Webinar Q&A Report: Optimizing Real-World Evidence for Maternal and Neonatal Outcomes

1. How is the concept of neonatal research perceived among parents? Overall, low-income non-English speaking parents have shown a lot of reluctance to participate, perhaps due to historical negative connotations associated with research.

Parents in general get approached at a very stressful time. Add in a language or racial barrier and mistrust is immediately there. There are many ways to build trust, but it has to happen at every level of the study, every key personnel involved. They have to be prepared.

2. What are some of the hurdles you have heard about families not participating in a trial?

A lot of the hurdles revolve around poor clinical trial execution at most levels especially not involving nurses in the study ahead of time for feedback. Nurses are the biggest trust for families and if they don't understand the trial or even support it, that will be reflected to the families.

3. Are SERA (or similar) screening tests covered by Anthem's Maternity Care Episode payment bundles?

Anthem has not made a coverage decision on the Sera PreTRM test as we await results from the ongoing clinical utility studies. Other screening tests do exist but are in even earlier phases of development.

4. Do NICUs always have access to the infant's gestational history if the pregnancy was handled by an obstetrician or midwife at a different institution?

Often, a NICU may be owned by a different entity from the one that owns the delivering hospital, but still be in the same building, easing the flow of information. In other cases, a baby may need to be transferred to a NICU in a different location. There is a standard prenatal form that the prenatal provider sends to the delivering hospital, which then also accompanies the infant in case of a transfer. This form includes key information for both mom and the unborn infant (e.g. fetal heart tones, dates of ultrasound and whether any issue was flagged).

5. Does the Anthem/HealthCore dataset include a representative percentage of midwife births?

Midwives attend ~10% of births in the US, and ~95% of these occur in facilities where a physician is typically present. The Anthem/HealthCore dataset is focusing on facility births; we have not studied home births. While we do find members with deliveries and other care attended by midwives, that capture may not always be complete as it is difficult to determine from claims whether a midwife attended a birth or not, as the claim is typically submitted under the physician's name. The same is true for prenatal care which is often multidisciplinary but gets billed under the OB/GYN's name.

6. Did you see a similar pattern of clinical effectiveness and cost savings in Medicaid births?

Yes, the PreTRM risk-screening-and -treat strategy was also found to be dominant over routine care in the Medicaid population, despite major differences in key assumptions such as intervention uptake and PTB costs.

7. What data sources and capabilities are crucial for payers to have to generate high-quality real world evidence (RWE) in maternity and other conditions?

Key factors are:

- a. Internal alignment to invest in the generation and use of RWE;
- b. A large, diverse membership in order to generate the deep data and representativeness needed for robust analysis;
- c. A data management process that enables the use of billing data for scientific research (e.g. via data cleaning, quality control, integration of information from medical and Rx benefits);
- d. Scientific talent that is trained in the use of real world data (RWD) and appropriate methodologies to extract reliable evidence.

8. What steps can we take to get the patient voice even better integrated into research projects and policymaking in this space?

By involving patient family voices before the study even launches. Jen and Deb belong to the NICU Parent Network which has 30 organizations in its membership and very strong partners. Jen is on the board and can connect anyone interested with the Executive Director. Deb helped co-found and run The Alliance for Black NICU Families which has a strong framework of founding member organizations, partnerships, and more. Contact Deb and Jen for more information.

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