High-Level Research Question

What models of perinatal care lead to better birth and patient-centered outcomes for patients at risk for experiencing disparities in care?

Assignment for Workgroup Participants

- Based on your perspective (patient, clinician, payer, etc.), what are two-three of the most relevant comparative effectiveness research questions focusing on reducing disparities and improving perinatal outcomes that warrant further research to address current gaps in knowledge?

- Present and discuss your two-three research questions on the day of the workgroup meeting. This should take no longer than 5 minutes total for each presenter. Note: Slides with your questions will be prepared in advance of the meeting.
Opportunity Snapshot

As part of PCORI’s efforts to fund high-impact and useful research on critical patient-centered health and healthcare issues, the Addressing Disparities (AD) and Improving Health Systems (IHS) programs are partnering to host a multi-stakeholder workgroup to discuss high-priority topics focusing on reducing disparities and improving perinatal outcomes. The AD and IHS programs intend to use the feedback from the workgroup to conduct further gap analyses on the list of topics/questions put forth by the workgroup in developing a funding announcement in this area. The objective of the workgroup is to achieve consensus on a set of comparative research questions with the potential to produce findings that improve patient-centered outcomes.

I. Introduction

The United States consistently ranks near the bottom on measures of birth outcomes, including infant and maternal mortality. Significant and persistent disparities in infant mortality are of particular concern. For decades, the infant mortality rate among black babies has been more than twice the rate of white babies. Preterm birth and the overlapping category of low birth weight are major contributors to disparities in infant mortality, as well as disparities in morbidity that persist throughout the child’s lifetime.

Disparities in birth outcome are driven by a complex web of social and environmental factors in addition to what happens within the healthcare system. The current evidence on how to reduce disparities in perinatal outcomes is mixed, but efforts are underway to understand better the etiology of these disparities and the effectiveness of new delivery models of perinatal care. PCORI is interested in complementing and enhancing current research efforts, and funding comparative effectiveness research focusing on delivery system improvements, particularly within safety net settings. Recognizing the role of social risk factors, and in concordance with recommendations by the Secretary’s Advisory Committee on Infant Mortality, PCORI is interested in research at the intersection of healthcare delivery and the community that has the potential to produce high-impact findings within a 3- to 5-year timeframe.

II. Terminology & Definitions

The literature commonly uses the term “perinatal care” to characterize interventions extending from pregnancy into the postpartum period and even infancy and toddlerhood. The “life span approach” to perinatal care, a framework rooted in the ecological model, extends this definition further. This framework argues that outcomes are determined by risk factors both preceding pregnancy and between pregnancies, and thus defines the perinatal period beyond proximal pregnancy periods to include preconceptional and interconceptional periods, essentially spanning a woman’s entire reproductive life.

However, these definitions are not consistent with the standard definition of perinatal used by the World Health Organization (WHO), which defines the perinatal period as commencing at 22 completed weeks (154 days) of gestation through 7 completed days after birth.
III. Patient-Centered Outcomes

The following is a list of patient-centered outcomes related to perinatal care often cited in the literature.

- **Short-term diseases and complications:**
  - Maternal: mortality, hemorrhage, pre-eclampsia, gestational diabetes, C-sections, duration of hospitalization, hospital visits and readmissions
  - Infant: infant mortality, Apgar score, intrauterine growth retardation, preterm birth (less than 37 weeks of gestation), low birth weight (less than 2,500 grams, or 5 pounds 8 ounces), small for gestational age (<10th percentile for gestation and gender), congenital malformations, respiratory distress syndrome, sepsis, duration of hospitalization, hospital visits and readmissions

- **Long-term diseases and complications:**
  - Maternal: postpartum depression, weight gain, subsequent pregnancy risks, cancer, osteoporosis
  - Infant: cerebral palsy, chronic pulmonary disease, other chronic illness and comorbidities

- **Maternal and infant health/functioning:**
  - Maternal: functional status, life expectancy
  - Infant: functional status, learning disabilities

- **Maternal and infant well-being:**
  - Maternal: satisfaction with care, anxiety/stress, economic stability, positive relationships, autonomy, self-acceptance
  - Infant: attachment, school achievement, employment

IV. Relevant National Vital Statistics

The following is a list of relevant vital statistics.

- In 2010, 3,999,386 births were reported to U.S. residents.
- 48 percent of births were covered under the Medicaid program in 2010.
- The birth rate for U.S. teens ages 15–19 fell 10 percent in 2010, to 34.2 per 1,000, reaching the lowest level reported in the United States in seven decades.
- Childbearing by unmarried women declined in 2010 for the second consecutive year, as reflected in fewer total births (1,633,471) and a lower birth rate (47.6 per 1,000).
- The cesarean section delivery rate reached 32.9 percent in 2009, increasing 60 percent since 1996. Since 2009, the rate has not increased.
- The preterm birth rate (less than 37 weeks of gestation) declined for the fourth year in a row, to 11.99 percent of births, down 6 percent since its peak in 2006. This rate is now down 6 percent since the 2006 peak.
- The low birth weight rate was essentially unchanged in 2010, at 8.15 percent of all births.
- Risks of infant mortality:
  - Higher for: non-Hispanic blacks, male babies, preterm births, low birth weight, multiple births, born
to unmarried mothers
  - Five leading causes: congenital malformations, preterm/low birth weight, sudden infant death syndrome, maternal complications, unintentional Injuries

V. Current Research and Evidence Base

There are a wide variety of perinatal care models studied and/or cited in the literature, including but not limited to:

- Addition of lay providers (doulas, peer counselors, community health workers, etc.)
- Birth environment models (hospitals, hospital-based birth centers, free-standing birth centers, home births)
- Interdisciplinary/collaborative maternity care (midwives, family practitioners, obstetricians/gynecologists)
- Maternity patient-centered medical home
- Midwife-led care – the “Midwifery Model”
- Regionalized care (for high-risk pregnancies)
- Traditional obstetrical-led care with hospital delivery
- Centering Pregnancy (trademarked group prenatal care)
- Nurse home visitation (from pregnancy through first 2 years of baby’s life)

Consensus across systematic reviews of current perinatal care models is that some interventions show promise, but there is insufficient evidence to endorse any single intervention and more research is required. In particular, while evidence suggests that some of these new delivery models are effective in improving continuity of care and maternal satisfaction, there is less evidence to suggest significant improvements in clinical outcomes. Across three identified systemic reviews of interventions to improve perinatal outcomes, there were no significant clinical outcomes reported. Currently, there are no existing Agency for Healthcare Research and Quality (AHRQ) evidence-based practice center reviews of interventions to improve perinatal outcomes, although there are planned systematic reviews around smoking cessation and depression treatment during pregnancy and the postpartum period.

Since 2009, the federal government has launched several initiatives to increase our understanding of and reduce disparities in perinatal outcomes. The National Children’s Study, launched in 2009, is a multisite, multiyear birth cohort study that will follow 100,000 American children from early gestational age (and possibly preconception) through age 21. The study will look at multiple factors such as individual-, community-, and policy-level actions, environmental exposures, diet, family dynamics, and local and cultural influences on birth outcomes and beyond.

In June, 2012, U.S. Department of Health and Human Services (HHS) Secretary Kathleen Sebelius made a commitment to the development of the nation’s first national strategy to reduce infant mortality. In January 2013, the Secretary’s Advisory Committee on Infant Mortality released recommendations for HHS action and a framework for a national strategy, which should include the following core principles:

- Reflect a life course perspective
- Engage and empower consumers
• Reduce inequity and disparities and ameliorate the negative effects of social determinants
• Advance systems coordination and service integration
• Protect the existing maternal and child health safety net programs
• Leverage change through multisector public and private collaboration
• Define actionable strategies that emphasize prevention and are continually informed by evidence and measurement.

Finally, in February 2012, the Center for Medicaid and Medicare Innovation, Human Resources and Services Administration, and Administration for Children and Families, launched *Strong Start for Mothers and Newborns* – a two-part initiative including, 1) a media campaign about preterm birth and 2) a 4-year funding program to test the following models of prenatal care targeting Medicaid/CHIP beneficiaries:

• Group prenatal care (e.g., CenteringPregnancy)
• Enhanced care at birthing centers
• Enhanced care at Maternity Care Homes (adaptation of patient-centered medical homes [PCMHs])
• Two nurse home visitation models (Nurse Family Partnership and Healthy Families America)

**VI. Research Areas of Interest**

PCORI is interested in potentially funding research related to:

• Comparative effectiveness of multilevel interventions to improve perinatal outcomes among mothers and infants at risk of experiencing disparities
• Comparative effectiveness of prominent perinatal care models (e.g., nurse home visitation, group prenatal care) to determine which subgroups benefit most from which interventions, in what settings, and under what circumstances
• Further exploration of interventions addressing “critical windows” outside of pregnancy (i.e., life span approach), including preconceptional and interconceptional periods.


