



**PBRN Pragmatic Research and Translation Working Group**  
**Wednesday, November 10, 2014**  
**Meeting Summary**

**Meeting Facilitators**

- Paul Meissner, Network Coordinator for the New York City Research Improvement Networking Group and Primary Facilitator
- Rowena Dolor, Network Director, Duke Primary Care Research Consortium
- Jonathan Tobin, Network Director, Clinical Directors Network, Inc.
- Rebecca Roper, Director of the AHRQ PBRN Initiative

**Attendees**

- Milton Eder "Mickey" – ACCESS Community Health Network
- Laura-Mae Baldwin – WPRN
- Walter Calmbach – STARNet
- Jeanette M. Daly – IRENE
- Jane Garbutt – WU PAARC
- David Hahn – WREN
- Susan LeBailly – REACH Network
- Aaron Leppin
- Paula Darby Lipman – Westat
- John Lynch – CPCC
- Rebecca Malouin – GRIN
- Donald Nease, Jr. – SNOCAP
- Amanda Ross – RAP
- Iman Sharif – Nemours PCRC
- Clare Sullivan – Meharry-Vanderbilt Community Research Network
- Denita Walston – SERCN
- Camille Washington – ACORN
- Richard "Mort" Wasserman – PROS
- Martyn Whittingham

**Definition of Pragmatic Trials**

- Drawing from the article “A National Strategy to Develop Pragmatic Clinical Trials Infrastructure” by Concannon, et al., the group agreed upon the following definitions:
  - *A pragmatic clinical trial* is a prospective comparison of a community-, clinical-, or system-level intervention and a relevant comparator in participants who are similar to those affected by the condition(s) under study and in settings that are similar to those in which the condition is typically treated.
  - *A pragmatic clinical trial infrastructure* includes the resources, systems, and processes needed to prioritize, conduct, and use the results of PCTs.

**Use of EHR Data in Pragmatic Research Trials**

- As the use of EHRs in pragmatic clinical trials increases, more sophisticated approaches to data extraction and manipulation are required. Many practices do not have the capacity for these

approaches, and those practices with EHRs managed externally through a vendor have access limited, at a high price, or precluded by the agreement with the vendor.

- One challenge in pragmatic research trials is using EHR data for most or all touch points (i.e., patient identification, baseline and follow-up assessments, and inclusion/exclusion criteria).
- Challenges to HIPPA compliance when obtaining centralized data include taking months to get the practice established and needing a business arrangement between the data extraction vendor and practice.

### **EMR Abstraction Resources**

- The Stepped Wedge Design uses time as a variable to compare exposure to one or a set of interventions (e.g., data abstraction using multiple time intervals and multiple sub-groups of patients requiring inclusion and exclusion criteria).
- The DARTNet model, developed by Wilson Pace and colleagues at the University of Colorado Denver, emerged through collaboration with an EHR vendor and involves putting a server in practices with read-only access to EHRs. The data is extracted, standardized, and then kept in a server on-site behind the practice firewall. Though it is very expensive, it enables real-time identification.
  - To win practices' trust and to set up governance and data use agreements, DARTNet requires a lot of staff time. Depending on the number of point of care tools (these provide feedback to clinicians around management of conditions, prevention and screening) used by/associated with a practice's infrastructure, it could cost \$3,000-\$15,000/year per practice site.
  - A current challenge is that the EHR software used by some practices competes with these DARTNet tools. Thus, they prefer to use their own EHR software within their own system (for example, for maintenance of a registry) to reduce expenses.

### **Additional Barriers to EHR Use and Potential Solutions**

- As described above, expensive tools pose a significant challenge for practices to utilize EHRs. If you want to identify patients having something happening on a particular day, this requires a point of care tool. Having research assistants tracking patients down may be just as expensive as the tool.
- The challenge lies in how to demonstrate to PBRNs that EHRs are a better use of resources than re-entering data or having a low success rate after an "army" of research assistants track down trial participants.
- If PBRNs are to be successful at competing on these large pragmatic clinical trials, we will have to be able to support these costs. This requires commitment from EHR providers, practices, and PBRNs and is rooted in the leadership and culture of the practice.
- As PBRNs mature, it is important to reaffirm our operating principles and to remind the practices and evolving leadership structures we work with that our principles continue to be acceptable. This may be a moving target across the country as systems become integrated, and ownership less common.
  - At PCORNet, the pitch to engage the system leadership is centered on the fact that so much information is being discarded, so the focus should be on studies that aggregate billing, record keeping, and patient visit data in meaningful ways.
  - Many learning institutes are building towards learning healthcare systems; these institutions should be included in the process.

- The promise of the EHR is still a promise. We are still learning how to utilize it, though the structural pieces required are still quite challenging from multiple perspectives.