

Department of Research Abstracts

PEDIATRIC CLINICAL RESEARCH NETWORKS: A DEEP DIVE Alison B. Bocian, Donna L. Harris, Eric J. Slora, Richard C. Wasserman.. Pediatric Research in Office Settings (PROS), American Academy of Pediatrics, Elk Grove Village, IL; Department of Pediatrics, University of Vermont, Burlington, VT. **Presented at the May 2009 Pediatric Academic Societies Annual Meeting.**

BACKGROUND: Pediatric clinical research networks (PCRNs) are complex, multi-institutional collaborations that arose in the mid-20th century to permit study of novel therapies for infrequent conditions. The barriers faced by these networks in this new century, with its funding challenges, have not been characterized.

OBJECTIVE: To deepen understanding of the barriers facing PCRNs, as well as potential solutions to those barriers.

DESIGN/METHODS: Twenty-one U.S. leaders and participants in PCRN research participated in semi-structured one-hour interviews between February and July 2007. The informant list was developed initially to maximize PCRN diversity and refined to explore emerging interview themes. A physician researcher (PR) led each phone interview, using a standard script with additional questions to address emerging concepts; health researchers (HRs) took notes and recorded calls. HRs produced detailed summaries, which were confirmed by the PR and informants. Qualitative analysis, using a grounded-theory approach, consisted of two main activities: post-interview debriefing, and coding/theme compilation using Atlas.ti to organize data. Two HRs independently coded each summary for themes and sub-themes. Coding variations were resolved by PR/HR discussion. Consensus was achieved on all themes/sub-themes.

RESULTS: Sixteen of the 21 informants were PCRN leaders, and the remainder stakeholders or participants in the PCRN process. Dominant barrier-related themes included: funding challenges (subthemes -- funding of core activities; funding of individual studies; cross-subsidization of PCRN expenses with local funds); data management (subthemes -- data flow; informatics; data standardization); governance (subthemes -- standardization of protocol review; protocol implementation; management of expectations; review of external proposals); inter-network relationships (subtheme -- competition between PCRNs); and ethical issues (subtheme -- lack of local pediatric expertise). Solution-related themes included collaboration between networks to address challenges (subtheme -- forum for sharing best practices); and human subjects collaborations (subtheme -- central institutional review boards).

CONCLUSIONS: PCRNs share many complex challenges, only some of which can be addressed with new resources. In the current funding environment, however, creative solutions to these obstacles may be best found through collaboration among PCRNs.

