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

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Abstract

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 CTSAs for a multisite 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), 1UL1TR001111 (University of North Carolina), UL1TR000071 (University of Texas – Medical Branch) and 1ULTR001067 (University of Utah).

Methods

Project Objective: to develop a shared multidisciplinary research infrastructure among our five institutions and to demonstrate our capacity to collaborate in a pilot comparative effectiveness study of selected rare obstetric events and their associated treatments.

Specific Aims:

1. Pilot a federated IRB model for clinical studies across our institutions;
2. Develop and implement a shared multi-institutional RedCap database;
3. Collect data on maternal and neonatal outcomes for these rare events, comparing outcomes among various management strategies used at our centers.

- We chose four adverse rare pregnancy complications for inclusion in our registry
  - mothers with congenital heart disease
  - placenta accreta
  - monochorionic twins
  - mechanical ventilation during pregnancy
- Each center assumed responsibility for leading development of study instruments for one condition. The fifth center led development of a shared data collection instrument for prenatal, intrapartum, postpartum and neonatal outcomes common to all four conditions.
- Center teams included experienced maternal-fetal medicine clinician-researchers and a multidisciplinary collaborator with expertise related to the center's condition of interest.

Results

Aim 1: Pilot a federated IRB model using IRBShare

- Of the 5 NPRC centers, 3 were participating in IRB Share when we initiated the project
- However, affiliated hospitals at NPRC centers were not participating in IRB share
- Several organizations expressed reluctance to join a central IRB
- After we submitted the primary IRB, we learned that IRB Share does not accept expedited applications, and therefore our project was ineligible

Results

Aim 2: Develop and implement a shared multi-institutional RedCap database

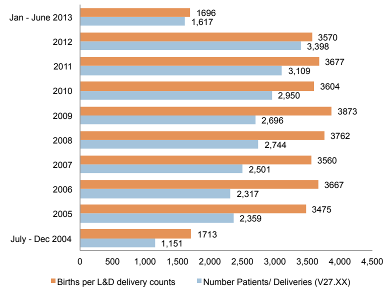
- PIs and research coordinators from each center held a two-day in-person meeting to develop study instruments
- Development continued via twice-monthly conference calls using WebEx to view study forms and refine areas of ambiguity
- All instruments have been deployed in RedCap, a user-friendly web-based data management system.
- We have piloted the instruments for all four conditions and are finalizing tools for maternal congenital heart disease
- Future projects include determining how to harmonize discrete obstetric outcome data captured by our respective electronic medical record systems

Aim 3: Collect data on maternal and neonatal outcomes for these rare events, comparing outcomes among various management strategies used at our centers.

We encountered several challenges in using administrative data to identify cases

- There is not a single code for "Pregnancy" that reliably identifies all women who have given birth. For example, V27, Outcome of Delivery, missed 24% of births over a 10-year period at one institution. We have identified a list of 50 ICD9 codes and 21 CPT codes to capture births. (Figure 1)

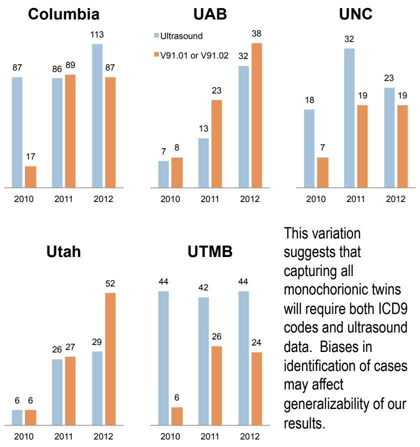
Figure 1



Results

- We found variation among institutions in coding for conditions that we were attempting to capture. The ICD9 code for monochorionic twins was implemented in October of 2010. When we compared the number of individual mothers with monochorionic twins by ICD9 code vs. our ultrasound databases, we found variation in the number of cases identified (Figure 2).

Figure 2



This variation suggests that capturing all monochorionic twins will require both ICD9 codes and ultrasound data. Biases in identification of cases may affect generalizability of our results.

Conclusions

- Our five-center consortium has successfully created a shared RedCap data collection system.
- Adding expedited review projects to the IRBShare common IRB may facilitate similar projects by potentially accelerating the IRB approval process.
- Local variation in coding limits the use of administrative databases to identify rare events.