8th International Conference on HIV Treatment and Prevention Adherence

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IAPAC
INTERNATIONAL ASSOCIATION OF PROVIDERS OF AIDS CARE

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“New Frontiers” Pre-Conference Symposia: Novel Technologies and Assays for Adherence Assessment and Support

Moderators:
Jane M. Simoni, Ph.D., Department of Psychology
University of Washington

Jeffrey Schouten, M.D. J.D.
Office of HIV/AIDS Network Coordination
Fred Hutchinson Cancer Research Center
Novel Technologies and Assays for Adherence Assessment and Support

Presenters/Panelists:


• Donn Dennis, Xhale Inc. *SMART®: A Breath-Based Technology to Definitively Document Adherence to HIV Medications (Oral and Microbicide Gels).*

• Maya Petersen, MD, PhD, Div. of Biostatistics and Epidemiology, University of California Berkeley: *Analytic Challenges and Tools.*
The Office of HIV/AIDS Network Coordination’s BSWG Data Capture Technologies Focus Group

Context and Goals:
• Provide recommendations for networks using (A)CASl and other electronic data capture technologies - particularly guidance on why, whether, and how trials might adopt these approaches.
• Identify key considerations for a cost/benefit analysis when protocols are considering new tools.
• Address the limits of “validation” given questions about transferability and challenges with self-report.
• Consider developing an electronic data capture technologies implementation costing tool applicable to a variety of clinical trial settings.
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Key Recommendations:

• Create a vendor/technology table for researchers to reference as they consider adopting a tool.

• Identify funds to pilot novel technologies and cognitive testing of questions.

• Conduct a cost/benefit analysis and develop a budgeting tool and best practices guidance document modeled on the HANC “Recommendations for Standardizing Budgets for Clinical Trial Sites”.

• Create a cross-network “Technology and Measures Task Force” to develop standards and recommendations.
Novel Technologies and Assays for Adherence Assessment and Support

Key Considerations:

• Participant self-report is not reliable (e.g. VOICE, FemPrEP, etc.)
• Real-time monitoring would compliment and potentially enhance the reliability of self report.
• Real-time monitoring would complicate trial conduct and design.
• Current trials have no objective means to access adherence in placebo recipients. This complicates an analysis of efficacy based on adherence (i.e. drug exposure) in only the active trial arm(s).
• No point of care testing exists for drug exposure monitoring.
• The FDA is considering new rules for Electronic Source Data in Clinical Investigations.*
• All new technologies are bio-behavioral interventions.

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