Creation of a Multi-Institutional CTSA-sponsored Obstetrics Registry for Adverse Rare Events (RARE)

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OBJECTIVES/SPECIFIC AIMS: Childbirth is the most common reason for hospitalization in the US, yet limited evidence informs treatment for many serious, but uncommon, pregnancy complications. We sought to assess the feasibility of developing a multi-institutional database among CTSA centers to evaluate treatments and outcomes for four rare obstetrical events (placenta accreta, monochorionic twins, maternal congenital heart disease, and mechanical ventilation during pregnancy).

METHODS/STUDY POPULATION: Members of the National Perinatal Research Consortium (NPRC) were awarded pilot funds by our respective CTSA for a multi-site project. We piloted use of CTSA IRBShare for a federated IRB and developed and implemented a multi-institutional REDCap database for abstraction of cases identified by querying administrative and clinical data at our institutions.

RESULTS/ANTICIPATED RESULTS: We encountered opportunities and challenges for multi-institutional collaboration. We easily implemented our database using REDCap’s secure, web-based application. However, we could not use IRBShare as planned, because exempt IRB applications are excluded. We also encountered challenges creating multi-site data-use agreements for our shared database. Institutional variation in ICD9 and CPT codes also affected the sensitivity and specificity of case-finding queries.

DISCUSSION/SIGNIFICANCE OF IMPACT: This project demonstrates that CTSA-supported multi-institutional collaboration is feasible, but roadblocks exist. Addressing these barriers may advance opportunities for collaborative clinical and translational research, as recommended by the IOM report.

Background

Childbirth is the most common reason for hospitalization in this country, yet data are limited regarding the effectiveness of treatment strategies for many serious, but uncommon, pregnancy complications. To address this gap, NIH-funded multidisciplinary researchers at five institutions have formed the National Perinatal Research Consortium (NPRC).

Funding

The five NPRC centers utilized the CTSA Consortium Translational Research Key Function Committee-Multi-CTSA Pilot Application process. Research reported in this publication was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under award numbers XXX (Columbia University, UL1TR00165; University of Alabama, U1TR001111; University of North Carolina, ULTR000071; University of Texas – Medical Branch; and ULTR001067; University of Utah). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

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