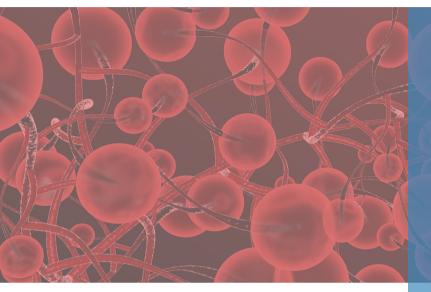
VASCULAR INNOVATION SUMMIT "PATIENT-CENTERED TECHNOLOGY FOR HARNESSING & USING DATA REMOTELY: OPPORTUNITIES AND LIMITATIONS IN PAD RESEARCH & CARE"



September 2020



Collaboration Speeds Innovation

Vascular Cures is a champion of forums in which diverse specialties and sectors of healthcare come together to collaboratively address timely topics and solve for pressing unmet needs. The 2020 virtual Vascular Innovation Summit brought together a multi-disciplinary, multi-stakeholder group of approximately 40 patients and key players from 27 institutions to address "Patient-Centered Technology for Harnessing & Using Data Remotely". The meeting consisted of a half-day of presentations from vascular health leaders followed by brainstorming sessions designed to discuss ways to address the most pressing unmet needs in vascular health. Through our breakout and post-summit reporting sessions, we leveraged the unique experiences of the participants to develop innovative strategies to accelerate collaborative solutions, including identification and collection of shared data.

PARTICIPATING ORGANIZATIONS:

Abbott Amgen **Boston Scientific Dartmouth College Derma-Flow Duke University** Food and Drug Administration (FDA) **Gilead Sciences** Harvard University LimFlow LunaDNA Medtronic Northwestern University **OptumCare Permanente Medical Group Rush University** Silkroad Medical Society for Vascular Ultrasound **Stanford University** University of California San Francisco **University of Toronto University of Michigan** University of Pittsburgh Wake Forest University Washington University in St. Louis Yale University

SUMMIT OBJECTIVES:

- Access and leverage the unique experiences of specialists, stakeholders, and patients to develop integrated approaches to addressing the field's highest unmet needs
- Develop innovative strategies to accelerate collaborative solutions, including identification and collection of shared data that could be leveraged
- Map out collaborative projects to address the identified issues and prioritize the patient experience
- Advance one high-impact project related to the topic and unmet need via the Vascular Cures Collaborative Patient-Centered Research (CPCR) Grants program

Speakers

Jeffrey Olgin, MD

"Landscape of Mobile Health and Mobile Trials in Cardiovascular Disease"

Gallo-Chatterjee Distinguished Professor of Medicine; Chief, Division of Cardiology; Co-Director, Heart and Vascular Center UCSF

Oliver Aalami, MD

"Clinical Validation of Smartphone Sensors in Peripheral Artery Disease" Clinical Assoc. Prof. of Surgery; Director of Biodesign for

Clinical Assoc. Prof. of Surgery; Director of Biodesign for Digital Health Stanford University

Mary McDermott, MD

"Preserving research integrity in a pandemic: Perspectives on remote data collection" Jeremiah Stamler Professor of Medicine Northwestern University Feinberg School of Medicine

JeAlejandro Reti, MD MBA

"Patient-Reported Outcomes-A Provider Perspective" National Vice President, Clinical Performance OptumCare

Donna Buckley, MD, MS O&A

Medical Officer Division of Coronary and Peripheral Interventional Devices ODE | CDRH | Food and Drug Administration

Our speakers offered their perspectives on the added benefits of digital research, not as a substitute for in-person research but as a tool that allows for certain efficiencies. Different populations have different needs and health equity issues that must be taken into consideration in each individual study. Therefore, remote data collection works best if the process is designed in a way that optimizes each user's experiences. The tools needed for this work require rigorous validation and an emphasis on using them in a way that builds trust with research participants. The efficacy of each remote intervention may additionally vary by the amount of face-to-face contact and any possible feelings of isolation that patients may experience based on their frequency of interactions with research staff.

The PAD and CLTI breakout sessions focused on applications for innovative and collaborative solutions that could lead to new initiatives for Vascular Cures and other researchers.

PAD Breakout Session

Moderators:

Peter Schneider, MD – Professor of Surgery, Division of Vascular Surgery, UCSF Edith Tzeng, MD – Professor of Surgery, Chief of Vascular Surgery, VA , UPMC

PAD patient participation in research can be expanded and improved with the use of remote platforms and tools that lower point of entry barriers and allow for the monitoring of patients outside of the office. With new technological tools, trainings that integrate digital tools, remote monitoring, and educational resources allow patients to become active and engaged study subjects. Exercise therapy and tools like VascTrasc can fill the need of those patients looking for condition management and supportive patient network communities. Uniform data standards must be established before the widespread use of patient engagement platforms. In addition, standardizing evaluation measures across studies to measure the correlation between daily activity and quality of life will lead to improved results and may have implications for future recommendations for treatment options.

Key Takeaways

- There are many common themes around the value of data outside of the healthcare system, patient-centricity & usability, participant trust and consent, how to bring siloed data together in one place and make it interoperable, how to collect "missing" data, and participant diversity
- There is incredible potential benefit to being able to monitor patients outside of the office or at defined time points in research (e.g. AFib study)
- Remote platforms and tools could enable, without a major increase in cost, inclusion of "non-traditional" patient populations, especially those who have barriers to traditional in-person trial participation
- There are numerous opportunities but we need to appreciate that remote technology cannot completely replace the value of in-person touchpoints and data collection

CLTI Breakout Session

Moderators:

Pat Geraghty, MD - Professor, Surgery and Radiology, Washington University Phil Goodney, MD, MS – Assoc. Professor of Surgery, Geisel School of Medicine, Dartmouth

There is an unmet need of understanding about the heterogenous CLTI patient population and their diverse, varied patient experiences. Reimagining research design and methodologies that account for the high rates of morbidity and treatment barriers may allow for the wound pain and care burden to be more accurately quantified. The development of a straightforward marker of physical activity that is appropriate for CLTI patients and is predictive of other major outcomes gives countless opportunities to track compliance of various physical activity interventions as we move towards "optimal" health functioning.

Key Takeaways

- No one outcome or study is going to provide the complete picture, we need the full story line not the singular data point
- We seem to have two major buckets of studies those that are very narrow and specific to development for market approval, and those that evaluate broad populations across outcomes (eg BEST CLI)
- There is a lot of interesting technology in the diabetic wound healing world that could be applicable to this patient population (eg smart socks)
- Industry researchers, specifically in devices, have an endless list of things they would like to evaluate but don't have the reimbursement codes to do so
- Potential research studies:
 - Focus should be on how to generate the greatest impact on the largest # of CLTI pts
 - There is potential to get more out of a cross-sectional vs prospective cohort approach (lower barriers/less resources required)