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Member Meeting

October 24, 2023
5:00 PM ET

Welcome and Agenda

I. Welcome

II. Work Group Updates

   A. Gaps

   B. Tools

   C. Real World Evidence

III. Driving Innovation in Wound Care Summit Update

IV. Other Business/Questions and Discussion

V. Adjourn

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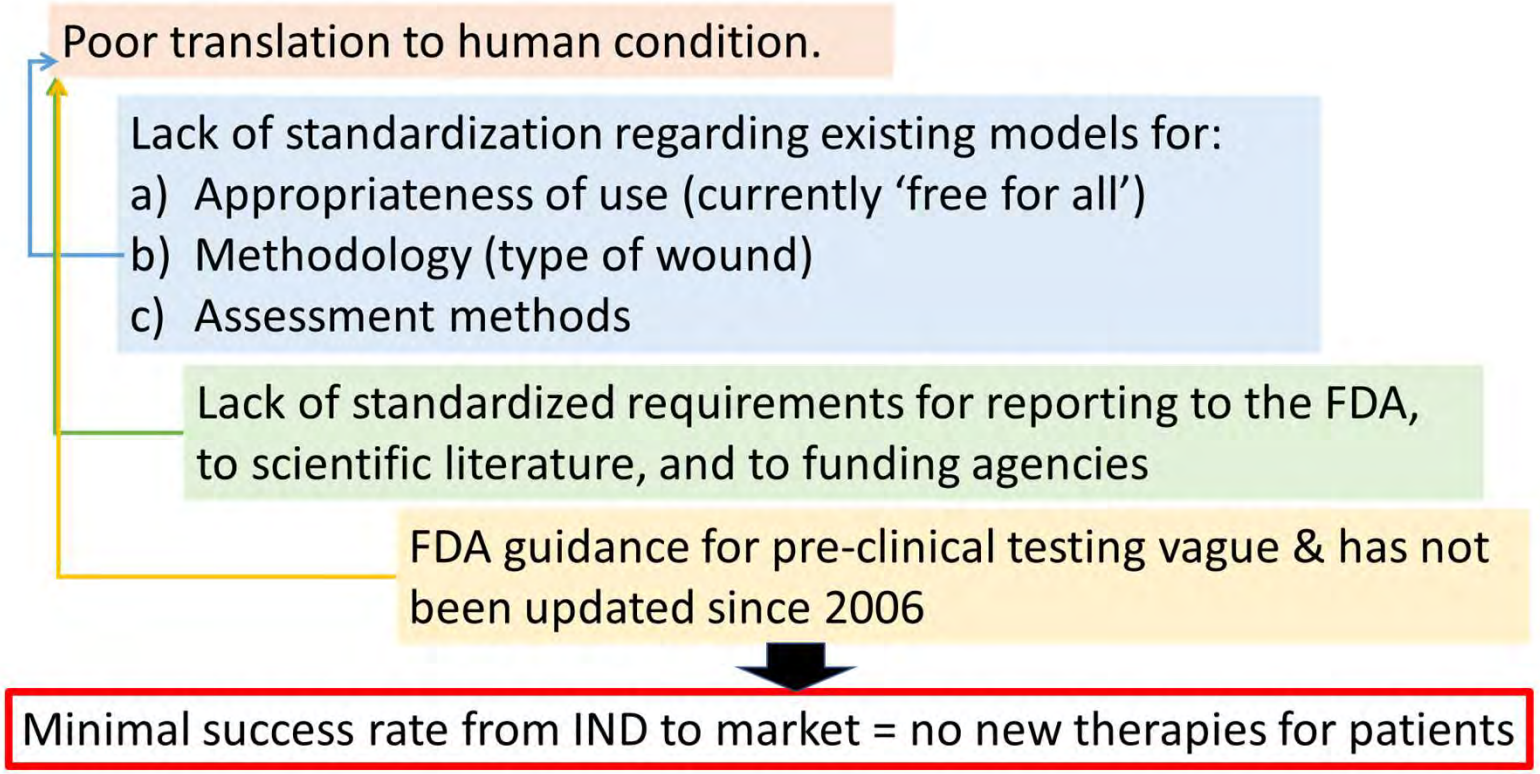
Gaps Work Group

Update

Standardizing Pre-clinical Testing
Important Gap and Feasible

Lack of appropriate guidelines for pre-clinical testing recognized as a significant challenge at the first WCCC SC meeting



Phase 1

Goal: To consolidate and standardize reporting for pre-clinical studies. To create a checklist document (like CONSORT) but for pre-clinical studies

Currently, there are no standards to guide reporting of pre-clinical experimental information. Consistency in reporting allows transparency, critical evaluation, comparative and meta-analysis studies and avoids repetition and redundancy.

The Wound Reporting in Animal and Human Preclinical Studies (WRAHPS) Guidelines

Strategy

- Draft checklists (includes rodent, pig, rabbit and human ex vivo models) DONE
- Provide brief summaries of models DONE
- Outline justifications/rationale of specific reporting requirements DONE
- Send for the review, edits and comments to WCCC membership and other organizations who have vested interest (WHS, FDA, NIH etc) October 2023
- Finalize the document for publication in multiple wound journals simultaneously (WRR, JWC, Wounds, etc) Estimated by EOY 2023

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Clinical Reporting Project

Phase 1

- Three groups of 2 persons each minimum
- What are we looking for? Primarily observation studies (cross-sectional/longitudinal); cause & effect; associations; odds ratios or relative risks
- Literature search
  - Use PubMed; Google Scholar; Embase
  - Develop list of papers
  - Develop extraction tables in Excel

Clinical Reporting Project

Phase 2

- Analyze data
- Develop evidence base for variables that can influence wound healing
- Develop CONSORT-like checklist of reporting variables (format; explanations)
- Share results within our group; after discussion and summary we can share with other WCCC groups and FDA to get their comments/input
- Take all results and draft a manuscript for publication; prepare a slide deck for our one-day pre-SAWC spring meeting
- Disseminate results via social media and other avenues.

Dressing Standards Gap: Proposed Strategy and Workflow

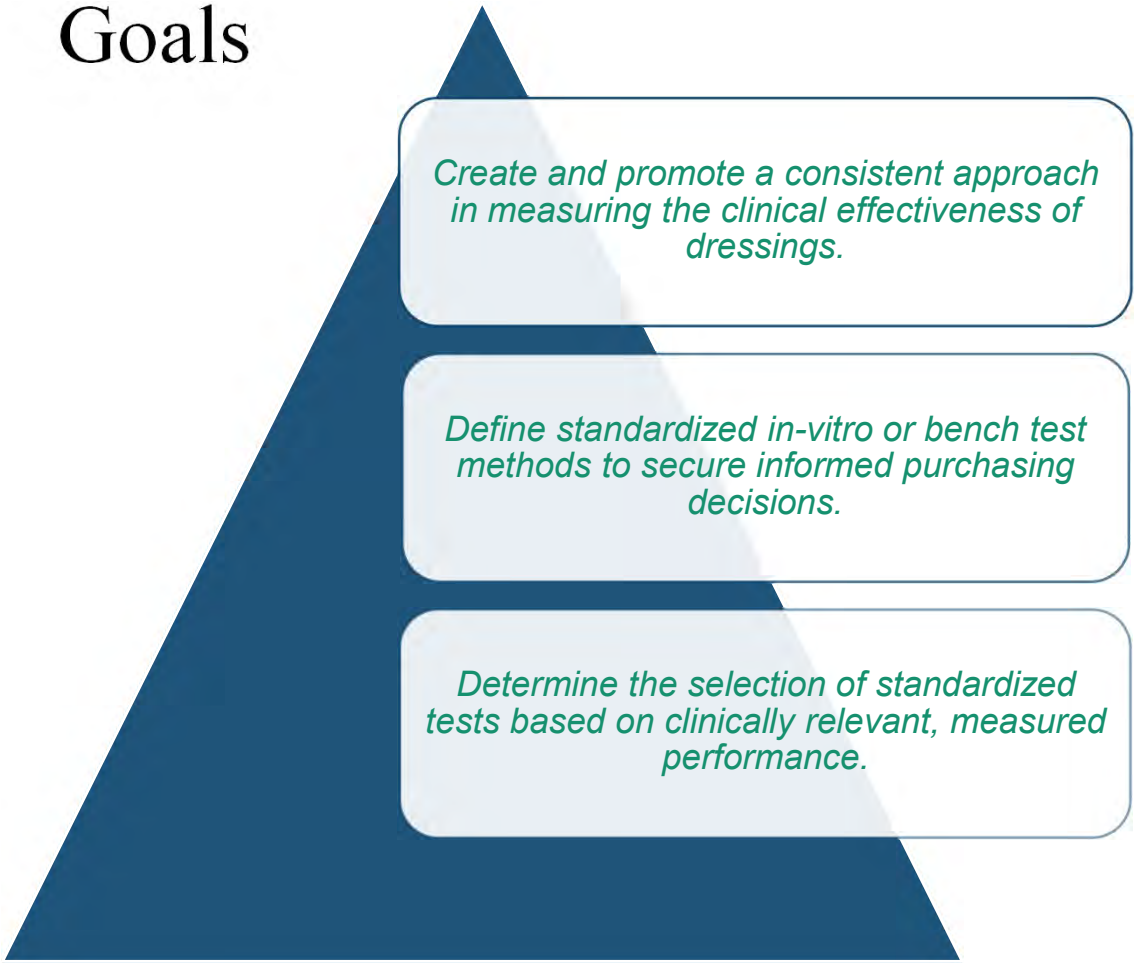
Sarah Griffiths, PhD

on behalf of

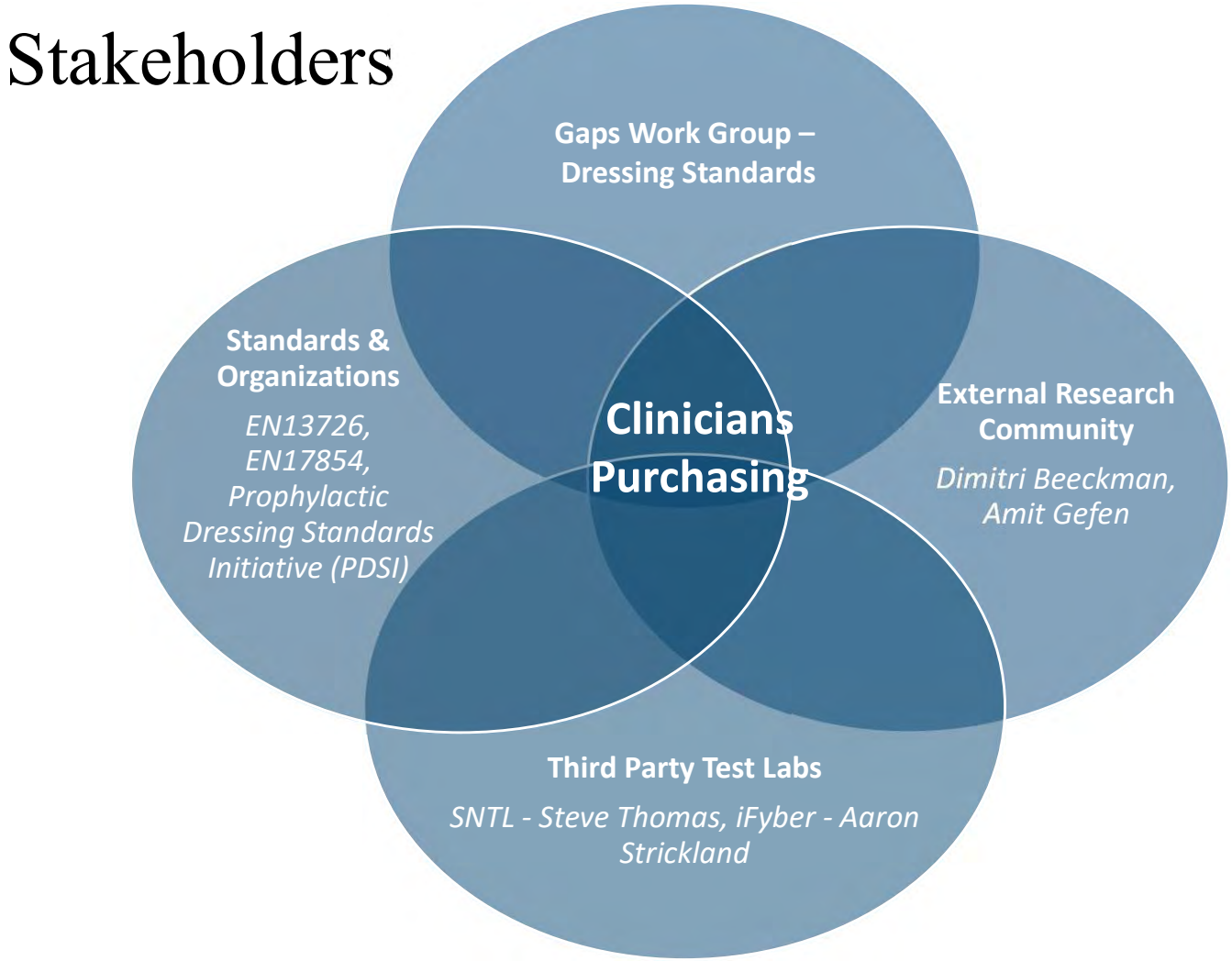
Dressing Standards Workstream Group:

Erik Nygren, Ankur Gandhi, Brandon Casey, Randy Schwartz, Howard Walthall, Vickie Driver

Dressing Standards Workstream



Dressing Standards Workstream



Dressing Standards Workstream

Framework

Phase 1 Foundational Questions

- Define foundational questions for voice of customer
- Review with select WCCC individuals
- Outline the decision-making process for selecting dressings
- Define survey scope, draft questions and identify participants
- Optional - Gain survey feedback from external research groups
- Output: Finalize survey and participant list

Q42023

Phase 2 Dressing Survey

- Circulate survey and collect findings
- Input from WCCC including clinicians and procurement managers
- Output: Identify the challenges or algorithms used in selecting dressings
- Identify if any test methods are being utilized in today's decision process
- Define how the value of dressings are currently measured
- Identify which dressings to be included in recommendations for standards and test methods

Q42023

Phase 3 Gap Analysis of Standards

- Use survey results to define set of standards for review (dependent on dressing type)
- Review marketing materials for current test methods used in promoting commercial dressings
- Collaborate with external researchers and third-party labs to identify standardized tests based on clinical relevance and identify any gaps in current test methods

Awaiting published updates to Standards
EN 13726 – Sept updates
EN 17854 – Nov updates
PDSI - updates

Q22024

Phase 4 WCCC Gap analysis publication

- Publish Gap analysis of current standardized tests based on clinically relevant measured effectiveness
- Provide recommendations for minimal dressing test requirements and reporting
- Provide recommendations for future directions in test method development

Q32024

Dressing Standards Workstream

Phase 1 Foundation questions for decision makers, chronic wounds

Phase 1 Goal: Define survey scope, draft questions and identify key survey participants

Outpatient Wound Clinic

- What is the most common dressing type(s) selected for chronic wounds?
- What are the primary criteria when selecting a dressing for:
  - controlling moisture level and exudate
  - mitigating contamination and odor
- Is there a standard algorithm for the selection of dressing for chronic wounds? What are the key criteria or attribute data used if any?
- Are there specific considerations regarding the wound dressing selection when used in combination with adjunct therapies?

Physician's Office

- Does the setting change the algorithm for the selection of dressings?
- Does the setting change the approach to treating a wound when combined with other therapies?

Other sites of service to capture inputs?

Dressing Standards Workstream

Next Steps:

- Member feedback on framework
- Execute on Phase 1 & 2 in Q4
- Agree to 2024 goals:
  - Submit for publication Gap analysis of current standardized tests based on clinically relevant, measured effectiveness
  - Initial WCCC recommendations for minimal test requirements and reporting for dressings used in chronic wounds
  - WCCC recommendations for future directions in test method development for for dressings used in chronic wounds

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Tools Work Group

Update

Strategy: In form WC Community of our Efforts

- Publications:

#1: Broad understanding of the WCCC and the goals of the Tools Work Group

- Rennie M, Dotson P. Wound assessments to measure endpoints: an update from the Wound Care Collaborative Community (WCCC). *Wounds*. 2023;35(9):8-9.

#2: Define issues w/ Digital Imaging tools used in wound care and how to determine which are reliable

- Oropallo A, Dotson P, Brindle T, Driver VR, Gould L. The Wound Care Collaborative Community, WCCC Tools Working Group Identifies Gaps and Makes Recommendations in Wound Imaging: The Importance of Percent Area Reduction and Percent Volume Reduction in Wound Care.
- *Submitted to Wounds - Oct. 2023*

#3: Analysis Report - current devices used for PAR/PVR, supporting data, & Recommendations to FDA to use in trials

- Potential timeframe – 1Q 2024.

Digital Imaging Devices – Minimum Features

- Minimum requirements to be defined for DI devices used to measure PAR/PVR as primarily or secondary feature.

- Approach:
  - Survey of TWG members – what is important from clinical perspective
  - Surveillance of market devices – core features
  - Collective list developed

Chart- TWG Team Input / Devices Measuring PAR

Wound Type(s)
Wound Size / Range
Does device calculate % surface area reduction, % wound volume reduction or both
Does device identify different tissue types? (yes/no)
Necrotic tissue (how?) A-Color. B-Percentage. C-Other
Granulation tissue (how?) A-Color. B-Percentage. C-Other
Epithelial tissue (how?) A-Color. B-Percentage. C-Other
Inter-rater Reliability
Validated (Y/N)
Validation Method
Additional Features: (e.g. imaging of deeper tissues, 3D rendering, etc.)
Limitation/ Restrictions
References

Chart-Surveillance Review of Marketed Devices

Wound width/length/area
Wound depth
Tissue Classification?
Certifications + MDD/MDR
Visual light/hyperspectral/UV, IR/ Multi-spectral/ Digital image
Clinical Activities
Telehealth/second opinion
“gadget’
Reference marker?
Chatbot
Web dashboard
AI
EMR/HER Integration
Risk Assessment
Both patient App & HCP app
Platform [IOS/Android]
IP on this solution
Standards
Portable

Summary Table in Publication #2

Table 1.

Device capture of tissue classifications and measurements including wound length, width, and depth, square surface area. Devices that required manual entry were not checked. The use of artificial intelligence and spectral analysis are included.

PRODUCT	3D Capture	AI	Spectral	Temp	Tissue Classifi.
Swift with Ray1	X	X	X		
eKare, Insight	X	X			X
Mimosa Diagnostics			X	X	
Healthy.io	X	X			X
Silhoutte Star, Lite	X	X			
Spectral MD	X	X	X	X	
Wound Zoom	X	X			
MolecuLight	X	X	X	X	
Wound Vision				X	
Kent Imaging			X		
Wound Matrix					
Tissue Analytics	X				
WoundWise IQ	X				X
Modulim CLARIFI		X	X		

Summary Table in Publication #2

Table 2.

List of FDA cleared devices with technical communication features included. Apps that did not include both patient and health care professional use were not checked.

PRODUCT	App	iOS/Android	IP	Portable	Telehealth
Swift with Ray1		X	X	X	X
eKare, Insight	X	X			X
Mimosa Diagnostics		Android	X	X	
Healthy.io		X	X	X	X
Silhoutte Star Lite	X	X	X		X
Spectral MD			X		
WoundZoom		X		X	X
MolecuLight			X	X	
Wound Vision			X	X	
Kent Imaging			X	X	X
Wound Matrix	X	X	X	X	X
Tissue Analytics	X	X	X	X	X
WoundWise IQ			X	X	X
Modulim CLARIFI			X	X	

Summary Table in Publication #2

PRODUCT	Chatbot	Web dashboard	EMR
Swift with Ray1		X	X
eKare, Insight	X	X	X
Mimosa Diagnostics		X	
Healthy.io		X	X
Silhoutte Star, Lite		X	X
Spectral MD			X
Wound Zoom		X	X
MolecuLight		X	X
Wound Vision	X		X
Kent Imaging: SnapshotNIR			
Wound Matrix		X	
Tissue Analytics	X	X	X
WoundWise IQ			X
Modulim CLARIFI			

Table 3.

List of devices including AI chatbot, web interface, and EMR integration capability for the health care professional access.

FDA-MDDT Program Feedback

- Dr. Jessica Mavadia-Shukla, PhD Medical Device Development Tools, Program Director, CDRH/FDA
- Member of TWG
- Advisory capacity to TWG
  - Help us better understand qualifications for new device validated through MDDT program
  - Discuss requirements for minimal validation data for current marketed devices

Next Steps

- Schedule CPIM meeting w/ FDA, as recommended by Dr. Jessica Mavadia-Shukla
- Conduct discussion w/ CDER to assess differences in approach for device vs. drug requirements for imaging devices for wound care applications
- Conduct further discussions w/ FDA –MDDT lead, Dr. Jessica Mavadia-Shukla

Opportunity for TWG Members

Serve on New FDA Committee

- FDA Digital Health Advisory Committee
  - Newly formed Committee – 9 voting members / includes chair
  - Work with all branches of FDA
  - Nominations open now until Dec. 11th
  - TWG members interested to date:
    - Dr. Alex Ortega Loayza, MD, Assoc. Professor Dermatology, Oregon Health & Science Univ.
    - Dr. Oscar Alvarez, PhD, Vol. Assoc. Professor, Dermatology, and Academic Researcher, Univ of Miami, Miller Sch. of Medicine
    - Dr. Kyle Wu, MD, MBA, Chief Medical Officer, eKare

      (experience in biomedical engineering, digital health, AI)

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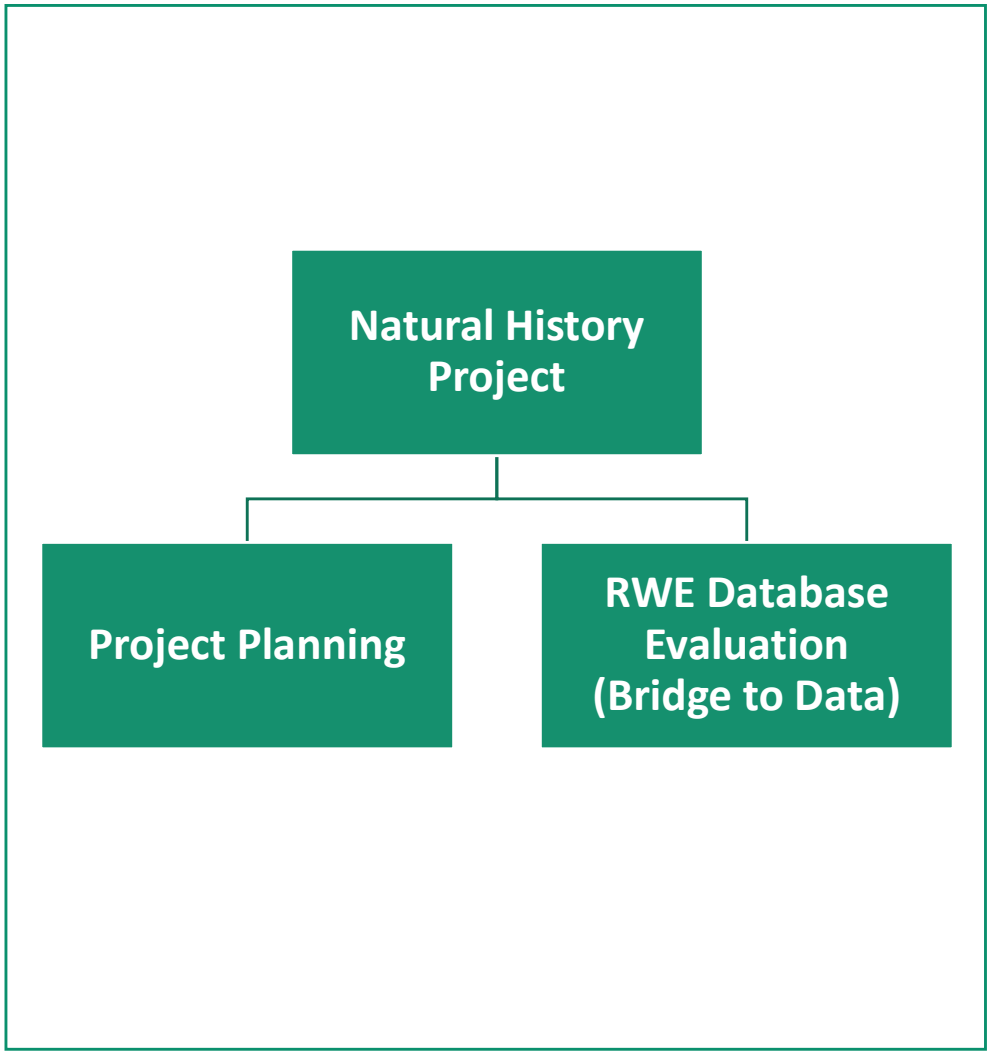
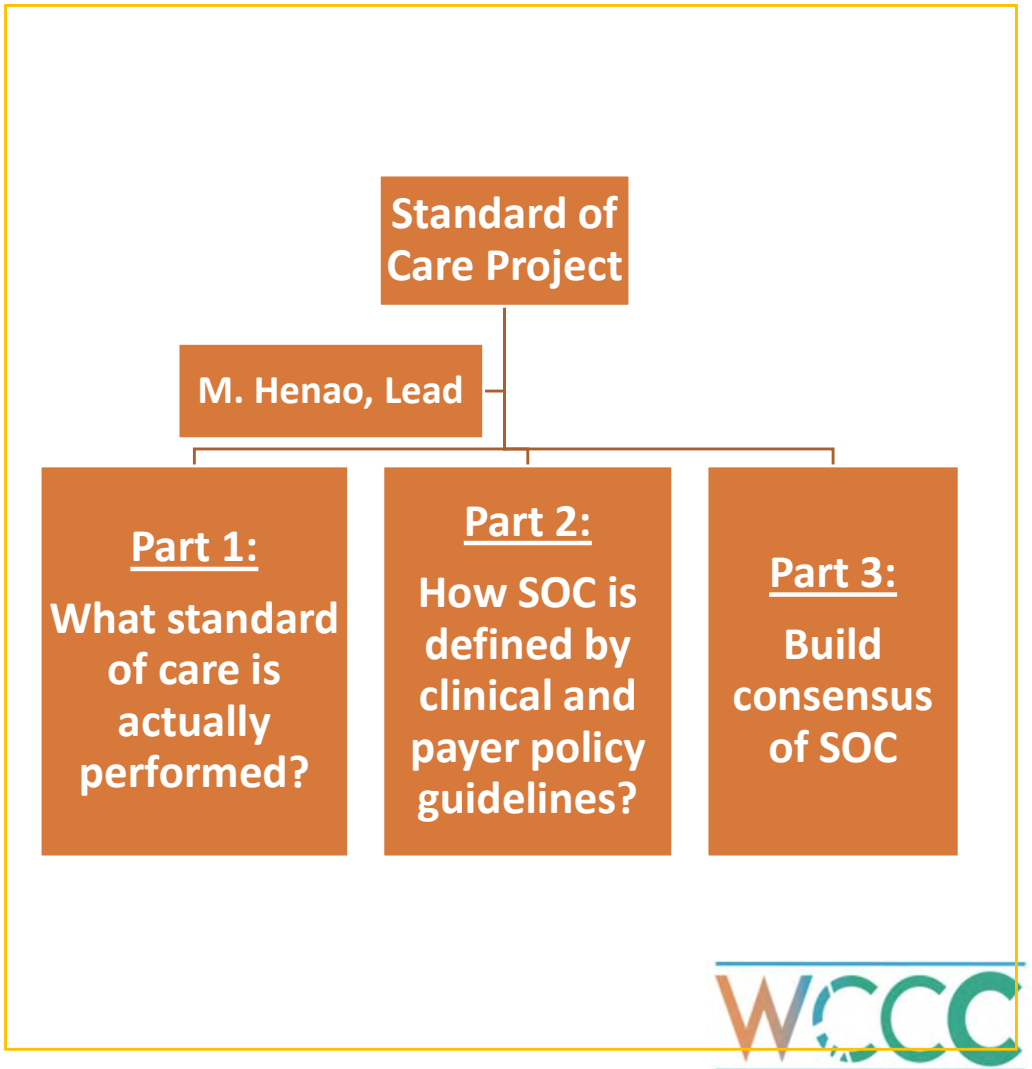
Real World Evidence Work Group Update

RWE Workstreams





Standard of Care Project

Lead: Dr. Maribel Henao

- **Goal:**
  - Build consensus of what constitutes “standard of care” across chronic wound indications for adoption in clinical practice and research
- **Impact:**
  - Disseminate through publication or white paper as Clinical Consensus

Systematic Literature Review Process

- Databases utilized to search for consensus guidelines.
  - PubMed
  - Cochrane
  - Medline
  - Google for grey literature
  - CINAHL (Payment required)
  - EBSCO (Payment required)
  - Embase (Payment required)
- Limited to within the US, with minor exceptions
  - If the international guidelines or consensus included majority of the authors/sponsors from the US, then it was included
- Anything published prior to 2000 was excluded
- Commercial payor policies to be included (results from recent project), FDA and CM

- Key words/terms/filters:
  - Names of organizations searched in tandem with
    - "wound care"
    - "chronic wounds"
    - "chronic ulcers
    - "diabetic foot ulcer"
    - "venous leg ulcer" OR "venous ulcer"
    - "pressure injury" OR "pressure ulcer" OR "decubitus ulcer"
    - "standard of care"
    - "Standard of care AND "venous leg ulcer""
    - "Standard of care" AND "Diabetic foot ulcer"
    - "standard of care" AND "pressure injury"
    - "Standard of care" AND "revascularization" AND "diabetic foot ulcer" OR "chronic ulcer"
    - "arterial ulcer"
    - "Components" AND "standard of care""
- Filters applied
  - "guideline"
  - "practice guideline"
  - "Consensus"
  - "systematic review"
  - "meta-analysis"

SOC Project Update

Phase 1	• Standard of care actually performed today	To be included in Natural History Project Statement of Work
Phase 2	▪ How SOC is defined by clinical and payer policy guidelines.	Data collection nearly completed. Consolidation and assessment next.
Phase 3	• Build consensus of SOC and publish results.	To be initiated after completion of Parts 1 and 2 in early 2024.

400 RWE Databases Narrowed to Top 6 That Are Ready and Able for Natural History Project

High-Level Scorecard

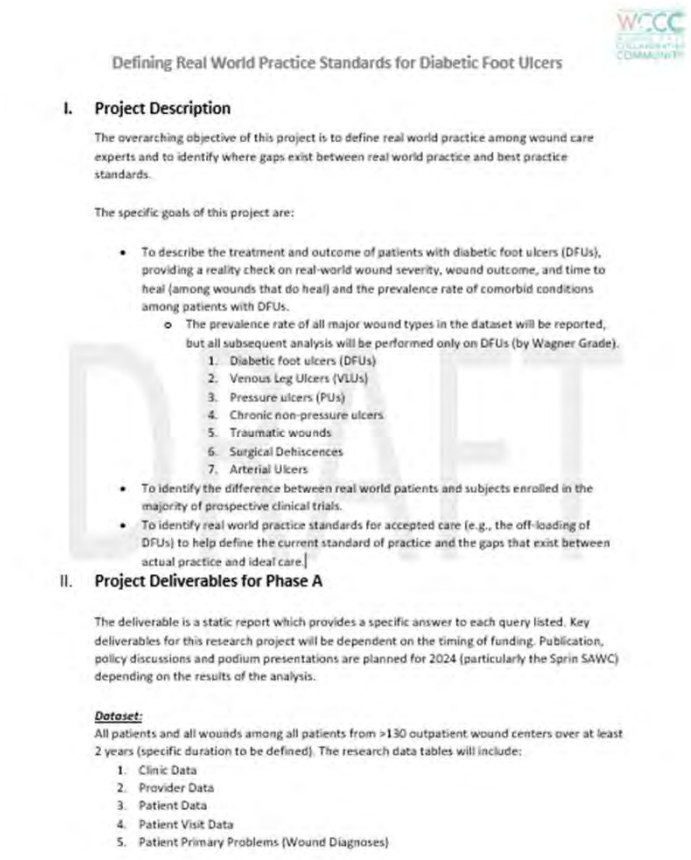
	Komodo	Net Health	Northwell	STATinMED (Partner EMR)	Vohra*	USWR
Size, Type, Region	+++	+++	+	++	++	+++
Source, Population, Years	+++	++	++	++	++	+++
Data Parameters						+++
Wound Types						+++
Patient Demographics						+++
Clinical Data						+++
Prevalence Rates	++	+++	+++	+++	+++	+++
Wound Outcome	+	++	+	++	+++	+++
Data Analytics In-House or WCCC?	Both available	WCCC	Both available	Both available	TBD	Both Available

Currently investigating publishing the findings from the RWE database assessment project

Natural History Project Plan Revision

Dr. Caroline Fife

- **Objective**: Define real world practice among wound care experts and to identify where gaps exist between real world practice and best practice standards.
- **Goals**:
  - Describe the treatment and outcome of patients with **diabetic foot ulcers (DFUs),** providing a reality check on real-world wound severity, wound outcome, and time to heal (among wounds that do heal) and the prevalence rate of comorbid conditions among patients with DFUs.
  - Identify the difference between real world patients and subjects enrolled in the majority of prospective clinical trials.
    - ✓ **Wounds that will heal on their own**
    - ✓ **Wounds which will never heal**
    - ✓ **Wounds that would most benefit from an advanced therapy**
  - **Identify real world practice standards** for accepted care (e.g., the off-loading of DFUs) to help define the current standard of practice and the gaps that exist between actual practice and ideal care.



Defining Real World Practice Standards for Diabetic Foot Ulcers

I. **Project Description**

The overarching objective of this project is to define real world practice among wound care experts and to identify where gaps exist between real world practice and best practice standards.

The specific goals of this project are:

- To describe the treatment and outcome of patients with diabetic foot ulcers (DFUs), providing a reality check on real-world wound severity, wound outcome, and time to heal (among wounds that do heal) and the prevalence rate of comorbid conditions among patients with DFUs.
  - The prevalence rate of all major wound types in the dataset will be reported, but all subsequent analysis will be performed only on DFUs (by Wagner Grade).
    1. Diabetic foot ulcers (DFUs)
    2. Venous Leg Ulcers (VLUs)
    3. Pressure ulcers (PUs)
    4. Chronic non-pressure ulcers
    5. Traumatic wounds
    6. Surgical Dehiscences
    7. Arterial Ulcers
- To identify the difference between real world patients and subjects enrolled in the majority of prospective clinical trials.
- To identify real world practice standards for accepted care (e.g., the off-loading of DFUs) to help define the current standard of practice and the gaps that exist between actual practice and ideal care.

II. **Project Deliverables for Phase A**

The deliverable is a static report which provides a specific answer to each query listed. Key deliverables for this research project will be dependent on the timing of funding. Publication, policy discussions and podium presentations are planned for 2024 (particularly the Sprin SAWC) depending on the results of the analysis.

Dataset:

All patients and all wounds among all patients from >130 outpatient wound centers over at least 2 years (specific duration to be defined). The research data tables will include:

1. Clinic Data
2. Provider Data
3. Patient Data
4. Patient Visit Data
5. Patient Primary Problems (Wound Diagnoses)

1

Natural History Project Plan Revision

- Project plan revised to focus deliverables and stagger costs over 2 – 3 years
  - 34 key parameters focused initially on DFU only
  - Includes SOC Part 1 deliverable (What standard of care is actually performed?)
- Focus initially on diabetic foot ulcers in 2024, followed by other chronic wound indications in subsequent years or sooner as funding becomes available

NESTcc

Catalyzing Real World Evidence

RWE Data Services & Technology Providers

partnering with data providers and technology companies to provide the best real-world evidence solutions to help address clinical care gaps already delineated in the real-world practice of medicine

Med Tech Companies

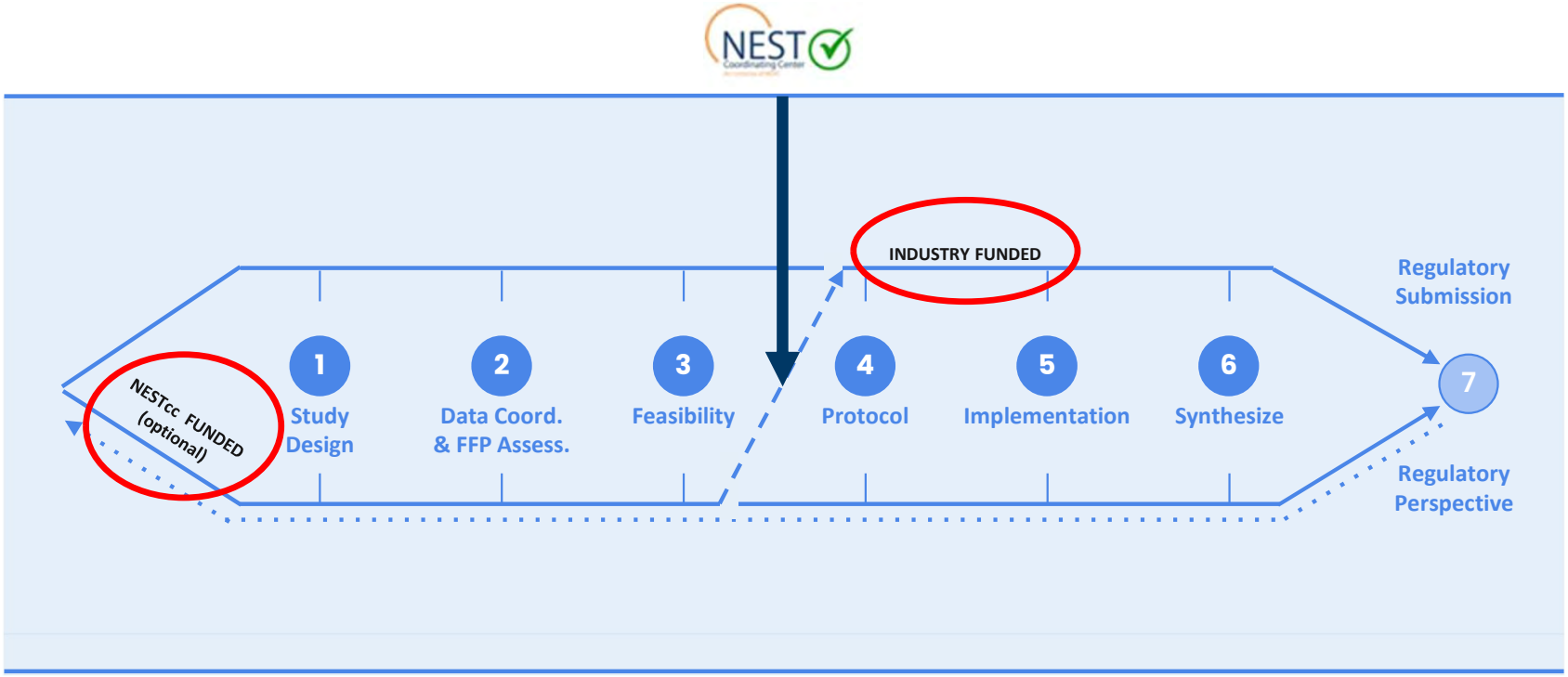
partnering with industry to drive implementation projects through the system to test Fit for Purpose

Regulators

partnering with regulators to improve predictability in the RWE data evaluation process

Improving and promoting the use of Real-World Evidence data

NESTcc – Project Armada Workflow



Impacting Clinical Practice and Research

Who do I study?

Natural History Project

Phase 1:

1. Which patients will heal on their own?
2. Which will never heal?
3. Which would most benefit from advanced therapies?

Phase 2:

- Wounds With No Name

What is my SOC comparator?

Standard of Care Consensus Project

- **Part 1**
  - Assess standard of care actually performed today
- **Part 2**
  - Compare/contrast how SOC is defined by clinical and payer policy guidelines.
- **Part 3**
  - Build consensus of SOC across chronic wound indications and publish results.

What type of RWE study do I need?

"Fit For Purpose" Collaboration

- Collaboration with NESTcc on Implementation Cases to ensure "fit-for-purpose" design for FDA

Other Business

- 2023 WCCC Innovations Summit at SAWC Spring 2024
- Q&A
- Discussion


THANK YOU
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