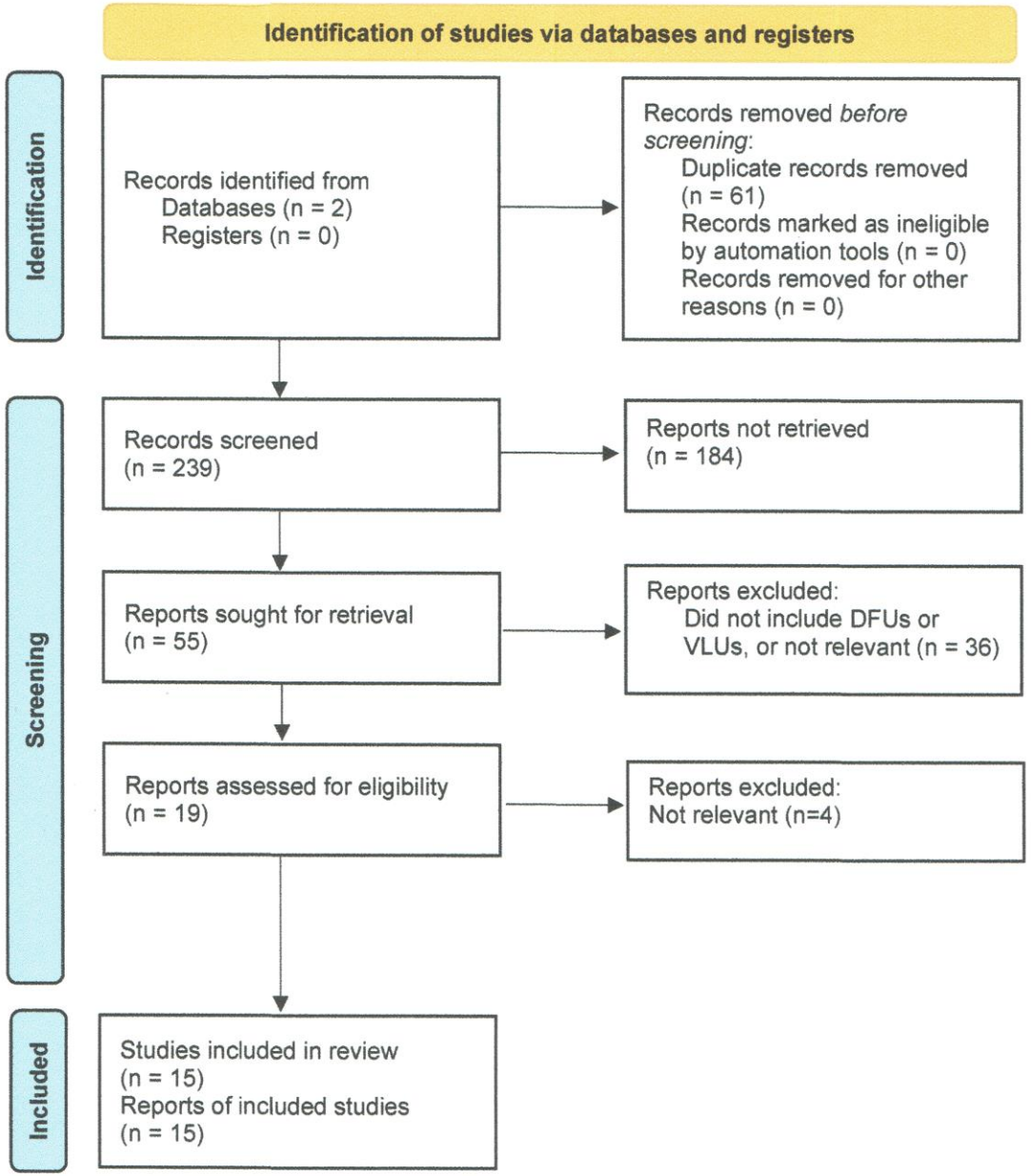
- Wound care journals do not always use CONSORT guidelines for the reporting of clinical trials despite existence for decades
- Reporting of clinical trials is hugely variable
- Frequently, important pieces of clinical studies are missing
- One particular area is reporting of patient- and wound-related variables
- This can make understanding of clinical studies and related health economic studies challenging
- Consequently, devices, drugs, and biologics used in wound care trials do not always get properly reimbursed and clinicians often do not know how to use them properly

Project Phases

- Literature search
- Study selection
- Characterization of studies
- Analysis of studies using a GRADE approach
- Selection of variables to be reported
- Creation of guidelines
- Publication and dissemination

Literature Search

- Systematic reviews reporting of prognostic factors for wound healing or wound healing models of chronic wounds in adult populations
- Focused on venous leg ulcers (VLUs) and diabetic foot ulcers (DFUs)
- English language
- Wound healing outcomes
- STN Platform in MEDLINE and Embase databases



Study Selection

- After the initial literature search, the group used a Delphi process to arrive at consensus for final study selection
- After 3 rounds of blind voting, 4 studies were dropped
- These included:
  - Protease activity
  - pH measurement
  - Exudate composition and temperature in wound healing
  - Effect of *Pseudomonas* colonization on lower limb venous ulcer healing

Study Characterization (I)

- All the studies were published relatively recently (2016-2024)
- Most of the literature searches within studies started at inception of the databases
- A few studies were updates of previous systematic reviews
- 10 studies listed the countries of origin
- Most studies did not present data on patient settings
- Numbers of patients varied hugely from 6 cohorts for DFUs (21,430 patients) to 5 cohorts for VLUs (29,775 patients) or 8 studies with only 909 patients

Study Characterization (II)

Prognostic variables included:

- Various vascular or microcirculation predictors (eg, ABI, AP, $TcPO_2$)
- Wound-related factors, such as wound age or area, infection, or severity of wounds (primarily for DFUs)
- Patient-related factors, such as sex/gender, patient age, smoking status, or comorbidities
- Percentage area reduction (PAR)
- Biomarkers (eg, CXCL6)
- Nutrition status
- Compression therapies

Selection of Variables to Be Reported

- For variables to be selected there had to be a **moderate certainty** in the evidence available using GRADE
- Larger studies (≥ 200 subjects) provided higher weights
- Use of biomarkers was rejected because they are not routinely available from central laboratories or hospital facilities
- PAR is also be an endpoint and so was not included
- High compression for VLUs should be part of reporting of standards of care (ongoing project within the Gaps group)
- Evidence for comorbidities was not strong enough (prevalence in many studies not high enough)

Guidelines: Selected Variables, Reporting Formats

- Patient-related:
  - Age, sex, BMI, hemoglobin
- Wound-related:
  - Area and age, multiple ulcers, wound severity, anatomical location, complications, history of venous ligation/venous stripping, deep venous insufficiency or presence of fibrin, etc.
- Diagnostics, such as ankle pressure, toe pressure, $TcPO_2$, and skin perfusion pressure
- Some of these pertain to DFUs, VLUs, or both
- Format example: Report mean (SD) and range; if distribution is non-normal, consider reporting BMI categories (counts/percentages) (categories will be listed)

Publication and Dissemination

- Manuscript submitted to *Wound Repair Regeneration*
- Consider dialogue with editors of other wound care journals regarding the guidelines
- Dissemination of information via other communication methods (posters or presentations at meetings, messaging via social media)

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Q&A 1: Discussion of WCCC Projects

Chair:
Alisha Oropallo, MD
Comprehensive Wound Healing Center and Hyperbarics, Northwell Health

May 2, 2025 10:25 AM – 11:25 AM

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Q&A Discussion of WCCC Projects

Participate in the audience Q&A by scanning the QR Code below:

meet.ps/attendee/wcccsummit

Panel Members

Dr. William Ennis
Healogics

Dr. William Tettelbach
RestorixHealth

Dr. Emma Wright
Mölnlycke Health Care

Dr. Dev Verma
FDA CDER (virtual)

Dr. Oscar Alvarez
Rutgers, New Jersey Medical School

Dr. Cyaandi Dove
University of Texas San Antonio

Dr. Yu-Chieh Chiu
FDA CDRH (virtual)

Recap: Tools to Measure Endpoints in Wound Care

TWG developed a ‘process’ to identify tools to measure PAR and other endpoints

- Process = engaging clinicians, industry, academia, and research experts
  - Establish capability and features for inclusion/exclusion criteria
  - Develop survey questionnaire to collect/confirm data from device manufacturers
  - Summarize results using unbiased quantitative tables to report findings
  - Generate technology reviews (education) for the wound care community
  - Publish research results

Benefits to the Wound Care Community

- Identified reliable tools to measure PAR and/or PVR
- Published results in support of the use of PAR as a primary endpoint
- Published educational papers for wound care community:
  - Clinical relevance of PAR
  - Importance of color accuracy in wound assessment
- Established applicable methodology to assessment of other tools/technologies
- Confirmed ‘value’ of collaboration with clinicians, industry, researchers, and government

What Can We Expect Next?

Evaluating tools for other validated endpoints

- Reduced infection
- Reduced bioburden
- Reduced recurrence/improved tissue quality/oxygenation
- Quality healing

Technology Reviews

Near Infrared Spectroscopy

(underway)

(circulation, support of PAR/PVR partial healing)

Fluorescence Technology

(underway)

(bioburden and infection detection/measurement)

Color Calibration Methods

(to be scheduled)

(improve imaging accuracy and move to a ‘standard’)

Feedback/Lessons Learned

- An organized process is essential to establish inclusion/exclusion criteria for evaluating tools
- Imaging tools require color control (calibration)
  - To ensure accuracy for interpretation by algorithms/humans
- Standards are needed for photo acquisition and imaging color validation

What Does the Wound Care Community Need Going Forward?

- Mobile/remote tools are in demand and coming fast
- AI will rapidly impact wound care
- Without standards for imaging color validation or photo acquisition, are we vulnerable?
- What focus should the WCCC take to ensure accuracy?

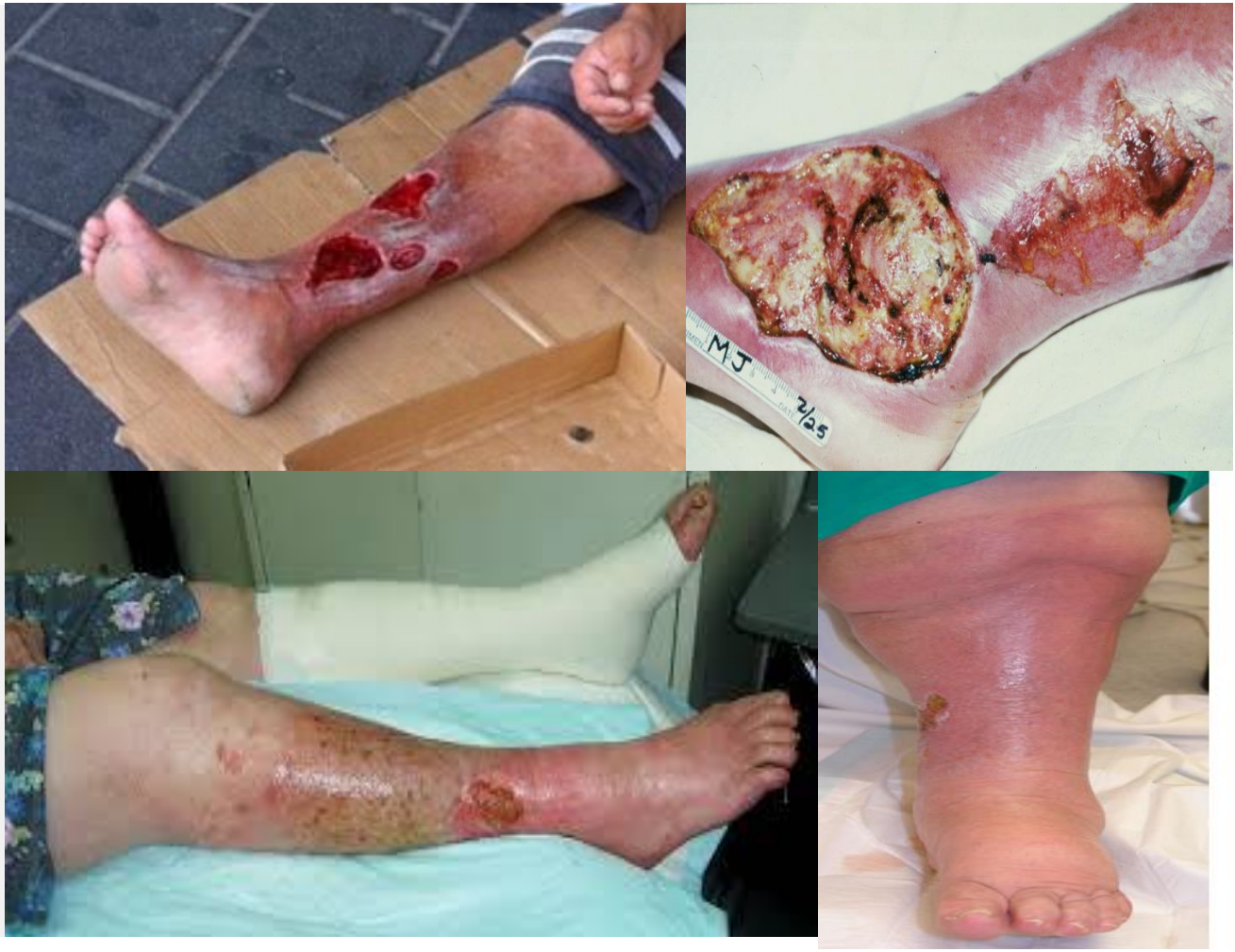
What Does the Wound Care Community Need Going Forward?

- Value-based health care for chronic wounds
- Considering the lifetime of care for patients with chronic wounds
- Importance of a shift from individual episode payments to a more holistic approach, potentially involving a fixed fee schedule model

Product Development Needs

Patients With Leg Ulcers

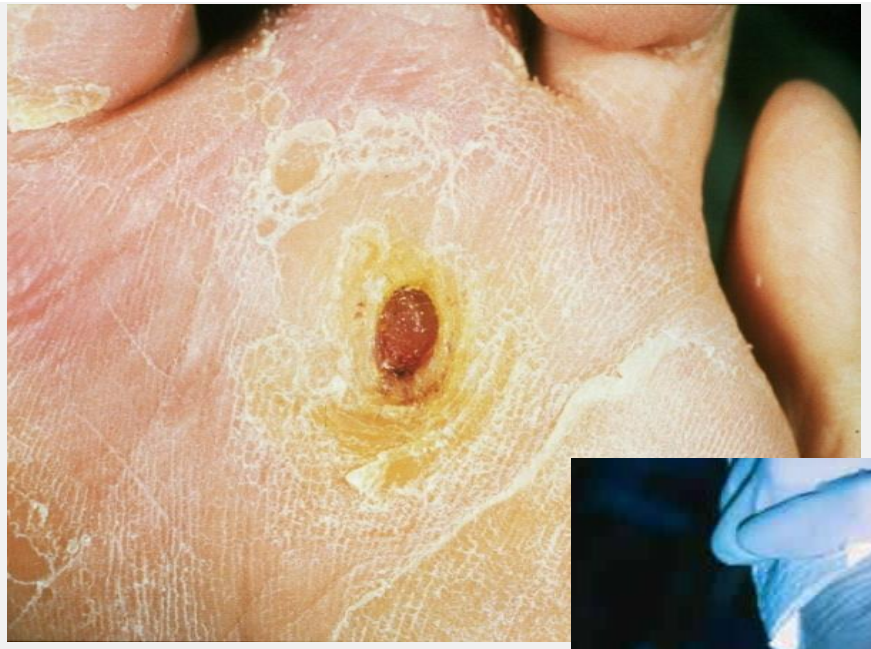
- Patient compliance and RPM: leg ulcers and edema
  - Patient empowerment
  - Garment sensors (eg, compression sock technology)
  - Addressing comorbidities (eg, cognitive impairment)

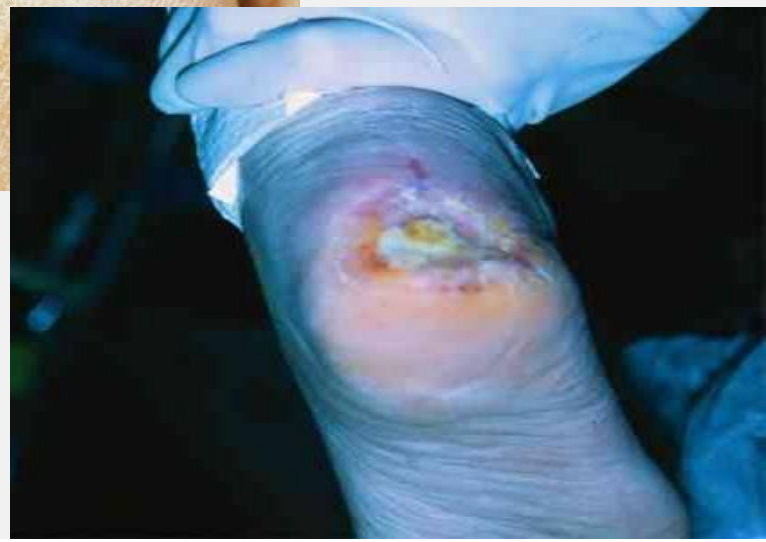


Product Development Needs

Caring for Patients With Diabetes

- Sock with sensors that can detect temperature changes and alert nurses
    - Allowing nurses to schedule visits based on clinical need rather than a fixed schedule
    - Importance of patient involvement





Address Post-Acute Wound Care and CAMPs

- Current regulatory environment unfavorably impacts access and outcomes
- Regulatory oversight
- Classification
- Evidence requirements for these products

FDA and CMS

- Share realistic goals and action items?
- Further feedback?

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Advanced Wound Care and Dressing Standards

Sarah Griffiths Langbord, PhD
CSO, NOxy Health Products

May 2, 2025 **11:25 AM – 11:50 AM**

Wound Dressings: A Massive Clinical and Economic Footprint

- 6.5 million people in the United States live with chronic wounds annually
- At just 1 dressing per day that's ~2.4 billion dressings per year
- That's only chronic wounds – excluding surgical wounds, trauma, postoperative care, etc.
- Total US usage may exceed 4 to 5 billion dressings per year

There is a lack of consistent, clinically relevant evaluation standards recognized by clinicians, industry, and materials management to support evidence-based dressing selection.

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Sen CK, Gordillo GM, Roy S, et al. Human skin wounds: a major and snowballing threat to public health and the economy. Wound Repair Regen. 2009;17(6):763-71.

Why Standardization Matters

Inconsistent Testing Practices:

- Wide variations in the preclinical evaluation of dressings
- No universal approach to performance assessment

Outdated or Incomplete Test Methods:

- Many are not clinically relevant or poorly specified
- Users often modify protocols

Absence of a Common Baseline:

- No standardized framework to reliably compare products
- Results in difficulties in comparing products and hinders innovation

WCCC Dressing Standards Workstream Mission

- **Goal:** Enhance patient access to the most clinically appropriate wound dressings
- **How:** Establish standardized, clinically relevant preclinical performance criteria
- **Focus:** Sheet-based dressings
- The aim is to set a benchmark for excellence in the assessment of wound dressings
- Preclinical testing is meant to complement—not replace—clinical evidence

Who Benefits from Dressing Test Standardization?

- **Clinicians:** Clear, relevant test data to support evidence-based choices
- **Industry:** Unified framework to align research and development with clinical needs
- **Procurement:** Transparent, performance-based evaluation criteria
- **Regulators:** More robust, clinically relevant, and standardized product data
- **Patients:** Enhanced access to the most clinically appropriate wound dressings

Framework Process

- Identify key clinical needs (eg, fluid handling, strength, antimicrobial action)
- Map those needs to existing standards and test methods
- Highlight gaps and inconsistencies
- Develop recommendations for performance-based test standards
- Collect stakeholder feedback via 2 survey rounds:
  - **Round 1:** Stakeholder feedback to narrow down and prioritize the most commonly used standards for evidence generation
  - **Round 2:** Stakeholder feedback on the specific recommendations that are developed by WCCC to determine whether stakeholders are willing to stand behind

Advanced Wound Dressings – Functional Parameters & Standards

Currently reviewing 30+ standards across European Standards (EN), American Society for Testing and Materials (ASTM), International Organization for Standardization (ISO), United States Pharmacopeia (USP), American Association of Textile Chemists and Colorists (AATCC)

Category	Distinct Standards	Details
Moisture Management	10	EN 13726:2023 + Annexes B–J, incl. fluid handling & MVTR
Mechanical Properties	6	Extensibility, tensile strength, peel force, radiopacity
Antimicrobial Properties	12 (plus ASTM E35 set)	Barrier tests, antibacterial activity, USP, AATCC, ISO
Antibiofilm	2	Biofilm reactor tests: ASTM E2647, E2871
Total	30+	Grouped by clinical performance needs

Excluded: General safety standards (eg, ISO 10993, ISO 22442)

Snapshot of Key Gaps

- **Lack of Clinically Relevant Test Conditions:** Many tests use non-representative fluids and omit real-world factors like compression or gravity. Methods often measure only maximum capacity without accounting for directional flow or realistic fluid dynamics.
- **Inadequate Antimicrobial Protocols:** Protocols are not developed to account for different technologies including form factor and anticipated mechanisms of action (MOA).
- **Limited Biofilm Modeling:** Typically tests only 1 species on artificial surfaces, missing the complexity of actual wound environments.

The Future of Dressing

- The next generation of wound dressings is already here – smart, responsive, and more personalized than ever.
- Recent breakthroughs include:
  - **Microneedle-Based Dressings:** Enable painless and targeted drug delivery.[1]
  - **Smart Hydrogels**: Respond to infection and inflammation, releasing antimicrobials and antioxidants as needed.[2]
- These technologies promise better outcomes for complex wounds — but only if we have standards that can accurately evaluate their preclinical performance.
- To fully support innovation, we must close today's gaps in testing — ensuring future solutions are validated, trusted, and accessible to patients.

1. Zhou Y, Wang X, Zhang W, et al. *Smart drug delivery and responsive microneedles for wound healing.* Exploration of Medicine. 2024. 2. Li Y, Gong H, Gan T, Ma X, Geng Q, Yin S, Zhang H, Wu Y. *Smart hydrogel dressing enhances the healing of chronic infectious diabetic wounds through dual-barrier drug delivery action.* Biomacromolecules. 2024..

Call to Action: Your Feedback is Critical

We want your input

- **Clinicians and Materials Management Teams**: What real-world clinical needs are not being met?
- **Wound Dressing Companies, Contract Research Organizations, Academic Researchers, and Regulatory Stakeholders:** How are current test standards working (or not)? Where are the knowledge gaps?
- **Other Wound Care Initiatives, Standards Organizations, Payers:** Let's align and accelerate progress together.

📢 Participate in our stakeholder survey (launched via HMP)

📅 Survey will remain open **till May 9th**

Scan the QR Code

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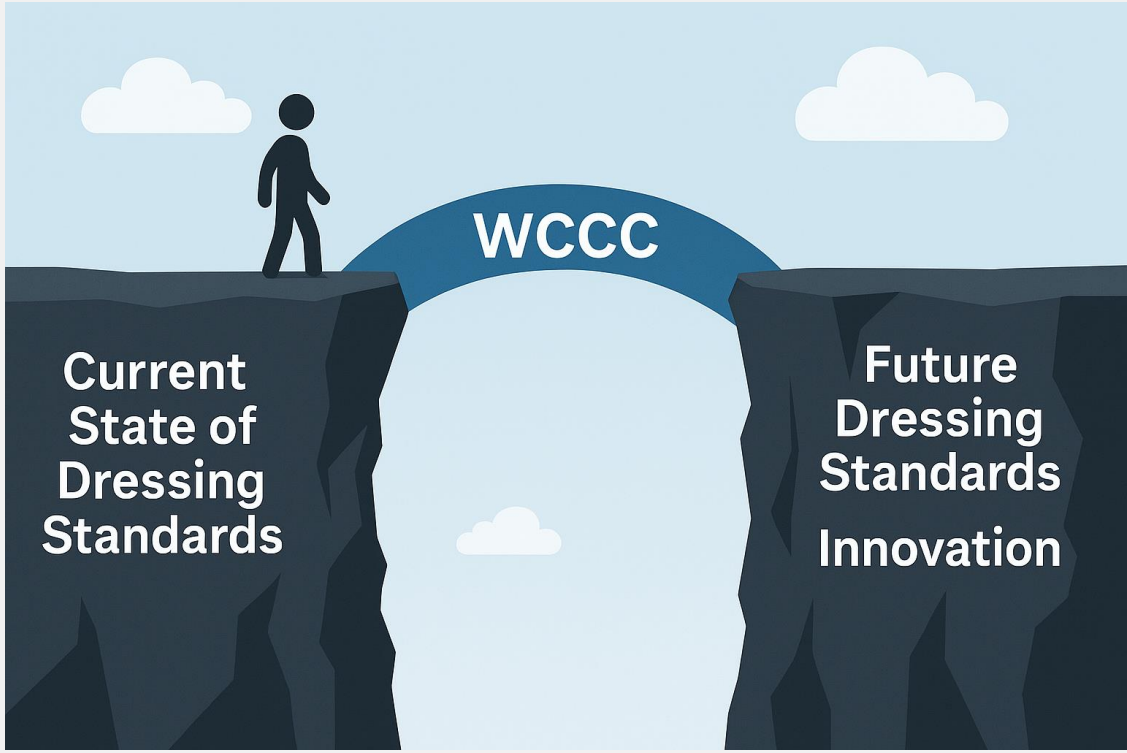
Next Steps: Join Us in Advancing Standards

- Mapping of clinical needs to standards underway
- Stakeholder Survey Analysis
- Establishing a Framework of Standards
- Gaps report and recommendations under development

📄 Final deliverables to be shared with FDA, research funders, and the wound care community

🤝 Join us in building the foundation for better wound dressing innovation



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Defining Standard of Care: Intro and Update

Maribel Henao, DPM, MSPT, BCMAS
Senior Director, Medical Affairs
Organogenesis, Inc

WCCC SOC Workstream Chair

May 2, 2025 **11:50 AM – 12:05 PM**

Standard of Care Project Team

Lucian Vlad, MD

Rob Fraser, MN, RN, NSWOC, WOCC (C)

Vickie R. Driver, DPM, MS

Lisa Gould, MD, PhD

Caroline Fife, MD

Alisha Oropallo, MD

Teresa Jones, MD

Shabnam Vaezzadeh, MD, MPA, BCMAS

Christine Bongards, PhD

Joseph Rolley, BS, MSIA

Standard of Care Project

- There is no unified recommendation on what constitutes “standard of care” for adoption in clinical research and practice.
  - Critical need for a universal SOC in wound care clinical trials
  - Lack of consensus on an SOC affects all wound care patients
- Currently, there is a lack of consistency and transparency in treatments provided as part of “standard of care” (SOC) in wound care clinical trials
- SOC has been described and published by different societies and organizations through practice guidelines, consensus documents, or compendiums
  - Due to multidisciplinary nature of wound care, some are not in alignment
- In clinical trials, standardization reduces bias, ensures validity, and allows for generalization to a larger real-world population

Examples of SOC in Published RCTs

Example 1

- Wound debridement
- Moist wound therapy
  - Silver gel and silver dressing at the discretion of the attending clinician
- Compression dressing
- Daily dressing changes
  - Provided with all necessary supplies on a weekly basis
- All wounds were offloaded using a removable cast walker

Example 2

- Wound debridement to remove all nonviable soft tissue from the wound by scalpel, tissue nippers, and/or curettes at each weekly visit
- Nonadherent dressing and either saline-moistened gauze or foam dressing for moderately draining wounds
- Application of an outer dressing
- Walking boots for wounds on the sole of the foot or a postoperative shoe if the wound was on the dorsum of the foot or at the ankle
- Custom offloading boots could be prescribed at the discretion of the site investigator
- Offloading device used could be changed as needed to accommodate changes in wound size or position

Standard of Care Project

2024 WCCC Summit Consensus Statements Review

1. As the FDA does not regulate SOC or the practice of medicine, professional practice organizations must define their own SOC.

- Critical need for a universal SOC in wound care

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

- Stratified by various patient populations rather as single immutable points
- Target the most appropriate care and innovate products toward a particular patient population

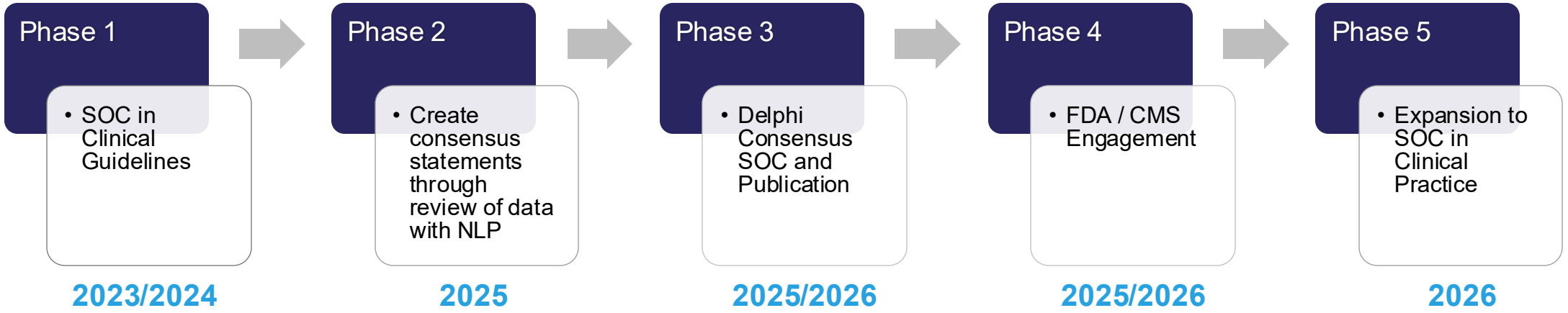
3. The entire Wound Healing Collaborative Community and its stakeholders must be held accountable for consistently implementing the established SOC.

- Entire wound healing community must commit to its adoption and promote same quality of science across the board

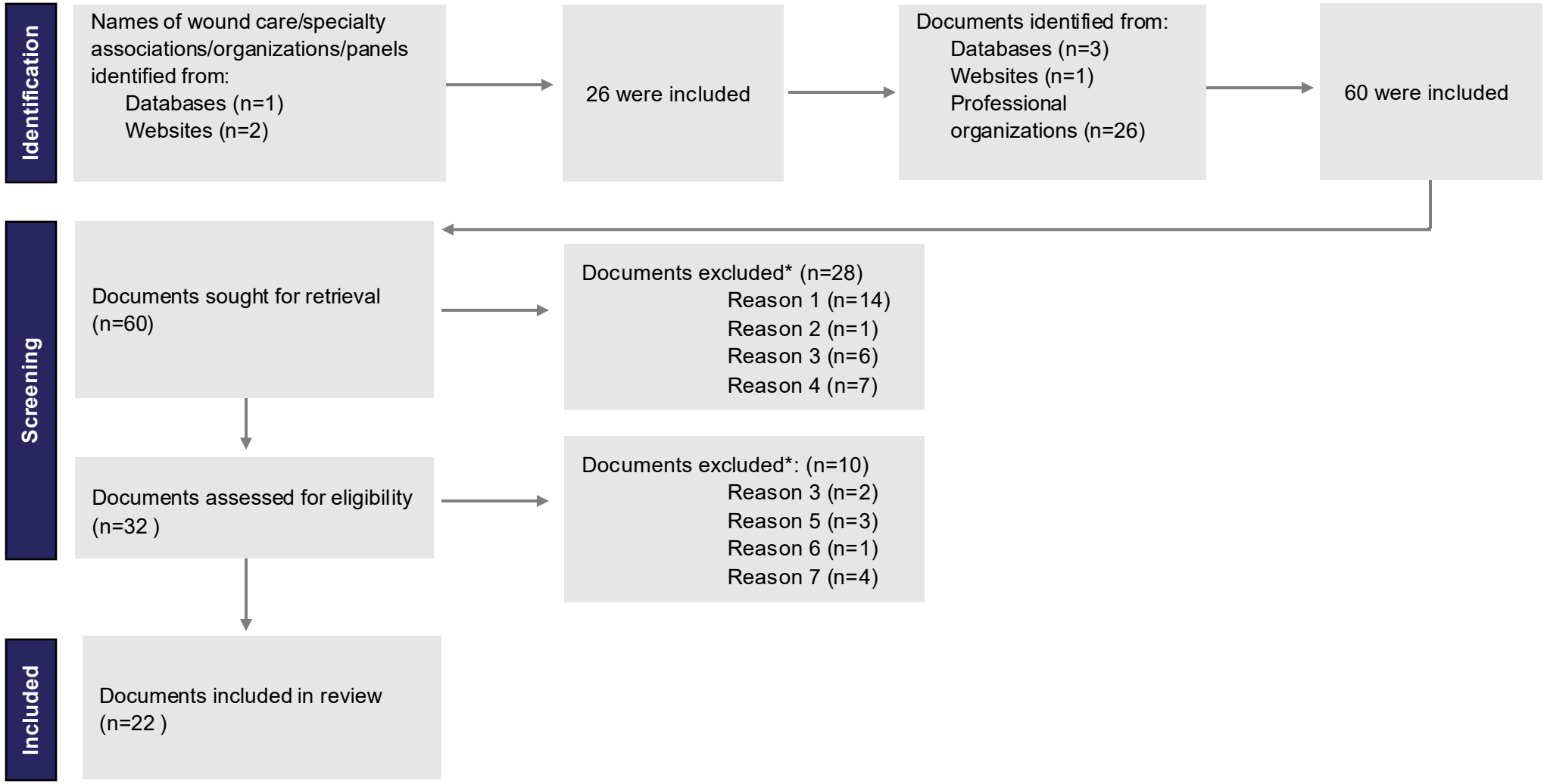
Standard of Care Project

Project Goal:

- The aim of this project is to identify the foundational elements that constitute an accepted SOC for use in comparative clinical trials for innovative wound technologies.
- Build consensus of what constitutes “standard of care” across chronic wound indications for adoption in clinical research.
  - Establish consensus statements for a Delphi Review after a systematic literature review of guidelines
- Focus is to improve and refine future clinical trial design—not to invalidate or denounce current published RCTs



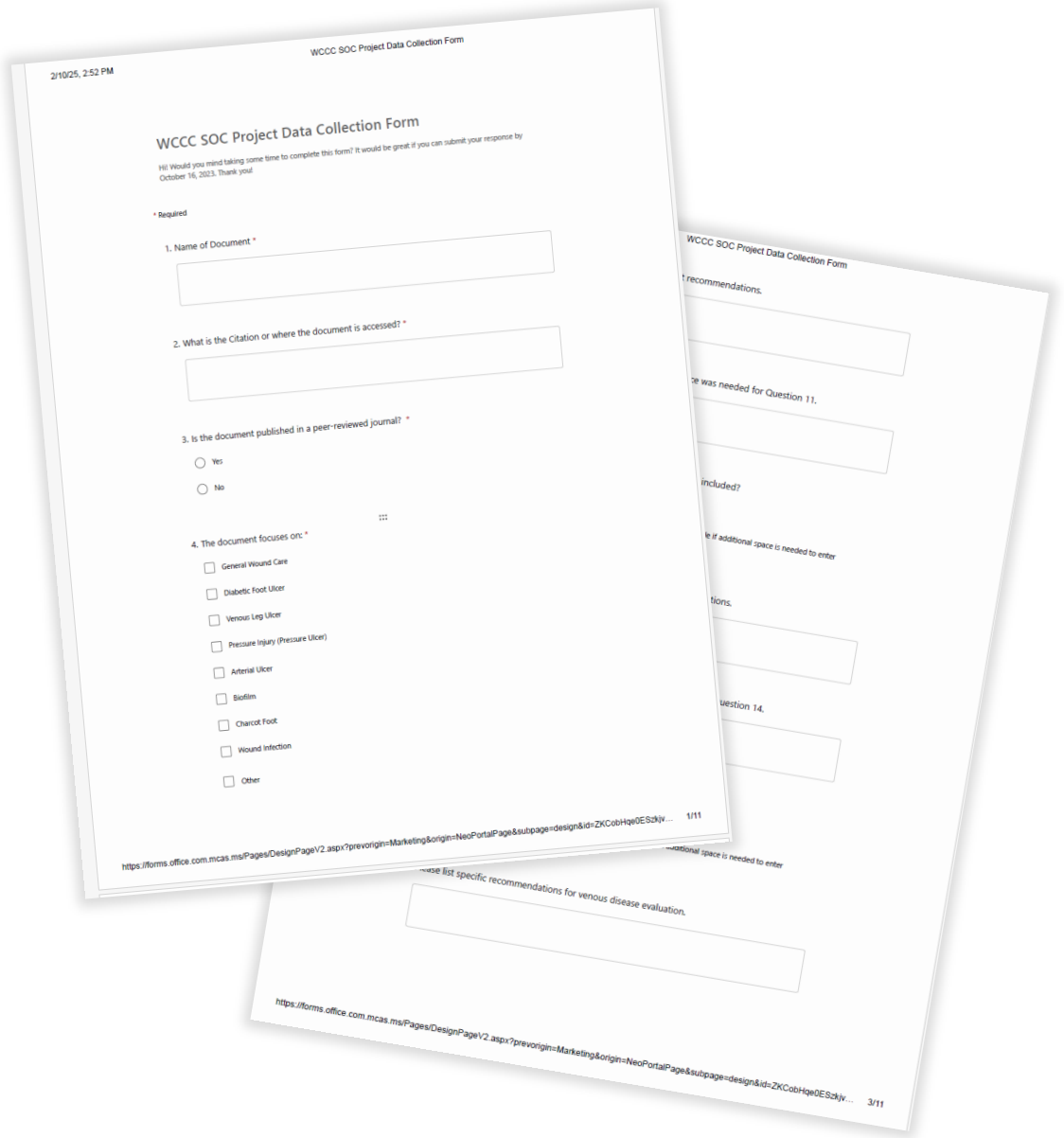
Identification of studies via databases, websites, and other methods



1. Older versions 2. Acute wounds only 3. Did not have SOC defined or included in the document. 4. Repeats or Summaries 5.Not peer-reviewed 6. Considered "inactive by society" 7. Did not use a standardized method to determine quality of evidence.

Data Extraction

- The inclusion and details for SOC in each guideline or publication were extracted systematically.
- An electronic data collection form in Microsoft Forms was utilized to enter information
  - 48 queries were included such as
    - Citation
    - Type of standardized method to determine quality of evidence
    - Whether elements of standard wound care treatment were included such as debridement, offloading, and others



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List of 22 Guidelines Included in Review

WHS

- Wound Healing Society 2015 Update on Guidelines for Venous Ulcers
- WHS (Wound Healing Society) Guidelines Update: Diabetic Foot Ulcer Treatment Guidelines. 2023
- WHS Guidelines for the Treatment of Pressure Ulcers—2023 Update
- Wound Healing Society 2023 Update on Guidelines for Arterial Ulcers

AAFP

- Chronic Wounds: Evaluation and Management. 2020

AAWC

- The International Consolidated Venous Ulcer Guideline Update 2015: Process Improvement, Evidence Analysis, and Future Goals
- The Association for the Advancement of Wound Care (AAWC) Venous and Pressure Ulcer Guidelines. 2014
- The Development and Content Validation of a Multidisciplinary, Evidence-based Wound Infection Prevention and Treatment Guideline

IDSA

- 2012 Infectious Diseases Society of America Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections
- Practice Guidelines for the Diagnosis and Management of Skin and Soft Tissue Infections: 2014 Update by the Infectious Diseases Society of America

IWDGF

- Guidelines on Interventions to Enhance Healing of Foot Ulcers in People With Diabetes (IWGDF 2023 update)
- IWGDF/IDSA Guidelines on the Diagnosis and Treatment of Diabetes-Related Foot Infections (IWGDF/IDSA 2023)

AFP

- Venous Ulcers: Diagnosis and Treatment. 2019

WOCN

- WOCN 2016 Guideline for Prevention and Management of Pressure Injuries (Ulcers)
- WOCN 2019 Guidelines for Management of Wounds in Patients With Lower Extremity Venous Disease
- 2021 Guideline for Management of Patients With Lower-Extremity Wounds Due to Diabetes Mellitus and/or Neuropathic Disease
- Guideline for Management of Wounds in Patients With Lower Extremity Arterial Disease 2024

SVS/AVF

- Management of Venous Leg Ulcers: Clinical Practice Guidelines of the Society for Vascular Surgery and the American Venous Forum 2014

SVS/APMA/SVM

- The Management of Diabetic Foot: A Clinical Practice Guideline by the Society for Vascular Surgery in Collaboration With the American Podiatric Medical Association and the Society for Vascular Medicine 2016

NPIAP

- Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guideline. 2019

IWII

- IWII Wound Infection in Clinical Practice Consensus Document: 2022 update.
- Schultz et al. Consensus guidelines for the identification and treatment of biofilms in chronic nonhealing wounds. 2017

High-Level Results From 22 Included Guidelines

Wound Assessment

- Proper wound assessment, including accurate diagnosis
- Evaluate arterial perfusion
- Evaluate deep tissue infection and/or osteomyelitis
- Soft tissue biopsy followed by bone and soft tissue

Patient Assessment

- Nutritional evaluation
- Referral to specialists

Patient Management

- Addressing tobacco cessation, weight management, or other psychosocial/patient-related factors

Wound Treatment

- Measures to prevent or treat wound infection/bioburden/biofilm
- Wound bed preparation
- Debridement recommended to remove necrotic/nonviable tissue/slough and excessive bacterial burden and to maintain the readiness of the wound bed for healing
- Surgical debridement as the type of debridement
- Selecting a proper wound dressing to control exudate and maintain moisture balance
- When applicable, offloading diabetic foot ulcers (DFUs) was listed
- Compression for venous leg ulcers
- Surgery recommended
- Change to advanced therapies when reaching a certain timeframe and/or objectives during clinical assessment

Baseline SOC Categories

1. Debridement
2. Offloading (DFU)
   - Repositioning and Pressure Redistribution (PRI)
3. Assess Adequate Circulation
4. Dressings—Maintain Moist Wound Environment
5. Management Wound Infection
6. Nutritional Support
7. Compression
8. Other Wound Cleansing and Wound Bed Preparation

SOC Project Next Steps

1. Reviewing different AI-based/NLP models/platforms for use in summarizing and creating consensus statements for each SOC Category

- Determine the appropriate questions to ask

2. Conclude with using a Delphi method to establish consensus opinions on the foundational elements that constitute a complete SOC in clinical trials

- Create a template for SOC to be utilized for clinical trial methodology

3. SOC in wound care is expected to change and will require updates in the future

Appendix: List of Organizations/Societies/Panels

Organizations/Societies/Panels included:

1. Wound Healing Society
2. Wound, Ostomy, and Continence Nurses Society
3. American Diabetes Association
4. American Podiatric Medical Association
5. International Working Group on the Diabetic Foot
6. American Association of Family Physicians
7. American Society of Plastic Surgery
8. Wound Healing Foundation
9. American College of Cardiology
10. Society of Vascular Surgery
11. International Consolidated Wound Infection Guideline
12. International Wound Infection Institute
13. American College of Physicians
14. National Pressure Injury Advisory Panel
15. Association for the Advancement of Wound Care
16. American Venous Forum
17. American Medical Doctors Association
18. American College of Foot and Ankle Surgeons
19. CLI Global Society
20. American Association of Plastic Surgeons
21. Society of Vascular Medicine
22. Infectious Diseases Society of America
23. *Journal of Wound Care*: TIMERS
24. *Ostomy Wound Management*: Consensus recommendations on advancing the SOC for treating neuropathic foot ulcers in patients with diabetes
25. International Clinical Practice Guidelines
26. Global Wound Biofilm Expert Panel

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Recommendations for Chronic Wounds: FDA Guidance Update on Clinical Trial Design

Windy Cole, DPM, CWSP, FFPM RCPS (Glasg)
Kent State University

Mitch Sanders, PhD
ProDevLabs

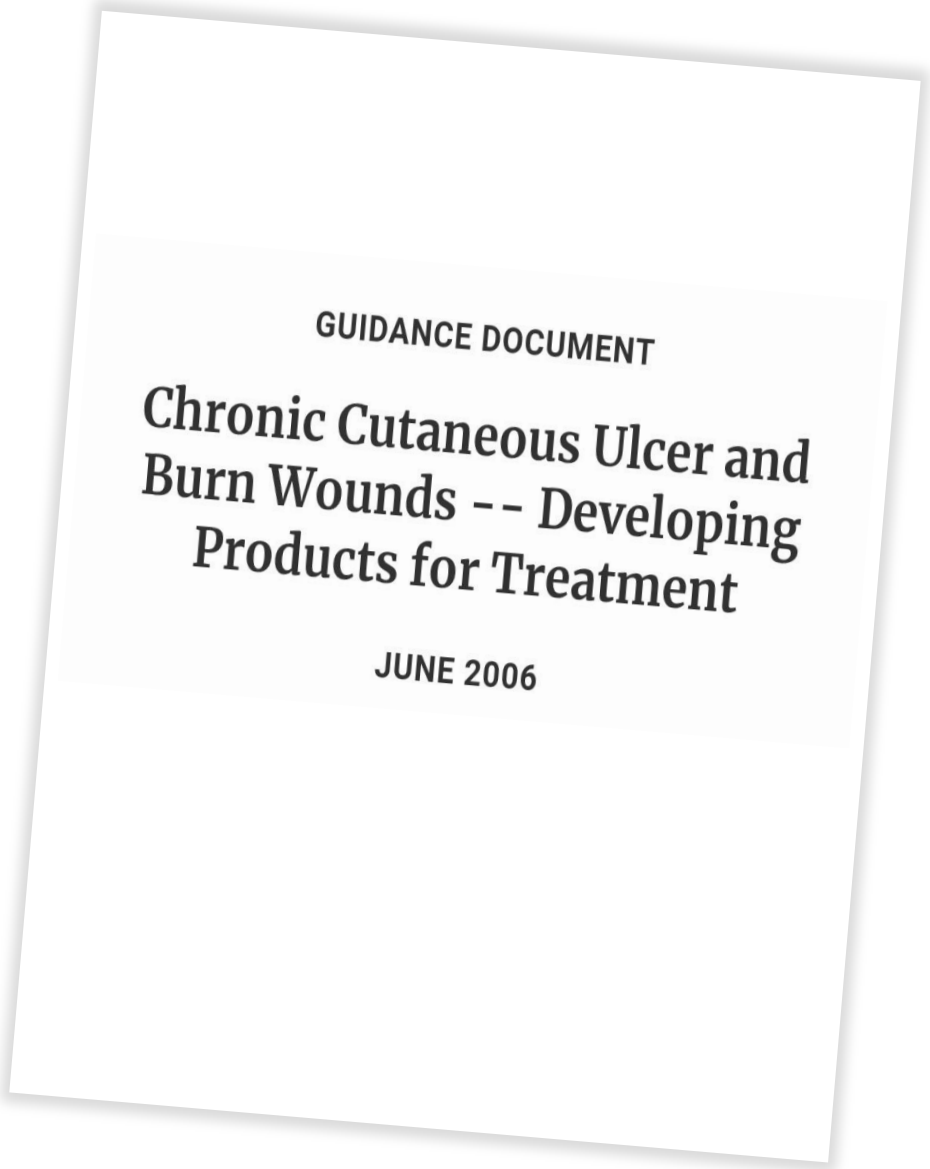
May 2, 2025 **12:05 PM – 12:20 PM**

Goals and Objectives

The current FDA Guidance Document on Chronic Cutaneous Ulcer and Burn trials is nearly 2 decades old.

In this time, new developments in our understanding of the pathogenicity of chronic wounds, along with the introduction of novel diagnostic methods, have significantly advanced the field.

The WCCC was established as a dedicated work group to revise key areas that urgently require updates to align with current evidence and best practices.



Deliverables Include

- Recommendations will be provided as official docket comments on the current FDA document through the established link, which can be used by the FDA as an addendum or update to the current guidance document. Once we submit our recommendations, the FDA will make all decisions regarding which recommendations they will accept.

- The WCCC will also publish the group's recommendations to disseminate the information broadly. The FDA would not be involved in this document. The contents would represent the views of the WCCC and not the official views of the FDA and are not to be viewed as an endorsement.

FDA Clinical Trial Design Guidance Document Work Group Update

We have successfully collected input from all relevant stakeholders and various work groups involved in the project.

This feedback has been compiled into a comprehensive document, which will be circulated for thorough review and constructive comments from all parties involved.

The Work Group (WG) will select areas of critical importance to submit to the FDA for consideration.

Thirty-five (35) new references have been included in the updated guidelines.

Preclinical Considerations

- Critical unmet need for standardizing preclinical testing (see Wound Reporting in Animal and Human Preclinical Studies [WRAHPS] guidelines).
- If whenever possible, correlate efficacy with human samples (eg, ex vivo preclinical human skin wound model or tissue samples from patients with wounds).
- Preclinical data can vary significantly based on the species, sex, age, hair cycle, microbiome diversity, metabolic factors, wound type, and depth.

Clinical Trial Design

- Regulatory requirements for devices and drugs/biologics can differ significantly; refer to recent guidance for CDRH and CDER/CBER
- Utilize established methods to produce objectively measurable accuracy, consistency, and integrity
- Use of digital wound imaging medical devices that automatically calculate wound area measurements and percent area reduction (PAR)/percent volume reduction (PVR) with accurate and reliable methods
- Includes information on various ulcer grading scales (e.g Wagner, WiFi, Sinbad)
- WCCC provides consensus findings on the standard of care (SOC) for offloading, compression, and debridement

Endpoints

The Wound-Care Experts/FDA-Clinical Endpoints Project (WEF-CEP) initiative identified, evaluated, and confirmed 15 clinically meaningful and/or patient-centered endpoints for wound care through a process agreed upon in collaboration with the FDA

Six new primary endpoints recommended and accepted for discussion with sponsors by the FDA

Four new suggested secondary endpoints recommended to the FDA

Statistical Analysis

- The statistical analysis section has been greatly expanded to include Maximum Likelihood Estimation (MLE), and Bayesian Estimation (BE) methods.
- Detailed parameters are provided for Null hypothesis testing (NHST), MLE, and BE to measure:
  - Wound healing rate (WHR)
  - Percent area reduction (PAR)
  - Wound time to healing (WTH)
  - Pain

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Project STEADY:

Study of Ten-Year Evaluation and Analysis of Diabetic Foot Ulcers in the US Population

Donna J. Cartwright, MPA, RHIA, CCS, RAC, FAHIMA
Integra LifeSciences
Project Lead

Vickie R. Driver, DPM, MS
Chair, Board of Directors, WCCC

May 2, 2025 12:20 PM – 12:40 PM

STEADY Scientific Committee

Vickie Driver, DPM, MS
Professor, Washington State University Medical School

COMMITTEE CHAIR

John Lantis, MD
Site Chief of Surgery,
Mount Sinai West Hospital

Cyaandi Dove, DPM
Direction of Clinical Research,
University of Texas San Antonio

Robert Snyder, DPM
Director of Clinical Research,
Barry University

David Alper, DPM
Trustee, American Podiatric Medical Association

Joseph Rolley, BS, MSIA
Principal at JTR Business Consulting

DFU Approval and Reimbursement Landscape Is Evolving Rapidly

- **FDA and CMS** deem the **existing clinical evidence insufficient** for treatment-related comparative effectiveness.
- CMS and FDA are showing increasing **interest in using real-world evidence** (RWE) for regulatory and coverage decisions, **but few sources** of RWE are suitable for wound technologies.
- **Medicare** Administrative Contractors (MACs) are **raising evidence thresholds** and creating Local Coverage Determinations (LCDs) that act as National Coverage Determinations (NCDs) without the rigorous review process and consideration of RWE.
- Wound technology developers must consider NCD pathways involving RCT and high-quality RWE or supplement LCD requests with comparative effectiveness studies to achieve coverage and payment goals.

Clinical Trials Face Challenges in Generating Evidence in DFU

5 common limitations of RCTs:

1

Strict eligibility criteria

- Difficulty recruiting participants

2

Lack of generalizability to a wide variety of:

- Wound presentations
- Types of sites
- Type of providers

3

Inability to show effectiveness in a real-world, uncontrolled environment

4

Short timelines, preventing ability to track:

- Time to total wound closure for all participants
- Recurrence rate

5

High cost

There are Few Existing Real-World Wound Databases That are Fit for the Purpose Conducting RW Studies for Regulatory and Coverage Decisions

Background: The Wound Care Collaborative Community conducted a comprehensive RWD landscape analysis and systematically screened 34 potential sources for chronic wounds.

Methods: Multiple data elements were used to determine suitability and usability: *Size, Type, Region, Source, Population, Years in Existence, Data Parameters Captured, Wound Types, Patient Demographics, Clinical Data, Prevalence Rates, Wound Outcome, Data Analytics Capabilities*.

- **Results:** Only 4 clinical US databases (DBs) had "high potential" for chronic wound research; a fifth met the criteria but had data access restrictions; just 1 DB was found that was fit-for-purpose of the WCCC's Natural History Project.

Real World Databases must have breadth and depth of data from multiple sites of care (inpatient, outpatient, physician office, mobile wound care, etc.) in scale that can produce statistically significant results.

REAL-WORLD EVIDENCE

Comprehensive Landscape Analysis for Usable Real-World Wound Care Data

Lucian G. Vlad, MD[1]; Joseph Rolley, BS, MSIA[2]; Shabnam Vaezzadeh, MD, MPA[3]; Lisa Gould, MD, PhD[4]; Caroline E. Fife, MD[5,6]; Vickie R. Driver, DPM, MS[7]; Anokhi J. Kapasi, PhD, BS[8]; John C. Lantis II, MD[9]; Sharmila A. Kamani, BA[3]; and Burak K. Pakkal, MD, MBA[3]

Affiliations: [1]Wake Forest University School of Medicine, Winston-Salem, NC; [2]JTR Business Consulting, LLC, Doylestown, PA; [3]Exquisite Biomedical Consulting, LTD, Vancouver, BC; [4]South Shore Health, South Weymouth, MA; [5]Baylor College of Medicine, Houston, TX; [6]Intellicure, The Woodlands, TX; [7]Washington State University, Elson S. Floyd College of Medicine, Spokane, WA; [8]B.R.I.D.G.E. TO DATA®, DG, LLC, Fairfax, VA; [9]Icahn School of Medicine at Mount Sinai, New York, NY

Contributions: All authors contributed equally to this work.

Ethical Approval: This project was exempt from institutional review board approval; it does not contain any patient personal health information.

Disclosure: The authors disclose no financial or other conflicts of interest. V.R.D. is Chair of Wound Care Collaborative Community (WCCC). L.G. is Vice Chair of WCCC. C.E.F. is the Executive Director of the USWR. All remaining authors are volunteer members of WCCC.

Correspondence: Lucian G. Vlad, MD; Atrium Health Wake Forest Baptist, Plastic & Reconstructive Surgery - Wound Care and Hyperbaric Center, 1 Medical Ctr. Blvd, Winston-Salem, NC 27157; lvlad@wakehealth.edu

Manuscript Accepted: September 3, 2024

Recommended Citation: Vlad LG, Rolley J, Vaezzadeh S, et al. Comprehensive landscape analysis for usable real-world wound care data. *Wounds*. 2024;36(9):###-###. doi:10.25270/wnds/24076

ABSTRACT

Background. The Wound Care Collaborative Community (WCCC) aims to assess current usable real-world data (RWD) sources to determine which real-world databases (DBs) are suitable and usable for studying the natural history of chronic wounds. Randomized controlled trials (RCTs) do not fully reflect the complexity of chronic wound patients. Using RWD, establishment of a scientifically grounded "road map" for RCTs is needed to better navigate the real-world complexity of the patients with chronic wounds. The long-term objectives include identifying patients ineligible to receive evidence-based advanced treatment and diagnostic options, reducing patient suffering, and providing decision support for regulatory bodies, payers, and clinicians. **Objective.** To identify available and usable RWD on US chronic wound care patients, as an early step toward the WCCC's objectives. **Methods.** Using B.R.I.D.G.E. TO DATA® methodology, the WCCC conducted a comprehensive RWD landscape analysis and systematically screened 34 potential sources for chronic wounds. Multiple data elements helped determine suitability and usability. **Results.** Four clinical US DBs have "high potential" for elucidating the natural history of chronic wounds; a fifth met the WCCC criteria but has data access restrictions. **Conclusion.** Identifying suitable, usable real-world DBs for research is complex. Only 1 DB was found that is fit for purpose and matches the goals to study the natural history of patients with chronic wounds.

According to a 2023 published analysis of 2014-2019 Medicare claims data, 16.4% of Medicare beneficiaries (10.5 million people) were affected by chronic wounds in that period, the annual cost of which was conservatively estimated at $22.5 billion but may have been in excess of $67 billion; this is a significant economic impact.[1] RCTs, which occupy the apex of the evidence pyramid, are designed to demonstrate the efficacy of a treatment under ideal conditions. These studies look at a particular wound type for a single treatment period, usually 12 to 16 weeks, and a narrowly defined population with many comorbid conditions excluded. RCTs provide limited insights into the natural history of specific wound types, their incidence in the general population, the number of concomitant wounds per patient, locations of care, wound outcome, frequency or number of recurrences, and the association of comorbid conditions with failure to heal.[2-4] This information can be obtained from RWD.[5-7] RWD are vital for identifying gaps in evidence-based clinical practice, disparities in care, unmet therapeutic needs, and promising signals that a medical treatment may be of benefit to a broader population than was explored in RCTs.

The FDA is placing increasing value on RWE in regulatory decision-making, and this has increased the demand for RWD in the field of wound care.[8] To date, analysis of large, structured data sets in this field have been limited to administrative data. Although interoperability standards facilitate the exchange of already structured health care in-

Keywords: chronic wounds, databases, fit for purpose, real-world data, registry, wound outcomes

Abbreviations: DB, database; DFU, diabetic foot ulcer; EHR, electronic health record; FDA, US Food and Drug Administration; RCT, randomized controlled trial; RWD, real-world data; RWE, real-world evidence; VLU, venous leg ulcer; WCCC, Wound Care Collaborative Community.

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RWE Can Help Bridge the Evidence Gap—5 solutions from Project STEADY:

1

Loose eligibility criteria

- Faster recruitment
- Increased diversity of participants

2

Strong generalizability to a wide variety of:

- Wound presentations
- Types of sites and providers

3

Ability to show effectiveness in a real-world, uncontrolled environment

4

Longitudinal, long-term design, providing ability to track:

- Time to total wound closure for all participants
- Recurrence rate

5

Lower cost:

- Pooling of resources to decrease cost per research team
- Not necessary to purchase investigational products, as products are already approved
- Utilization of data already collected in a real-world environment

Project STEADY

- Patient registry: longitudinal cohort study
- Varied data sources, including:
  - CRF
  - EMR
  - PRO
  - Claims (optional)
- 5000 participants
- 10 years of follow-up
- 50 sites, including Indian Health Services, VA, long-term care, and mobile wound clinics
- Upfront funding from leading wound care companies

Uses of STEADY Dataset

For Industry:

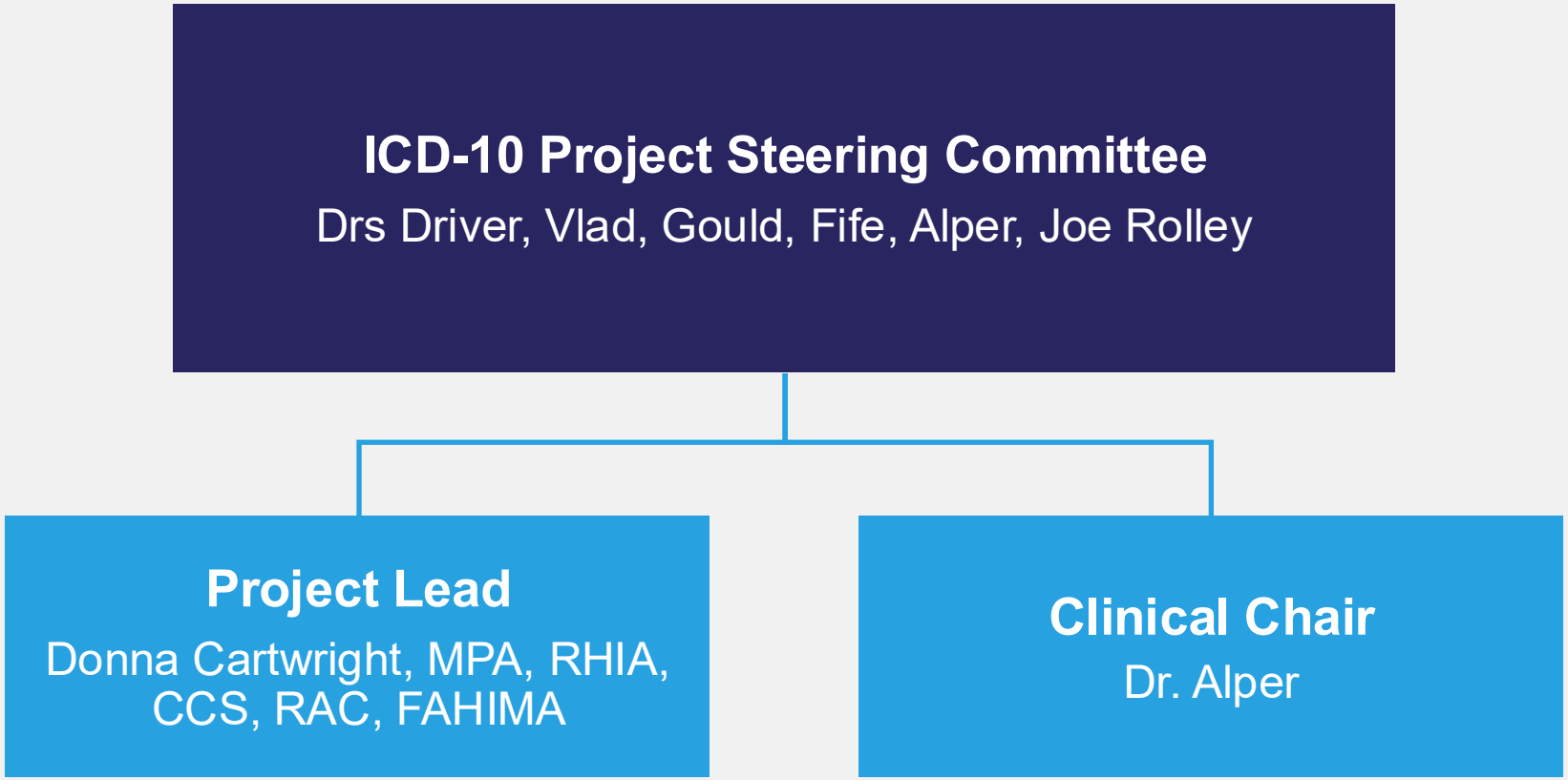
- Post-approval safety studies
- Post-approval efficacy studies
- External control arms
- Comparative effectiveness research
- Label expansion
- Coverage with Evidence Development (CED) studies
- Scientific strategies for medical affairs

For Researchers:

- Disease epidemiology
- Natural history of disease
- Burden of illness
- Economics
  - Direct
  - Indirect
- DFU in the context of diabetes
- Role of caregivers

Thank you, Alira Health

Project Leadership



Rationale for Necessary Changes to Current ICD-10-CM Codes for Diabetic Foot Ulcers

A new, detailed ICD-10-CM code set for **diabetic foot ulcers (DFUs)** will help address critical gaps in clinical documentation, improve patient care, and support better health care management. The new code set will enable clinicians to more specifically describe **wound depth, location, progression, and severity.** Clinicians will be empowered to provide targeted treatment plans, monitor response to treatment more accurately, and contribute to ongoing research efforts. Engaging professional societies and stakeholders in this process is essential to ensure that the codes are comprehensive, clinically relevant, and actionable. The goal of achieving this by 2026 is both feasible and necessary to improve the care and outcomes of individuals with diabetic foot ulcers.

Lack of Specificity

The lack of detailed coding results in:

- Inaccurate data for clinical decision-making.
- Inconsistent reporting and tracking across health care systems.
- Inaccurate reporting for national health care statistics.
- Difficulty in aligning treatment plans with the ulcer's severity, which may lead to suboptimal care.
- Inadequate prognostic assessment and risk assessment. It is known that the mortality and life expectancy of patients with DFUs is comparable to cancer patients.
- Inadequate recognition of the prevalence, incidence of this condition and inadequate allocation of resources.

Lack of Specificity (2)

Currently, the ICD-10-CM code set for DFUs requires the use of 2 separate codes:

- E11.621 (Type 2 diabetes mellitus with foot ulcer) or E10 for type 1
- L97.x codes (for the site of the ulcer)
- The “Non-Pressure” nomenclature in the L codes can be confusing and a deterrent to proper coding.
- E codes are medical codes and describe the underlying condition (diabetes) with the *complication* of a foot ulcer. These codes are not suitable for documenting the ulcers themselves since they lack the ability to depict even the most basic ulcer-related information.

Clinical Differentiation

- DFUs are distinct from other types of ulcers (eg, pressure ulcers, venous ulcers) due to their unique pathophysiology involving neuropathy, ischemia, infection, and high incidence of amputation.
- A discrete code helps clinicians quickly identify the condition and apply appropriate management strategies, such as offloading, infection control, and revascularization.
- Treatment of DFUs requires a team approach. Accurate and discrete coding further ensures all stakeholders are "on the same page" as to severity, prognosis, and treatment plan.

Comparison to Pressure Ulcer Coding

Pressure ulcers are already more thoroughly coded with unique ICD-10 codes that capture:

- Ulcer stage, ie, depth (eg, Stage 1, Stage 2, Stage 3, Stage 4, unstageable, deep tissue injury)
- Location and laterality (eg, right elbow, left buttock).
  Example: L89.012 for "Pressure ulcer of right elbow, stage 2" allows for comprehensive documentation and more accurate tracking of clinical progress

In contrast, DFU coding lacks this level of granularity, which limits its utility in providing accurate clinical information.

Note that the pressure ulcer codes do not include midline or bilateral, which provides some insight into deficiencies that new DFU coding can address.

Improving Clinical and Operational Efficiency

Enhanced Treatment Planning

- Specific codes for DFUs that include depth and location would allow health care providers to tailor and coordinate treatment strategies to the precise nature of the wound.
- For instance, knowing whether a DFU is a superficial ulcer vs a deep, infected wound with or without bone exposure can significantly change the treatment approach (eg, topical vs surgical intervention).

Accurate Severity Classification

- Different stages of DFUs (eg, non-infected, infected, gangrenous) require different treatment approaches.
- Specific codes can guide risk stratification and help prioritize high-risk patients for more intensive care.

Improving Clinical and Operational Efficiency (2)

Improved Monitoring of Disease Progression

- The ability to code for healing stages would enable providers to track changes over time, allowing for better management of the wound and more timely interventions.

Standardization Across Healthcare Systems

- A standardized, detailed coding system would **improve communication** between clinicians, facilities, and regions, leading to more consistent care and better coordination between multidisciplinary teams (eg, endocrinologists, podiatrists, wound care specialists).

Supporting Research and Epidemiological Data Collection

Better Data Collection

- A more detailed coding system for DFUs would enhance the quality of epidemiological data related to diabetes complications, specifically for foot ulcers which are one of the most common and debilitating complications of diabetes.
- More accurate coding could support research efforts to identify the best treatments, track long-term outcomes, and analyze trends in ulcer prevalence across different demographics.
- A separate ICD-10 code will enable accurate data collection specific to DFUs, facilitating better understanding of prevalence, treatment outcomes, and cost burden.
- Specific coding for DFUs will support research into preventive strategies and help track trends in hospitalization and amputation rates.

Alignment with Stakeholders and Professional Societies

Healthcare Industry Support

- It is critical to gain support for new, detailed codes from stakeholders across various professional societies and organizations, such as the American Diabetes Association (ADA), American Podiatric Medical Association (APMA), Wound, Ostomy and Continence Nurses Society (WOCN), and others who treat patients with DFUs.
- Stakeholder consensus on the need for more specific DFU coding can drive collaboration, ensuring that new codes are clinically meaningful and practical for health care providers.

Enhancing Quality Metrics and Healthcare Policy

- A more detailed DFU code set would allow for better quality measurement in clinical practice, facilitating initiatives like value-based care and quality reporting.
- Many health care systems use ICD-10 coding for quality improvement programs and to assess the effectiveness of interventions.
- Proper documentation to support coding selection can impact hospital rankings, funding allocations, public health strategies, and creation of Centers of Excellence.
- Supports epidemiological studies tracking the incidence and progression of DFUs.
- Helps identify disparities in diabetes care and informs policy decisions regarding preventive foot care programs as well as treatment opportunities and options.

Adherence to Current Medical Guidelines for Wound Care

- Medical guidelines for DFU care (such as those from the International Working Group on the Diabetic Foot [IWGDF]) emphasize the need for precise assessment of ulcer severity and depth.
- Having corresponding ICD-10 codes that reflect these characteristics would bring clinical documentation in line with evidence-based practices and guidelines.
- Specific and detailed codes can help the development of clinical guidelines. It is known that wound care guidelines are vague and a subject of debate.

Implementation Timeline

Given the complexity of revising the ICD-10-CM code set and the need for collaboration across various stakeholders, the timeline for obtaining the new DFU codes should be targeted for 2026 to allow for:

- Comprehensive stakeholder engagement and consensus-building
- Testing and validation of the new codes in real-world settings
- Ensuring the new codes align with clinical workflows and are widely adopted across health care institutions

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Q&A 2: Discussion of WCCC Projects

Chair:
Windy Cole, DPM, CWSP, FFPM RCPS (Glasg)
Kent State University

May 2, 2025 **1:20 PM – 2:20 PM**

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Q&A Discussion of WCCC Projects

Participate in the audience Q&A by scanning the QR Code below:

meet.ps/attendee/wcccsummit

Panel Members

Dr. William Ennis
Healogics

Dr. William Tettelbach
RestorixHealth

Dr. Emma Wright
Mölnlycke Health Care

Dr. Dev Verma
FDA CDER (virtual)

Dr. Dheerendra Kommala
ECRI

Dr. John Lantis
Mount Sinai West and the Icahn School of Medicine

Dr. Teresa Jones
NIDDK

Yu-Chieh Chiu, FDA CDRH
(virtual)

Advanced Wound Care and Dressing Standards

1 Will the FDA use the WCCC WG recommendations when new dressings seek approval? How about CMS?

2 How can the industry evaluate the cost-effectiveness of advanced dressing materials compared to traditional options to inform clinical practice decisions?

3 How do we measure the success of new dressing standards in terms of patient outcomes, and what metrics should be prioritized? Can the panel opine on the following?

- Tracking the time wounds take to heal under the new dressing standards. Shorter healing times suggest that the new protocols benefit patient recovery
- Use of surveys or interviews to gauge patient satisfaction with the new dressings' comfort, ease of use, and overall experience
- Analyzing the cost implications of the new dressing standards compared to previous methods, considering direct costs (supplies, labor) and indirect costs (extended hospital stays, re-admissions)

Defining Standard of Care: Intro and Update

1. How can the WCCC help reach an agreement on how the principles of SOC should be consistently applied across the continuum of wound management?

2. The WCCC sees a void in the field, but will our work be accepted?

3. Will the FDA request that it be considered for clinical trial design?

4. How should the effectiveness of the SOC for wound management be measured?

Recommendations for Chronic Wounds: FDA Guidance Update on Clinical Trial Design

We know existing standards and protocols for wound care clinical trials do not meet the needs of modern practice.

1

The WCCC WG is actively working on initiatives to support updates to clinical trial reporting standards. How can we take this work to the next level?

- Will the FDA support the adoption of these recommendations?
- The use of alternative endpoints? (PAR, infection prevention, pain management, PROMs, reduced amputation) RWE?
- How can we define the target patient population for wound care studies to ensure the generalizability of results and ensure patients are not left behind?

2

Should we consider adaptive trial designs to respond to interim findings, and how could this influence our approach to wound care research?

3

How can we integrate digital health technologies into wound care trials to enhance data collection methods and improve the accuracy and reliability of our findings?

New Initiatives: ICD-10 DFU and 10-Year DFU Wound Registry

1. How can data from the DFU Registry influence clinical practices and treatment guidelines for DFUs?

2. How would the information gathered through the DFU Registry enhance the understanding of long-term outcomes for patients with DFUs?

3. How could a 10-year wound registry contribute to developing improved management strategies for hard-to-heal ulcers?

4. How do we attract multidisciplinary interest in this important project (ICD-10 DFU), and how will it benefit patients?

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Decentralized Clinical Trials and Remote Patient Monitoring

Moderator:
Rob Snyder, DPM, MSc, MBA, CWSP, FFPM RCPS (Glasg)
Barry University

May 2, 2025 **2:50 PM – 3:20 PM**

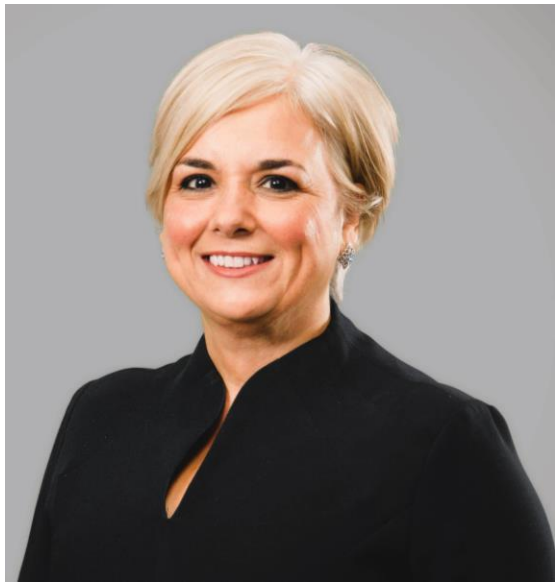
Panel Members

Rober Snyder, DPM, MBA

Professor, Barry University

Dev Verma, MD

Medical Officer, FDA



Emma Wright, PhD

Chief Medical Officer and
EVP, Molnlycke Healthcare

Karen Cross, MD, PhD

CEO, MIMOSA

Questions 1, 2 (Dr. Wright)

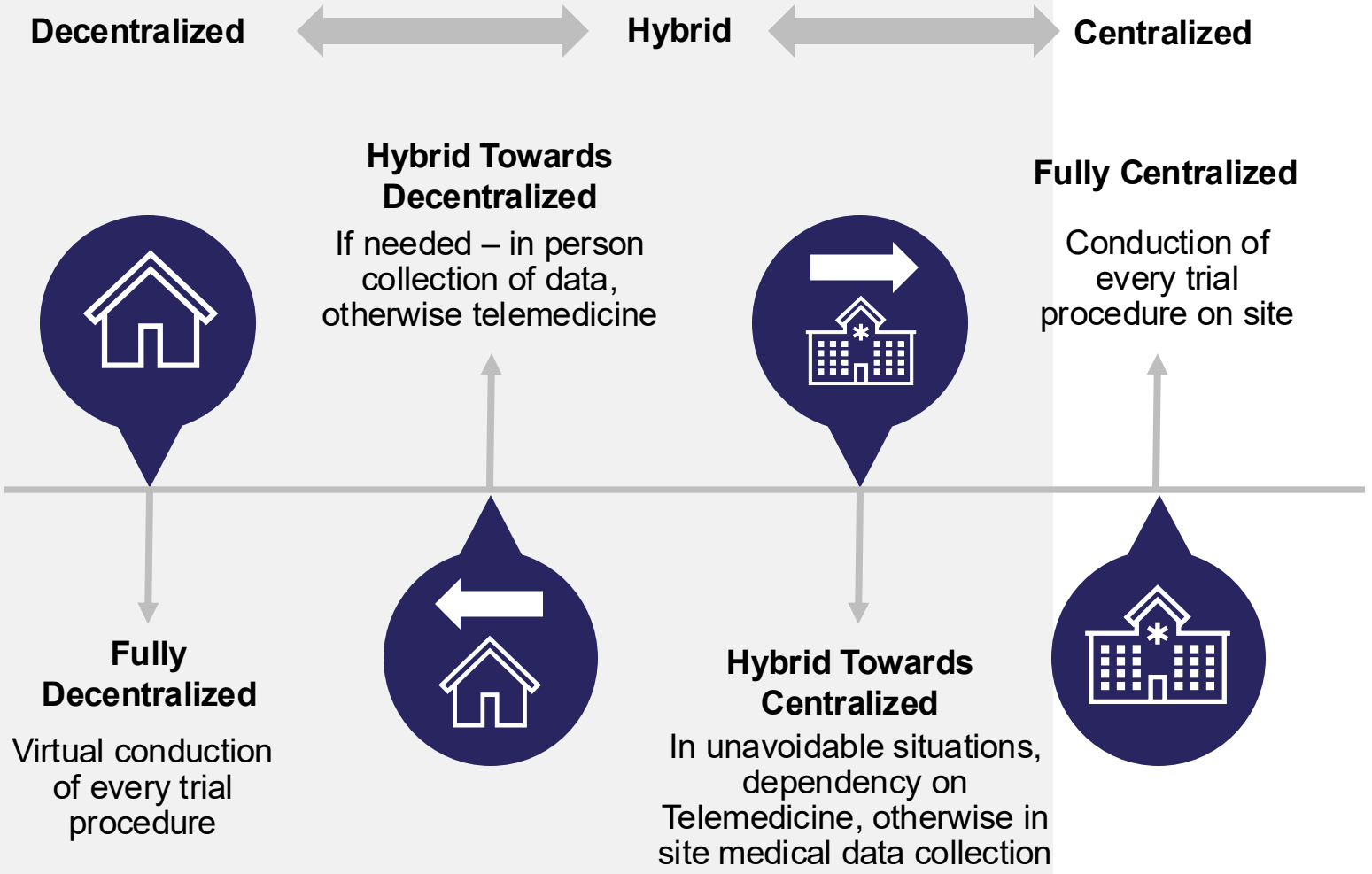
1

Can you explain the concept of decentralized clinical trials?

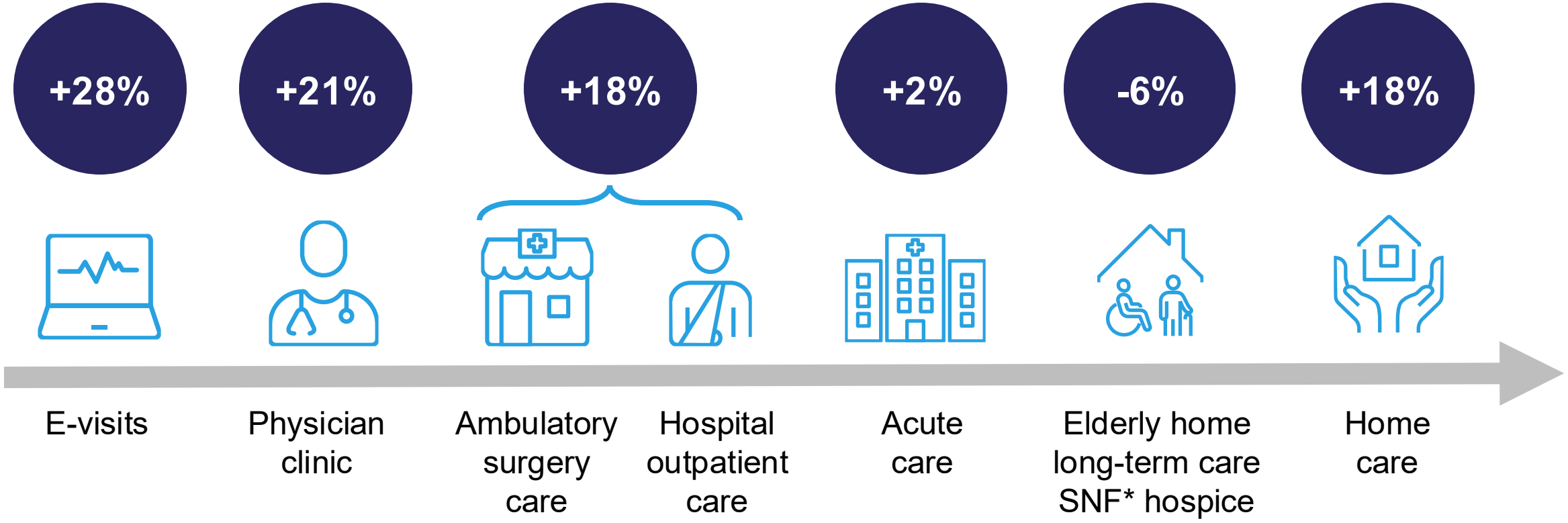
2

Do you feel that this new concept would be accepted by commercial sponsors?

A Decentralized Trial ≠ a Fully Virtual Trial



Trends in Health Care Influence How We Conduct Clinical Trials



Source: Vizient/Sg2 (2023), US largest GPO, Abbreviation: SNF = Skilled Nurse Facility

Questions 3–5 (Dr. Verma)

3

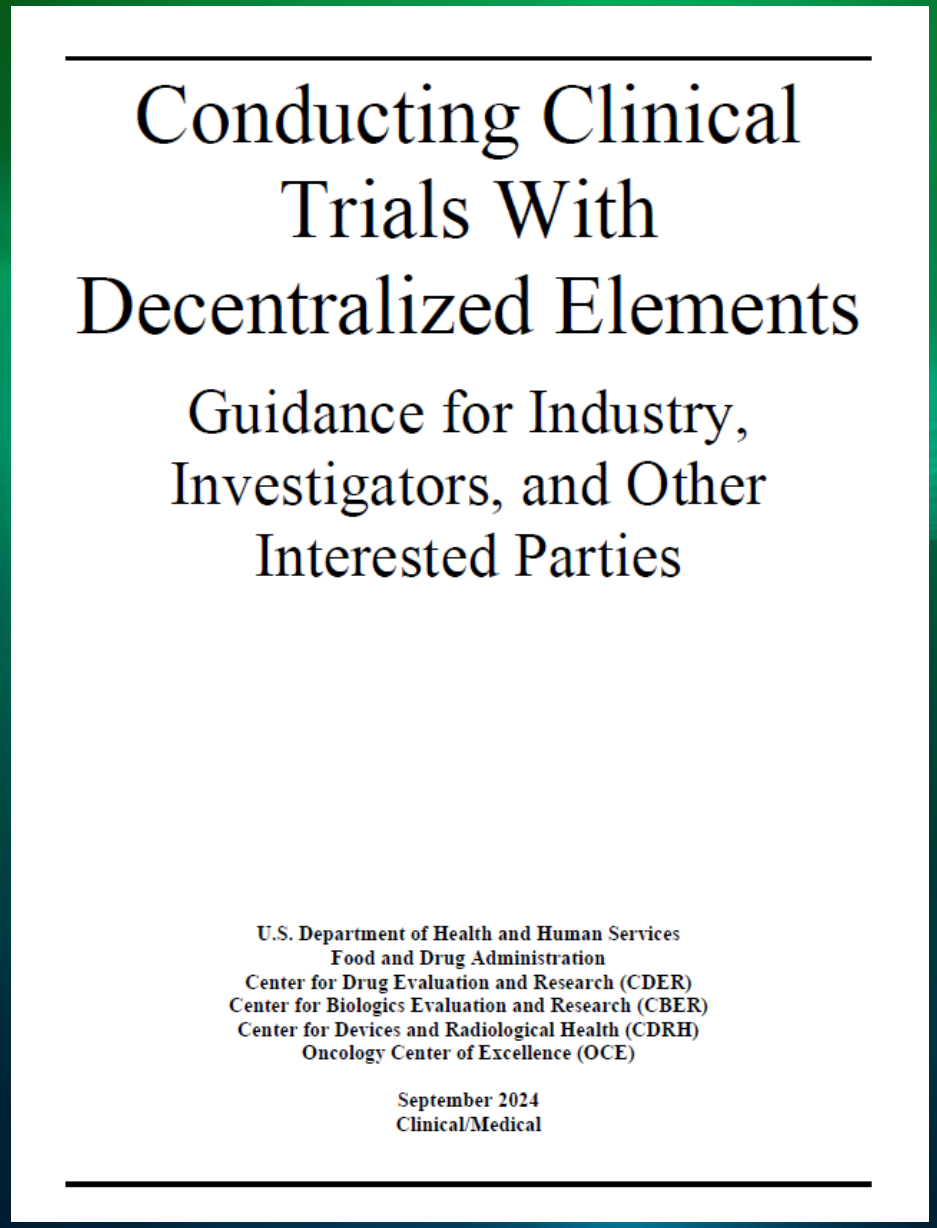
What are the pros and cons of remote patient monitoring?

4

Do you believe that the FDA would embrace this methodology?

5

How could this model fit when performing research on surgical patients?



- Provides recommendations for sponsors, investigators, and other interested parties regarding implementation of decentralized elements in clinical trials
- Decentralized clinical trial (per Guidance definition) refers to a clinical trial that includes decentralized elements where trial-related activities occur at locations other than traditional clinical trial sites
- Decentralized elements can include telehealth visits with trial personnel, in-home visits with remote trial personnel, or visits with local health care providers

Pros and Cons of Remote Monitoring

Improved Access and Convenience
Monitoring without frequent site visits, reducing burden and improving retention

Early Detection of Complications
Real-time data (eg, healing rates) allows for early intervention, preventing adverse events like infections

Enhanced Data Collection & Compliance
Wearable sensors and digital wound tracking could provide objective, continuous data that may be more accurate than intermittent site assessments

Cost Savings for Subjects and Sponsors
Reduces time-related travel costs, and need for frequent in-person visits

Broader Subject Recruitment
Enables participation from diverse geographical and socio-economic backgrounds

Data Reliability and Standardization Issues
Variability in subject-captured images and sensor accuracy can affect data quality

Digital Divide and Accessibility Challenges
Not all subjects have access to smartphones, Wi-Fi, or digital literacy needed for remote monitoring

Security and Privacy Concerns
Continuous remote monitoring requires stringent HIPAA-compliant data protection measures

Regulatory and Validation Uncertainty
New digital biomarkers and wearables may lack established regulatory pathways, requiring additional validation

Limited Scope for Certain Procedures
May not fully replace hands-on procedures like wound debridement, assessment of final wound closure

Additional Considerations for Wound Care Trials Using Remote Monitoring and Decentralized Clinical Trials

Infection Risk and Early Detection

- Establish clear triage/escalation protocols and stopping criteria (eg, for infection suspicion, wound deterioration) to guide when subjects should transition from remote to in-person care

Chronic Wound Population

- Most have comorbidities (eg, diabetes, vascular disease), necessitating comprehensive monitoring beyond just wound site

Monitor Adherence

- Wound patients often face adherence challenges; consider adherence monitoring (eg, ensure adequate compression between site visits for VLU)

Objective Wound Assessments

- Consider implementation of a centralized expert review committee (eg, of wound images) to minimize interobserver variability
- Final wound assessments for efficacy should still be in person; long-term safety follow-up may be able to be remote

Questions 6,7 (Dr. Cross)

6

What devices could be utilized in remote patient monitoring?

- Is there evidence to support these devices?

7

How will payors respond?

Takeaways

Industry is aligning to digital tools and remote data acquisition in decentralizing clinical trial monitoring

FDA is open to sponsors employing decentralized clinical trial elements with the caveat that subject safety, data reliability, and validation of assessments are ensured (refer to guidance for further details)

New point-of-care diagnostic tests represent important innovations in evaluating patients while augmenting quantitative analysis of healing potentials

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AI, Should We Plan and What Do We Know

Moderator:

Alisha Oropallo MD FSVS, FACS, FABWMS
Comprehensive Wound Healing Center and Hyperbarics, Northwell Health

May 2, 2025 **2:20 PM – 2:50 PM**

Panel Members

Patrick Cheng, MS, MBA
eKare

Beate Hanson, MD, PhD, MPH
Convatec

Karen Cross, MD, PhD, FRCSC
Mimosa Diagnostics

Christopher Harte
COO, Kerecis

Yu-Chieh Chiu, FDA CDRH

(virtual)

Substantial Equivalence for AI

?

“How does FDA establish substantial equivalence for AI solutions, especially when comparing dynamic AI software to older or static predicate devices?"

Risk Profiles and Mitigation

?

"What guidance can FDA share on risk stratification for AI? Are there specific mitigation strategies the agency considers best practice?"

Adaptive Algorithms

?

“How does FDA handle continuous learning and improvement for AI?

Are there any updated guidelines on real-time model updates or algorithm drift?”

"As you navigate FDA regulations for Device X, how do you envision determining the appropriate classification and regulatory pathway for your AI solution? Have you considered whether it may require a 510(k), De Novo, or another path?"

?

Would depend on type of medical device: predicated vs De Novo?

Industries will need a pre-submission process and discussion?

How do you validate and test the performance of your AI solution? Example: Prior FDA response to Device X technology

Validation and Synthetic Data:

- Premarket validation using large, diverse real-world datasets including use of synthetic data
- FDA should establish a standardized testing dataset and test protocol for AI-driven wound solutions

How do you validate and test the performance of your AI solution? Example: Prior FDA response to Device X technology

Ongoing Monitoring and Transparency:

- Monitoring is ongoing and upon updates exceeding defined PCCP boundaries, FDA is notified
- Sharing algorithm transparency details with clinicians—explaining any performance changes, new data sources, or key limitations
- Initial validation with continuous post-market surveillance

Standardized AI Testing

?

Could the FDA lead an effort to create or endorse a standard testing protocol for wound AI solutions, including a public repository of test data?

Synthetic Data Acceptance

?

Are there official FDA guidelines on synthetic data usage for validation? Under what circumstances does CMS view synthetic or augmented data as valid evidence for reimbursement?

Does your solution currently qualify for any CPT codes? How do you plan to get Device X reimbursed under Medicare or private insurance?

Current Reimbursement Landscape:

- “At present, our solution is not covered under a dedicated CPT code. However, we’re exploring whether Device X can be integrated into existing Evaluation & Management (E/M) or remote patient monitoring (RPM) codes that cover the interpretation of wound-care data, especially in telehealth or chronic care management settings.”

Does your solution currently qualify for any CPT codes? How do you plan to get Device X reimbursed under Medicare or private insurance?

Future Pathways:

- We're evaluating the potential for a Category III CPT code for emerging technologies, which could eventually transition to a Category I code if we demonstrate sufficient clinical use and improved patient outcomes. We also plan to work closely with CMS to explore coverage under value-based care models—for instance, by showing reduced hospitalizations, shorter wound healing times, or lower infection rates among Medicare beneficiaries.

Clinical and Economic Evidence

- "To support **reimbursement** from CMS and private payers, we're generating **real-world evidence** of Device X's impact on cost savings (eg, fewer dressing changes, decreased readmissions) and improved quality measures.
- Our approach includes **pilot programs** in diverse clinical sites to prove both clinical efficacy and economic benefits. Over time, we hope to secure **broad coverage determinations** once we have robust, peer-reviewed data demonstrating the value of AI-assisted wound care."

?

"How might **New Technology Add-On Payments (NTAP)** or **Transitional Pass-Through (TPT)** apply to AI-driven wound solutions in inpatient or outpatient settings?"

?

“What data does CMS look for to justify coverage under **Remote Patient Monitoring (RPM)** codes for AI-based wound assessment?”

?

"Are there any **value-based care** initiatives or specific **quality measures** (eg, wound-related hospital readmission rates) that Device X could integrate with to facilitate reimbursement?"

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Engagement with FDA, CMS and WCCC for Start-Up Companies

Moderators:
Vickie R. Driver, DPM, MS
Chair, Board of Directors, WCCC

Joe Rolley, MSIA
JTR Business Consulting, LLC

May 2, 2025 **3:30 PM – 4:30 PM**

Panel Objectives

- Examine the hurdles encountered by start-up companies creating innovative wound care technologies aimed at enhancing patient outcomes and reducing overall care costs
- Investigate how organizations like the FDA, CMS/MACs, NIH, and WCCC can support these typically underfunded start-ups in maneuvering through the various regulatory and payer systems, procedures, and obstacles
- Outline the essential next steps

Panel Members

Dr. K. Dev Verma, FDA CDER (virtual)

Dr. Kathleen Fritsch, FDA CDER (Biostatistics) (virtual)

Dr. David M. Sommers, Medical Director, Novitas Solutions, Inc. and First Coast Service Options, Inc.(virtual)

Yu-Chieh Chiu, FDA CDRH (virtual)

Dr. Marissa Carter, Epidemiology, Strategic Solutions, Inc.

Howard Walthall, CEO Progenacare

Dr. Shabnam Vaezzadeh, CEO, Exquisite Biomedical Consulting

Dr. David Alper, WCCC

Medical device innovation comes from a blend of academic research, industry research and development (R&D), feedback from health care providers, patient needs, and technological advancements.

- Academic and Research Institutions
- Corporate R&D Departments
- Entrepreneurs and Start-Ups
- Clinicians and Health Care Professionals
- Industry Collaboration and Partnerships
- Government and Non-Profit Organizations
- Patient-Driven Innovation
- Technological Advancements
- International Collaboration

Challenges of Medical Device Start-Ups

Regulatory hurdles	Financial strain	Market competition	Intellectual property protection	Manufacturing & supply chain	Team building & expertise	Physician & patient adoption	Insurance reimbursement
FDA approval & compliance Ongoing compliance	High capital needs for R&D, clinical trials, and regulatory approvals Cash flow issues Commercial launch costs	Established competitors Pricing pressures	Patent issues Patent expenses Life cycle management Competitor 'me-too's'	Production scalability Supplier relationships	Lack of experienced leadership Hiring challenges	Clinical validation Patient education	Coding, coverage and payment Payer relationships

Discussion Topics

1

What barriers to innovation have you seen or experienced with companies you have worked for?

2

Putting yourself in the position of a start-up company, what support would ***you*** like to see from FDA, CMS, and WCCC in navigating the regulatory, payer, evidence, and financial challenges to bring an innovation to market, and is that support being provided today? What are the gaps and how will/could they be addressed going forward?

3

Why is there not better coordination between FDA and CMS/MACs on evidence requirements? Other than Break-Through designation and a few other pathways reserved for technologies going through a National Coverage Determination, there are no cross-agency coordination efforts for most wound innovations that go through drug, PMA, 510(k) DeNovo, and LCD pathways. Evidence requirements for market approval/clearance and coverage can be quite different and require sequential studies which can add years and millions of dollars to the cost of developing new technologies. What are potential remedies for this situation?

4

The Coverage with Evidence Development (CED) pathway today is reserved solely for National Coverage Determinations. Its availability for LCDs where most wound technologies are covered could be a significant enhancement for entrepreneurs that may not have the capital to generate high-quality RCTs. Will CED ever be available for LCDs, especially for LCDs that are the same across all MAC regions? What would it take to make it possible? (Dr. Sommers)

5

As a collaborative community working closely with FDA, CMS, and NIH, what role can the WCCC play to support start-ups as an interface between all the players? How can we help these companies connect-the-dots?

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Supporting Innovation: Roundtable Discussion with FDA and CMS

Moderators:
Howard Walthall, BSE, JD
CEO, Progenacare

Joseph Rolley, BS, MSIA
JTR Business Consulting, LLC

May 2, 2025 **4:30 PM – 5:30 PM**

Panel Objectives

Examine the obstacles to innovation in wound care highlighted during the 2024 Innovation Summit, along with the consensus recommendations put forward by the Wound Care Collaborative Community Expert Panel

Evaluate select statements for their relevance in 2025, and discuss the advancements made toward each recommendation and the work that remains

Outline the essential next steps

Panel Members

Dr. Dev Verma
FDA CDER (virtual)

Dr. Julia Ju
FDA CDER (virtual)

Dr. Weimeng Wang
FDA CDER (virtual)

Dr. Dheerendra Kommala
ECRI

Dr. David M. Sommers
Medical Director, Novitas Solutions, Inc. and First Coast Service Options, Inc. (virtual)

Dr. Beate Hanson
Convatec

Dr. Windy Cole
Natrox

Dr. Vickie Driver
WCCC

Yu-Chieh Chiu
FDA CDRH (virtual)

2024 WCCC Expert Panel Consensus Recommendations

CONSENSUS STATEMENTS

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[3,4]; Marissa J. Carter, PhD, MA[5]; Marjana Tomic-Canic, PhD[6]; Joseph Rolley, MS[7]; and Maribel Henao, DPM, MSPT[8]

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 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."

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Investor Hesitancies in Commercial Investment, Research, and Development

- Investor hesitancy resulting from poorly executed clinical trials, poor clinical trial design, and/or insufficient endpoints hinders innovation in wound care.
- Investors hesitate from lack of clarity on evidence requirements, performance thresholds, and consistency in the interpretation of results.
- The wound care community has a significant need for updated clinical trial reporting guidelines.
- Established clinical trial reporting guidelines should be communicated with national and international journals, associations, and conferences for successful adoption.
- Standardized, universal data entry metrics are needed to help calibrate results between RWE and RCTs.

Still relevant? Advancements made over past year? Work that remains?

Investor Hesitancies in Commercial Investment, Research, and Development

Develop and Implement Plan of Action

- Research and publications defining meaningful and patient-centric endpoints
  - WEF-CEP initiative
- Develop a standardized approach to RWD in wound research and the role it plays in FDA approvals and public and commercial payer coverage decisions
- Identify a minimal set of treatment standards for use in comparative clinical trials—higher quality evidence for regulatory decision-making
- Initiatives to modernize systems and streamline processes to reduce the burden of confusion and ineffectiveness of clinical research in wound care that drives investors away

Insufficiencies in Preclinical Testing and Clinical Trial Design

- Complete wound closure remains the gold standard in primary endpoints for clinical trial design.
- 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.
- Innovative tools, devices, products, or diagnostics must accurately and reproducibly measure primary endpoints and provide reliable consistency across study results.
- The SOC should be specific and granular, with reasonable parameters to eliminate trial inconsistencies while allowing flexibility for patient-specific needs.
- The entire Wound Healing Collaborative Community and its stakeholders must be held accountable for consistently implementing the established SOC.

Still relevant? Advancements made over past year? Work that remains?

Insufficiencies in Preclinical Testing and Clinical Trial Design

Develop and Implement Plan of Action

- Develop preclinical and clinical trial reporting guidance—Minimum Core Dataset
- Develop clinical trial development standards/guidelines
- Develop clinical SOC best practices for clinical trials
- Identify barriers to utilization of new endpoints
- Identify valid tools that accurately and reproducibly support new primary and secondary endpoints, validated through the WEF-CEP initiative and publish findings
- Identify a minimal set of treatment standards for use in comparative clinical trials

Next Steps?

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Q&A and Closing Remarks

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Thank you for attending!

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Invitation Only Reception for Panelists and Sponsors

Room: Mesilla 1-2 **6:00PM**