



Agenda

At the Wound Care Evidence Summit, expect lively interactive conversation between panelists, speakers and attendees - including opportunities for extensive Q&A throughout. The agenda is below.

Day 1: May 19, 2022

8:00-8:15 AM - WELCOME AND INTRODUCTIONS; OPENING REMARKS AND EXPECTATIONS

- **Speakers:**

- Marcia Nusgart, RPh, Alliance Executive Director and Founder

8:15-9:30 AM SESSION 1 - PANEL DISCUSSION: CHALLENGES AND OPPORTUNITIES IN WOUND CARE RESEARCH, CLINICAL CARE AND COVERAGE

Stakeholders, specifically those representing providers, payers, clinical associations and manufacturers will present their views on both challenges and opportunities currently in wound care research, clinical care, and coverage issues.

- **Panelists:**

- Steve McLaughlin, CEO, RestorixHealth
- Manish Mishra, MD, MPH, Director of Professional Education, Dartmouth Institute for Health Policy and Clinical Practice at the Geisel School of Medicine at Dartmouth
- James Rollins MD, Medical Officer, Center for Medicare and Medicaid Services, Coverage and Analysis
- Ron Silverman MD, Chief Medical Officer, 3M Health Care
- Dyane Tower, DPM, MPH, MS, American Podiatric Medical Association Senior Medical Director and Director, Clinical Affairs

- **Moderator:** Lynn Shapiro Snyder, Esq., Senior Member, Epstein Becker Green, Washington D.C.

9:30-10:45 AM SESSION 2 – STATE OF SCIENTIFIC RESEARCH IN WOUND CARE: AN OVERVIEW, RESEARCHERS' PERSPECTIVES AND LESSONS FROM THE FIELD OF ONCOLOGY

What are the challenges in wound care research and possible solutions? Dr. Marissa Carter will address this issue including strengths and limitations of observational studies (real world evidence) and RCTs, impact of COVID-19 and management of research methods moving forward. Dr. William J. Ennis will have a discussion with a prominent research oncologist Dr. Vijay Trisal regarding approaches in the oncology field that may have value in wound care.

- **Panelists:**

- David Armstrong, DPM, MD, PhD, Professor of Surgery, University of Southern California
- Marissa Carter, PhD, President, Strategic Solutions
- William J. Ennis, D.O, Professor of Surgery at University of Illinois at Chicago
- Bert Slade, MD, Managing Director, Chisholm Clinical Research Services
- Vijay Trisal, MD, Chief Medical Officer, City of Hope

- **Moderator:** William J. Ennis, D.O, Chief Medical Officer, Healogics, Professor of Surgery at University of Illinois at Chicago, President, American College of Wound Healing and Tissue Repair

10:45-11:00 AM - BREAK

11:00-12:15 PM SESSION 3 – STATE OF CLINICAL PRACTICE GUIDELINES AND COMMERCIAL HEALTH TECHNOLOGY ASSESSMENT (HTA) AND REVIEW GUIDELINES: HOW ARE THEY CREATED AND USED BY CLINICIANS AND PAYERS?

This session will highlight the commonalities and differences between the various clinical practice guidelines written by physician specialty societies and clinical associations, including developmental methodologies, inconsistencies, gaps, and their use by clinicians and payers. For the commercial HTAs and guidelines, the panelists will discuss how these assessments and guidelines are developed, how often they are updated and how payers, providers, and other stakeholders use them.

- **Speakers:**
 - Shannon Brode, MPH, Scientific Director of Evidence Analysis, Hayes - a Symplr Company
 - Kara Couch, MS, CRNP, CWCN-AP, FAWWC, Director, Wound Care Services, George Washington University Hospital, Alliance Board Member
 - Laura Coughlin, VP, Innovation and Content Development, Change Healthcare
- **Moderator:** Winifred Hayes, MS, PhD, RN; Founder & CEO Emeritus, Hayes, Inc.

12:15-1:00 PM - LUNCH

1:00-1:15 PM SESSION 4 - IN THE TRENCHES ISSUES: MANUFACTURERS' AND PROVIDERS' PERSPECTIVES

- **Speaker:** Donna Cartwright, MPA, RHIA, CCS, FAHIMA, Sr. Director, Health Policy and Reimbursement Services, Integra Life Sciences Corporation

1:15-2:30 PM SESSION 5 – PANEL DISCUSSION: PAYER MEDICAL DIRECTORS' PERSPECTIVES ON CURRENT STATE OF WOUND CARE RESEARCH AND COVERAGE: PROCESS ISSUES AND EVIDENTIARY REQUIREMENTS - PART 1

This is the first of four sessions where medical directors from both commercial and government payers will share perspectives. This session will focus on the processes that the medical directors use to create their coverage policies and the type, quantity and characteristics of clinical evidence needed to obtain a positive coverage decision. Each payer panel will feature several of these payer medical director speakers.

- **Panelists:**
 - Nancy Awadallah, MD, Senior Medical Director, National Medical Policy & Operations, **Aetna**
 - Deneen Bowlin, MD, Medical Director, Health Care Policy, **CareFirst Blue Cross Blue Shield**
 - Bob McDonough, MD, JD, Head of Clinical Policy Research, **Aetna**
 - James Rollins, MD, Medical Officer, **CMS**
 - Charles Stemple, MD, former Vice President, Health Guidance Organization, **Humana**
 - Jeffrey Stone, DO, MPH, Medical Director, **Molina Healthcare of Texas**
- **Moderator:** Winifred S. Hayes, MS, PhD, RN, Founder & CEO Emeritus, Hayes Inc.

2:30-3:15 PM SESSION 6 – NATIONAL INSTITUTES OF HEALTH (NIH) AND AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ) PERSPECTIVES ON WOUND CARE RESEARCH, DATA, AND GRANT FUNDING

AHRQ has funded and conducted many technology assessments over the years on chronic wound care (i.e., cellular and/or tissue-based products for skin wounds, negative pressure wound therapy), primarily through their Evidence-based Practice Centers (EPCs). Obtain a better understanding of how AHRQ and its EPCs perform its technology assessments and the Agency's view of wound care research. NIH will explain their Agency opportunities to provide grant funding for wound care research, with the applicable Institutes describing their areas of focus.

- **Panelists:**
 - Teresa Jones, MD, Program Director for Diabetes Complications (NIDDK)
 - David Niebuhr, MD, MPH, MSc, Medical Officer, Evidence-Based Practice Center Program, Agency for Healthcare Research and Quality (AHRQ)
 - Marcel Salive, MD, MPH, Medical Officer, Division of Geriatrics and Clinical Gerontology (NIA)
- **Moderator:** Joan E. DaVanzo, PhD, MSW, Chief Executive Officer Dobson/DaVanzo

3:15-3:30 PM BREAK

3:30-5:00 PM SESSION 7 – PANEL DISCUSSION: PAYER MEDICAL DIRECTORS PERSPECTIVES ON COVERAGE: PROCESS ISSUES AND EVIDENTIARY REQUIREMENTS – PART 2

This is the second of four sessions where medical directors from both commercial and government payers will address their perspectives. This session will focus on the processes that the medical directors use to create their coverage policies and the type, quantity and characteristics of clinical evidence needed to obtain a positive coverage decision. Each payer panel will feature several of these speakers.

- **Panelists:**
 - Nancy Awadallah, MD, Senior Medical Director, National Medical Policy & Operations, **Aetna**
 - Wyndolyn Bell, MD, Senior medical director, retired, **UnitedHealthcare**
 - Bob McDonough, MD, JD, Head of Clinical Policy Research, **Aetna**
 - James Rollins, MD, Medical Officer, **CMS**
 - Charles Stemple, MD, former Vice President, Health Guidance Organization, **Humana**
 - Jeffrey Stone, DO, MPH, Medical Director, **Molina Healthcare of Texas**
- **Moderator:** Eric Greig, Partner, Latham & Watkins LLP

5:00-5:30 PM SESSION 8 – DAY 1 WRAP-UP

- **Speakers:**
 - Lynn Shapiro Snyder, Esq. Senior Member, Epstein Becker and Green
 - Kara Couch, MS, CRNP, CWCN-AP, Director, Wound Care Services, George Washington University Hospital and Alliance Board Member

5:30-6:30 PM Reception

Day 2: May 20, 2022

8:00-8:15 AM OPENING REMARKS

- **Speakers:**
 - Matthew Garoufalis, DPM, Past President, American Podiatric Medical Association and Alliance Co-chair
 - Caroline Fife, MD, Chief Medical Officer, Intellicure; Executive Director, U.S. Wound Registry and Alliance Co-chair

8:15-9:15 AM SESSION 9 – PANEL DISCUSSION: FDA, WOUND CARE EVIDENCE & SUMMARY OF FDA APRIL 2022 MEETING – WHAT DID WE LEARN AND NEXT STEPS?

Dr. Dev Verma, organizer of the FDA April 2022 wound healing workshop, will present a summary and findings from it. There will be a panel discussion of FDA staff from CDRH, and CBER who were at the workshop adding their input about it. They will be joined by wound care researchers who spoke at the conference and will address what they heard at the conference and what they learned.

- **FDA Panelists:**
 - Cynthia Chang, PhD, Director, Division Infection Control and Plastic Surgery Devices, Center for Devices and Radiological Health, FDA
 - Rosa Sherafat-Kazemzadeh, MD, Acting Clinical Team Lead, Center for Biologics Evaluation and Research, FDA
 - K. Dev Verma, MD, Medical Officer Division of Dermatology and Dentistry, Center for Drug Evaluation and Research FDA
- **Wound Care Researcher Panelists:**
 - Vickie Driver, DPM, Chair, Wound Care Collaborative Community and System Wide Medical Director, Wound Care and Hyperbaric Centers at INOVA Healthcare
 - Thomas Serena, MD, CEO and Medical Director, The SerenaGroup
- **Moderator:** William Padula, PhD, Assistant Professor, Dept. of Pharmaceutical and Health Economics, USC School of Pharmacy; President, National Pressure Injury Advisory Panel

9:15-10:30 AM SESSION 10 – USING REAL WORLD DATA TO GENERATE REAL WORLD EVIDENCE

The speakers will explore such topics as: the difference between real-world data and real-world evidence; the value of real-world evidence and its limitations; how potential bias is controlled; are patient registries part of the solution? Why are we not making progress with RWE?

- **Panelists:**
 - Elise Berliner, Global Senior Principal for Real World Evidence Strategy, Cerner Enviza
 - Danica Marinac-Dabic, MD/PhD, Associate Director, Office of Clinical Evidence and Analysis, CDRH, FDA
 - Thomas O'Donnell Jr., MD, Professor and Chair of Surgery, Tufts University School of Medicine
 - Mita De, PhD, Director of Research, American Academy of Orthopedic Surgeons
- **Moderator:** Caroline Fife, MD, Chief Medical Officer, Intellicure; Executive Director, U.S. Wound Registry and Alliance Co-chair

10:30-10:45 AM BREAK

10:45-11:45 AM SESSION 11 – PANEL DISCUSSION: PERSPECTIVES FROM MEDICAL DIRECTOR PAYERS ON FDA ISSUES AND REAL-WORLD EVIDENCE OPPORTUNITIES

This is the third of four sessions where the medical directors from both commercial and government payers will address their perspectives. This session will focus on their reaction of the FDA April 2022 conference and their view of real-world evidence (e.g., what would it take to gain acceptance of real-world evidence by these payers?) Each payer panel will feature several of these payer medical director speakers.

- **Panelists:**
 - Nancy Awadallah, MD, Senior Medical Director, National Medical Policy & Operations, **Aetna**
 - Wyndolyn Bell, MD, Senior medical director, retired, **UnitedHealthcare**
 - Franklin Chen, MD, MBA, Medical Director, **Anthem**
 - Bob McDonough, MD, JD, Head of Clinical Policy Research, **Aetna**
 - Deneen Bowlin, MD, Medical Director, Health Care Policy, **CareFirst Blue Cross Blue Shield**
 - James Rollins, MD, Medical Officer, **CMS**
 - Charles Stemple, MD, former Vice President, Health Guidance Organization, **Humana**
 - Jeffrey Stone, DO, MPH, Medical Director, **Molina Healthcare of Texas**
- **Moderator:** Winifred S. Hayes, MS, PhD, RN, ANP, Founder and CEO Emeritus, Hayes Inc.; Wini Hayes Consulting LLC

11:45-12:45 PM LUNCH

12:45–2:30 PM SESSION 12 – PANEL DISCUSSION: PERSPECTIVES FROM MEDICAL DIRECTOR PAYERS AND RESEARCHERS ON CLINICAL TRIALS DESIGNS AND POSSIBLE SOLUTIONS

This is the fourth of four sessions where the medical directors from both commercial and government payers will join other stakeholders—i.e., wound care researchers and manufacturers, to address elements of clinical trial design (inclusion/exclusion criteria, trial duration, standardization of key variables, number of patients, comparators, standards of care, research methodology standardization) and modifications that can be done to advance the quality and generalizability of our research base. Each payer panel will feature 3-4 of the listed speakers.

- **Researcher Panelists:**
 - David Armstrong, DPM, MD, PhD, Professor of Surgery, University of Southern California
 - John Lantis, MD, FACS, Vice chairman of the Dept. of Surgery Director of Surgical Clinical Research, Icahn School of Medicine at Mt Sinai
 - Thomas Serena, MD, CEO of The SerenaGroup
 - Paul Trueman, PhD, VP of Global Market Access, Smith & Nephew
- **Payer Panelists:**
 - Nancy Awadallah, MD, Senior Medical Director, National Medical Policy & Operations, **Aetna**
 - Wyndolyn Bell, MD, Senior medical director, retired, **UnitedHealthcare**
 - Franklin Chen, MD, MBA, Medical Director, **Anthem**
 - Bob McDonough, MD, JD, Head of Clinical Policy Research, **Aetna**
 - Deneen Bowlin, MD, Medical Director, Health Care Policy, **CareFirst Blue Cross Blue Shield**
 - James Rollins, MD, Medical Officer, **CMS**
 - Charles Stemple, MD, former Vice President, Health Guidance Organization, **Humana**
 - Jeffrey Stone, DO, MPH, Medical Director, **Molina Healthcare of Texas**
- **Moderator:**

- William Ennis, D.O, Chief Medical Officer, Healogics, Professor of Surgery at University of Illinois at Chicago, President, American College of Wound Healing and Tissue Repair

2:30-3:30 PM SESSION 13 – PANEL DISCUSSION WITH WOUND CARE RESEARCHERS TO SUMMARIZE SECOND DAY, IDENTIFICATION OF ACTION ITEMS, NEXT STEPS CLOSING REMARKS

- **Panelists:**

- Kara Couch, MS, CRNP, CWCN-AP, Director, Wound Care Services, George Washington University Hospital and Alliance Board Member
- Marcia Nusgart, RPh, Founder and Executive Director, Alliance of Wound Care Stakeholder
- Lynn Shapiro Snyder, Esq. Senior Member, Epstein Becker and Green

3:30 PM - SUMMIT CONCLUDES