

Diabetic Wound Healing— Translation and Clinical Opportunities

Wednesday October 9, 2013
NIH Neuroscience Center 6001
Executive Blvd, Rockville, MD, USA

The goal of this workshop, sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK and held in conjunction with the Diabetes Limb Salvage Conference sponsored by MedStar Georgetown University Hospital, is to explore scientific opportunities and challenges in translating and testing new therapeutic interventions for diabetic wound healing.

8:00 am **Welcoming Remarks from the NIDDK Director** - *Griffin Rodgers, MD, MACP*

Pre-clinical Research – Moderator - *Marjana Tomic-Canic, PhD*

8:10 – 8:25 Of the many molecular and cellular changes from diabetes that impact the many steps in wound healing, which ones play a central role in the pathology of diabetic foot ulcers? What are the most promising drug targets and biomarkers? *Marjana Tomic-Canic, PhD*

8:25 - 8:40 What is the current state of progenitor cell research for wound healing? What are the barriers for moving this research to clinical testing? *Geoffrey G. Gurtner, MD*

8:40 – 8:55 Do we have the right animal models for pre-clinical testing? Which ones are the most predictive? *Matthew J. Hardman, PhD*

8:55 – 9:25 Panel discussion *Jeffrey M. Davidson, PhD; Song Hong, PhD; Julie M. Jameson, PhD; Aristidis Veves, MD, DSc*

9:25 – 9:55 **Current successes and failures in the prevention and treatment of diabetic foot ulcers in the clinic and in clinical trials. How can we improve?** *Andrew J. M. Boulton, MD, DSC, FRCP*

9:55 **Break**

Local Interventions Moderator – *Andrew J. M. Boulton, MD, DSC, FRCP*

10:10 – 10:25 What are the NICE recommendations for dressings? Which areas need more evidence-based research and how to translate this research to the clinic? *William Jeffcoate, MB, MRCP*

10:25- 10:40 Is hyperbaric oxygen therapy effective compared to other therapies? What is the state of clinical research in this area? *Stephen R. Thom, MD, PhD*

10:40-10:55 What is the role of drug-releasing matrices and nanostructures in diabetic wound healing? What properties of the structures are important? What therapies would benefit from application through a drug-release matrix? *Aristidis Veves, MD, DSc*

10:55 – 11:10 What advantage does gene therapy offer for diabetic wound healing? What is the current state of the methodologies? *Jeffrey M. Davidson, PhD*

11:10 – 11:25 How does the FDA handle treatments at the interface between drugs and devices? In what areas would the FDA like more evidence-based research? *Speaker from the FDA*

11:25 – 11:55 Panel discussion *David M. Armstrong, DPM, MD, PhD; Michael Edmonds, MD; Robert G. Frykberg, MPH, DPM; Benjamin A. Lipsky, MD; MD; Dane K. Wukich, MD*

11:55 Lunch

Population studies and databases Moderator - *David J. Margolis, MD, PhD*

12:45 – 1:00 What are the highest priority epidemiology questions for directing future clinical research, evaluating access and differences in care and assessing cost-effectiveness? *David J. Margolis, MD, PhD*

1:00 – 1:15 What database resources on diabetic wound healing are available? What data on patient characteristics, treatment and outcome are essential for a database? *Jack L. Cronenwett, MD*

1:15 – 1:30 Can we test interventions through population studies? Can alternative study design compensate for the lack of randomization? *Stephen M. Warren, MD, FACS*

1:30 – 2:00 Panel Discussion *Harold Brem, MD; William Jeffcoate, MB, MRCP*

2:00 Break

Clinical Issues Moderator - *Lawrence A Lavery, MPH, DPM*

2:15- 2:30 Recruitment and retention strategies including inclusion/exclusion criteria. *Lawrence A. Lavery, MPH, DPM*

2:30 – 2:45 Standard of care for clinical trial protocols: off-loading, debridement, dressings, diagnosis and treatment of infections. *Robert S. Kirsner, MD, PhD*

2:45-3:00 Outcome measures and surrogate end-points: the value of complete epithelialization as a principal endpoint. *David J. Margolis, MD, PhD*

3:15 – 3:30 The incorporation of behavioral factors and quality of life measurements in trial design. *Loretta Vileikyte, MD, PhD*

3:30 – 4:15 Panel Discussion on the highest priority research questions for prevention and treatment: weighing public health impact and cost, feasibility and scientific opportunity. Examples include: recurrence prevention; prevention and treatment in dialysis patients; osteomyelitis treatment; hyperbaric oxygen efficacy; prevention of infections in diabetic foot ulcers; and acellular dermal matrix products *David M. Armstrong, DPM, MD, PhD; Christopher E. Attinger, MD; Paul J. Kim, DPM, FACAS; Benjamin A. Lipsky, MD; Stephen R. Thom, MD, PhD*

4:15 **Summary Discussion** - Moderators – *Christopher E Attinger, MD; Andrew J. M. Boulton, MD, DSC, FRCP; Marjana Tomic-Canic, PhD.*

5:00 **Adjournment**

Workshop Organizing Committee Co-chairs

Christopher E. Attinger, MD, Medstar Georgetown University Hospital (Co-chair)

Andrew J. M. Boulton, MD, DSc, FRCP, University of Manchester (Co-chair)

Marjana Tomic-Canic, PhD, University of Miami (Co-chair)

Teresa Jones, MD, NIDDK

Aaron Pawlyk, PhD, NIDDK