Perinatal Care and Outcomes Workgroup Meeting

October 24, 2013
Welcome and Introductions

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Program Director, Improving Healthcare Systems, PCORI

Jeff Schiff, MD, MBA
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Introductions
Program Directors

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Program Director, Addressing Disparities
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Chad Boult, MD, MPH, MBA
Program Director, Improving Healthcare Systems
Patient-Centered Outcomes Research Institute
Introductions
Workgroup Chair

Jeff Schiff, MD, MBA
Medical Director, Minnesota Health Care Programs
Minnesota Department of Human Services
Introductions
Workgroup Participants

Mary Ellen Mannix, MRPE
Mother and Head Teacher, The Haverford School
Advocate/Founder, The James’s Project

Ginger Paulsen
Director of Education and Programs
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* Participant representing this organization.
Introductions
Workgroup Participants

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* American Congress of Obstetricians and Gynecologists

Nikki Fleming, MSW
Community Advocate/Volunteer and Social Worker
* March of Dimes Ambassador

Nicole Garro, MPH
Director, Public Policy Research, Office of Government Affairs March of Dimes

Debra Bingham, DrPH, RN
Vice President of Research, Education, and Publications Association of Women's Health, Obstetric & Neonatal Nurses

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National Medical Director, Women’s Health & Genetics Line of Service UnitedHealthcare
* America’s Health Insurance Plans

Caitlin Cross-Barnet, PhD
Social Science Research Analyst Center for Medicare and Medicaid Innovation, Centers for Medicare and Medicaid Services

Maureen Corry, MPH
Executive Director Childbirth Connection

* Participant representing this organization.
Background: PCORI and the Improving Healthcare Systems Program

Chad Boult, MD, MPH, MBA
Program Director, Improving Healthcare Systems
About PCORI

- An independent non-profit research organization authorized by Congress as part of the 2010 Patient Protection and Affordable Care Act (ACA).

- Committed to continuously seeking input from patients and a broad range of stakeholders to guide its work.
PCORI’s Mission and Vision

Mission
The Patient-Centered Outcomes Research Institute (PCORI) helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

Vision
Patients and the public have the information they need to make decisions that reflect their desired health outcomes.
What Research Questions Are Within PCORI’s Mandate?

Questions should:

- **Be patient-centered**: Is the proposed information gap of specific interest to patients, their caregivers, and clinicians?

- **Assess current options**: What current guidance is available on the topic and is there ongoing research? How does this help determine whether further research is valuable?

- **Have potential for new information to improve care and patient-centered outcomes**: Would new information generated by research be likely to have an impact in practice?

- **Provide information that is durable**: Would new information on this topic remain current for several years, or would it be rendered obsolete quickly by subsequent studies?

- **Compare among care options**: Which of two or more approaches to care leads to better outcomes for particular groups of patients?
Questions External to PCORI’s Mandate

Cost effectiveness: PCORI will not answer questions related to cost-effectiveness, costs of treatments or interventions. However, PCORI will consider the measurement of factors that may differentially affect patients’ adherence to the alternatives such as out-of-pocket costs.

Medical billing: PCORI will not address questions about individual insurance coverage or about coverage decisions from third party payers.

Disease processes and causes: PCORI will not consider questions that pertain to risk factors, origin and mechanisms of diseases, or questions related to bench science.

Lacking comparative nature or foundation: PCORI will not consider questions that lack any comparative aspect.
Background: PCORI Improving Healthcare Systems (IHS) Program

The IHS Program funds research that:

- Compares the effectiveness of alternate features of healthcare systems designed to optimize the quality, outcomes, and/or efficiency of care for the patients they serve.

- Provides information of value to patients, their caregivers and clinicians, as well as to healthcare leaders, to help them choose features of systems that lead to better outcomes.
Background: The Addressing Disparities Program and Evolution of the Perinatal Care Topic

Romana Hasnain-Wynia, PhD
Program Director, PCORI Addressing Disparities Program
Addressing Disparities Program’s Mission Statement

PCORI’s Vision, Mission, Strategic Plan

Program’s Mission Statement
To reduce disparities in healthcare outcomes and advance equity in health and health care

Program’s Guiding Principle
PCORI is not interested in studies that describe disparities; instead, we want studies that will identify best options for eliminating disparities.
Addressing Disparities: Program Goals

1. **Identify Research Questions**
   - Identify high-priority research questions relevant to reducing long-standing gaps in disparate populations.

2. **Fund Research**
   - Fund research with the highest potential to address healthcare disparities.

3. **Disseminate Best Practices**
   - Disseminate and facilitate the adoption of research and best practices to reduce healthcare disparities.
PCORI’s Process for Identifying Research Gaps

Topics come from multiple sources

- Board topics
- Workshops, workgroups, and roundtables
- 1:1 interactions with stakeholders
- Guidelines development, evidence syntheses
- Website, staff, Advisory Panel suggestions

Gap confirmation

(PCORI staff in collaboration with AHRQ and others)

- Eliminating non-comparative questions
- Aggregating similar questions
- Assessing research gaps
- Preparing topic briefs

Priority topics/questions

(Multi-stakeholder Advisory Panels and Workgroups)

Topics proposed for funding
Advisory Panels for two of PCORI’s programs, Addressing Disparities and Improving Healthcare Systems, identified perinatal care as a top priority:

- **Addressing Disparities:**
  Interventions for improving perinatal outcomes—Compare the effectiveness of multi-level interventions (e.g., community-based, health education, usual care) on reducing disparities in perinatal outcomes.

- **Improving Healthcare Systems:**
  Models of perinatal care—Compared to usual care, what is the effect of care management (designed to optimize care coordination and continuity) on patient-centered outcomes among pregnant and post-partum women?
Workgroup Objective

Workgroup participants will serve as advisors to the Addressing Disparities and Improving Healthcare Systems Program. The goal is to:

- Obtain input on important comparative research questions related to perinatal care and management;
- Establish consensus on topics for further exploration.

The workgroup will generate questions related to perinatal topics that:

- Compare two or more approaches to perinatal care;
- Address disparities;
- Incorporate clinical interventions, and also address social risk factors that we know are central to improving perinatal outcomes; and
- Will produce high-impact findings within 3-5 year time frame.
PCORI program staff will use input from the workgroup to create a rationale for a targeted funding announcement.

Upon Board approval, PCORI will develop a funding announcement for comparative effectiveness research related to improving perinatal care, particularly among populations likely to experience disparities, including racial/ethnic minorities, and low-income and rural populations.
How PCORI Gathers Input

PCORI distinguishes “input” to the PFA development process from “involvement” in the process.

Input is information that may or may not be considered or used in crafting the PFA. Involvement is the activity of determining what will be in the PFA.

- The researchers, patients, and stakeholders who’ve been invited to this workgroup give input during the workgroup.
- The broad community of researchers, patients, and other stakeholders can give input via info@pcori.org.
- Webinar participants can provide input via the webinar “chat” feature.
How PCORI Manages the Potential for Conflict of Interest

The participants who have been invited to this workgroup will serve as advisors by helping to determine specific subject areas that we could address in a potential future PCORI funding announcement (PFA).

Participants in this workgroup are eligible to apply for funding if PCORI decides to produce a funding announcement in studying perinatal care because their roles are advisory, rather than prescriptive.

Input received during the workgroup deliberations will be broadcast via webinar, and the webinar will be archived and made available to other researchers, patients, and stakeholders via the PCORI website.
Setting the Stage

Jeff Schiff, MD, MBA
Medical Director, MN Health Care Programs, Dept. of Human Services
Defining “Perinatal”

World Health Organization (WHO):
- The perinatal period commences at 22 completed weeks (154 days) of gestation and ends seven completed days after birth.
- Perinatal mortality refers to the number of stillbirths and deaths in the first week of life (early neonatal mortality).

Centers for Disease Control and Prevention (CDC)
- Perinatal Deaths Definition I:
  - Infant deaths of less than seven days and fetal deaths with stated or presumed period of gestation of 28 weeks or more.
- Perinatal Deaths Definition II:
  - Infant deaths of less than 28 days and fetal deaths with stated or presumed period of gestation of 20 weeks or more.

Sources:
WHO [link] accessed 8/22/13
Defining “Perinatal”: In Practice

- The standard definition of “perinatal” is not consistent with the use of the term in the literature.

- The literature commonly uses the term “perinatal care” to characterize interventions extending from pregnancy into postpartum period, and even infancy and toddlerhood.
  
  - Prevailing Framework in the Literature: A Life Span Approach (Misra, et. al. 2003) looks beyond proximal periods
Perinatal Outcomes

- Measures of perinatal care are predominantly rates of infant and maternal mortality.

- Infant mortality is of particular concern in the United States.

- Preterm birth, and the overlapping category of low birthweight, are primary causes of infant mortality.
Perinatal Outcomes

Maternal
- **Short-term diseases & complications**
  - Mortality
  - Hemorrhage
  - Pre-eclampsia
  - Gestational diabetes
  - C-section
- **Long-term diseases & complications**
  - Postpartum depression
  - Pregnancy weight gain
  - Subsequent pregnancy risks
  - Cancer
  - Osteoporosis
- **Maternal health / functioning**
  - Life expectancy
  - Limitations of daily living activities
- **Maternal well-being**
  - Economic stability
  - Positive relationships
  - Autonomy
  - Personal growth
  - Self-acceptance
  - Reproductive lifespan

Infant
- **Short-term diseases & complications**
  - Mortality
  - Intrauterine growth restriction
  - Preterm birth
  - Low birth weight
  - Congenital malformations
  - Respiratory distress syndrome
  - Sepsis
- **Long-term disease & complications**
  - Cerebral palsy
  - Chronic pulmonary disease
- **Infant Health and Functioning**
  - Learning disabilities
- **Infant well-being**
  - Attachment
  - School achievement
  - Employment

Since the 1980s, efforts to improve perinatal outcomes and address disparities have been directed toward enhancing access to prenatal care.

These efforts have been insufficient. From 1981 to 2006, the preterm birth rate increased by 35%, and since, has fallen 8% since its peak.

Despite an increase in black women receiving prenatal care, there has not been a coincident decrease in infant mortality.

Source: PCORI. Addressing Health Disparities Topic Briefs.
White - African American Infant Mortality Comparison
United States

Adopted from “Healthy Babies through health Equity: Minnesota’s efforts within Region V Coiin.” Presented by: Edward P. Ehlinger, MD, MSPH, Commissioner, Minnesota Department of Health. October 1, 2013
African American Infant Mortality with Disparity Ratio compared to Whites  United States

Adopted from “Healthy Babies through health Equity: Minnesota’s efforts within Region V Coin.” Presented by: Edward P. Ehlinger, MD, MSPH, Commissioner, Minnesota Department of Health. October 1, 2013

U.S. IMR: 6.59 per 1,000
4.76 in NH – 11.48 in DC

Adopted from “Healthy Babies through health Equity: Minnesota’s efforts within Region V CoiIN.” Presented by: Edward P. Ehlinger, MD, MSPH, Commissioner, Minnesota Department of Health. October 1, 2013
Additional Population Considerations

Infant mortality higher for:
- Male babies
- Babies born preterm
- Low birthweight babies
- Multiple deliveries (i.e., twins)
- Babies born to unmarried mothers

3 Leading Causes of Infant Death accounted for 46% of all infant deaths:
- Congenital malformations
- Low birthweight
- Sudden Unexpected Infant Death

Existing Perinatal Care Models:
Informal List

- Lay Support and Education (doulas, peer counselors, community health workers, etc.)
- Birth environment models (hospital, hospital-based birth center, free-standing birth centers, home birth, etc.)
- Interdisciplinary / Collaborative Maternity Care (Midwives, family practitioner, Ob/Gyn)
- Maternity Patient-Centered Medical Home
- Midwife-led care – the “Midwifery Model”
- Regionalized care (for high-risk pregnancies)
- Traditional obstetrical-led care with hospital delivery
- Nurse home visitation (pregnancy through first 2 years)
Perinatal Care Interventions – What’s the evidence?

To date, few studies on multilevel interventions; thus evidence base does not yet exist.

There is more literature around interventions targeting individual and interpersonal levels (e.g., group prenatal care, nurse home visiting).

Notably: across three identified systematic reviews of interventions to improve perinatal outcomes in the U.S., there were no significant clinical outcomes reported.

- Significant reported outcomes pertained to care utilization, delivery (C-section), and psychosocial issues (e.g., patient satisfaction)

Consensus across systematic reviews:

- Some interventions show promise; however, there is insufficient evidence to endorse any intervention. More research is required.

There are no existing AHRQ EPC reviews, but there are planned reviews around smoking cessation and depression treatment during pregnancy and postpartum period.
Gaps in Research

- Comparative effectiveness of multi-level (integrated and vertically aligned) interventions to improve perinatal outcomes among mothers and infants at risk of experiencing disparities.

- Further exploration 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.
Government Context:
National Strategy to Address Infant Mortality

In June 2012, Secretary Sebelius made a commitment to the development of the nation’s first strategy to address infant mortality.

In January 2013, the Secretary’s Advisory Committee on Infant Mortality issued a report and recommended national strategy, outlining the following key areas for action:

- Focus on improving the health of women *before, during, and after pregnancy*.
- Ensure access to a *continuum of safe and high-quality, patient-centered care*.
- Redeploy evidence-based, highly effective *preventive interventions* to a new generation.
- Increase health equity & reduce disparities by *targeting social determinants of health*.
- Invest in adequate *data, monitoring, and surveillance systems* to measure access, quality, and outcomes.
- Maximize the potential of *interagency, public-private, and multi-disciplinary collaboration*.
Summary & Conclusion

- Adverse birth outcomes for women and infants is a pervasive problem in the U.S.
- There are significant disparities that must be addressed with interventions at intersection of healthcare delivery and community.
- Existing evidence base is mixed.
- There are large research efforts underway that need to be considered when formulating research questions.
Participant Perspectives: Proposed Research Questions

Moderated by: Jeff Schiff, MD, MBA
Medical Director, MN Health Care Programs, Dept. of Human Services
Participants to present 2-3 research questions related to perinatal care that need to be addressed.

This should take no longer than **5 minutes** for each presenter.

Slides include questions submitted in advance.

*All* participants will have an opportunity to speak about proposed questions.
Questions Submitted by Participants

Maureen Corry, MPH, Executive Director, Childbirth Connection

1. Compare the effectiveness of maternity care led by obstetricians, family physicians, and midwives with respect to postpartum outcomes in low- and mixed-risk childbearing women and their newborns.

2. Compare the effectiveness of maternity care in usual settings (office or clinic and hospital) and in freestanding birth centers with respect to postpartum outcomes in low- and mixed-risk childbearing women and their newborns.

3. Compare the effectiveness of usual care intrapartum caregiver model (with responsibilities for outpatient and inpatient maternity care and other types of health care) and laborist model (with sole responsibility for in-hospital maternity care) with respect to care processes, and their associated health and cost outcomes, in childbearing women and their newborns.
Questions Submitted by Participants

Caitlin Cross-Barnet, PhD
Social Science Research Analyst, Center for Medicare and Medicaid Innovation

1. **Smoking Cessation**
   - Would household-level smoking cessation efforts be more effective in reducing prenatal smoke exposure and producing healthy birth outcomes than individually targeted cessation efforts? Would household-level smoking cessation efforts make postnatal relapse less likely and lead to a reduction in respiratory illness, SIDS, and other infant health problems (as well as adult health problems)?

2. **Neonatal Intensive Care**
   - Does putting parents in charge of NICU infant care (as opposed to traditional NICU care that allows for parental involvement) increase health and decrease pathology in a US context? If so, how is parental agency and independence best accomplished (peer counseling, postpartum doula, nursing intervention, social workers, team approach, etc.)?

3. **Reducing Primary Cesareans**
   - Does a hard stop on elective induction prior to 41 weeks decrease cesareans and improve maternal-infant health outcomes?
Questions Submitted by Participants

1. Vaginal Progesterone vs. 17 alpha-hydroxyprogesterone caproate (17P) to prevent preterm delivery in women with a short cervix (<20-25 mm) and/or history of prior spontaneous preterm delivery

2. Group vs. traditional prenatal care to reduce incidence of preterm delivery in an average risk population

3. Timing of maternal postpartum exam (2 weeks vs. 6 weeks) and its impact on postpartum depression, breastfeeding, and contraception initiation
Questions Submitted by Participants

Debra Bingham, DrPH, RN,
Vice President of Research, Education, and Publications,
Association of Women's Health, Obstetric & Neonatal Nurses

1. Childbirth (Prenatal) Education Modalities
   ▪ What educational modalities and tools, e.g., online, small group, home visits, public health campaigns, shared decision-making tools, are the most effective for increasing women’s (regardless of whether their care is paid for by Medicaid or Private Insurance) knowledge of evidence-based childbirth options that support their ability to make informed choices about the risks and benefits of complex choices such as whether to choose to have an elective induction of labor, trial of labor after cesarean, or to breastfeed?

2. Measuring RN Staffing and Nursing Care Quality Practices
   ▪ What are the differences in RN staffing and RN nursing care quality practices at hospitals with low, medium, and high rates of cesarean sections and severe perinatal morbidities?

3. Transition between hospital and home for vulnerable infants
   ▪ Are current education modalities and tools effective for reducing the readmission rates of Late Preterm Infants (those infants born 34 0/7 weeks through 36 6/7 weeks gestation)?
Questions Submitted by Participants

Nicole Garro, MPH
Director, Public Policy Research, Office of Government Affairs, March of Dimes

1. How do various types of hospital interventions, i.e. hard stop vs. provider and patient education affect rates of elective inductions and c-sections? What is the effect on birth outcomes?

2. What is the role of participation in home visiting programs (versus usual prenatal/postpartum care) in improving interconception care, and birth outcomes for subsequent children (e.g. preterm birth, low birthweight)?

3. What is the role of community-based prematurity prevention programs (e.g. Healthy Babies are Worth the Wait) in rates of preterm birth and other adverse birth outcomes compared to communities without such programs? What are the most effective patient centered programs for improving pregnancy outcomes among women and families from medically underserved populations?
BREAK

• Visit us at www.pcori.org
1. **Periodontal disease** is a known risk factor for preterm birth and treatment may reduce the risk of preterm birth. Significant sociodemographic disparities exist in clinical oral health status in pregnancy.
   - Proposed intervention: Treatment of periodontal disease mid-trimester vs. none
   - Outcome measured: Preterm birth rate

2. Disparities exist in access to routine **cervical length screening**. Vaginal progesterone has been shown to decrease the preterm birth rate by 44% when given to low-risk women found to have a short cervix (cervical length < 15mm at 20-25 weeks).¹
   - Proposed intervention: Making cervical length screening available and treat those with short cervix vs. routine prenatal care
   - Outcome measured: Preterm birth rate

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Questions Submitted by Participants

Ann R. Knebel, RN, PhD
Deputy Director, National Institute of Nursing Research

1. Investigate the perinatal outcomes associated with pre-natal interventions that compare lay workers (such as promotoras in Latina populations) to group approaches (such as CenteringPregnancy) in geographically and/or culturally diverse populations.

2. Compare the effect of community-based clinics that use mHealth technology vs more traditional group practices on perinatal outcomes in pregnant teens.

3. Compare the effectiveness of stress reducing integrative, behavioral interventions versus traditional educational interventions on low birth weight outcomes in pregnant Black women.

4. Investigate the perinatal outcomes associated with targeted prenatal interventions that address acculturation across immigrant generations.
Questions Submitted by Participants

Ann E.B. Borders, MD, MSc, MPH
Division of Maternal-Fetal Medicine, NorthShore University HealthSystem

1. System-based approaches to identifying high-risk women either post-delivery at the time of a birth with an adverse outcome or when a patient engages the health system with a pregnancy-related charge. Goal to efficiently direct limited resources to the most high-risk women.

2. Does increased patient navigation and care coordination for high-risk women postpartum (navigate into interconception care / medical care home / family planning) and for high-risk women prenatally (navigate into prenatal care / social services / social support) reduce adverse pregnancy outcomes and reduce disparities?

3. What do women who have had adverse pregnancy outcomes feel that they need the most in order to be empowered to engage in interconception care, planning next pregnancy, and regular prenatal care?
Sharon Rising, MSN, CNM
Chief Executive Officer, Centering Healthcare Institute

1. Does continuing for care with a group cohort in the postpartum period, such as what happens in Centering Parenting, make a difference in achievement of weight goals, continuance of breastfeeding, initiation and maintenance of contraception, depression screening and treatment, follow-up for appropriate diabetes testing, infant and adult immunizations, and community-building/engagement in care?

- If we could do a longitudinal study, this would ideally start with pregnancy and continue through 3-5 years with a focus on chronic health indicators.
1. Importance of investigating what aspects of perinatal care pregnant women, particularly those who experience poorer outcomes, believe are important or are in need of improvement.

2. Centering of Pregnancy is a concept that has been promoted for some time as a mechanism to improve perinatal outcomes; however, it does not appear that there is supporting evidence.
Questions Submitted by Participants

Ginger Paulsen
Director of Education and Programs, Nevada Business Group on Health

1. With a program of education and vitamin D testing for pregnant women, what is the effectiveness in reducing preterm births vs. the general population? Versus the participating groups’ records for the prior year?

2. What is the effectiveness of reducing the healthcare disparity between the percent of preterm births among Caucasians (over 10%) vs. darker skin (18%) by the women getting their vitamin D serum levels to at least 40 mg/ml?

3. With a program of education and testing about the need to remove toxins from the body and environments of pregnant women (and those in a period of preconception), what is the difference in the woman's early testing of toxin load vs. follow-up testing (how effective was the education?) and, what is the difference in the outcome of the pregnancy, especially preterm births?
Questions Submitted by Participants

Mary Ellen Mannix, MRPE
Mother and Head Teacher, The Haverford School, Advocate/Founder, The James’s Project

1. Are the outcomes and/or parent's satisfaction levels of care by clinicians who have completed some formal training in collaboration/communication skills better/higher than those of clinicians who have not participated in any professional development in this arena?

2. Heart defects are the most common birth defect in newborns. Recently, newborn screening (specifically the RUSP) recommendations include critical congenital heart defects. There is a wide array of heart defects with an equally impressive number of treatment options. Out of the less severe heart defects (or severe like HLHS), which treatments produce a better outcome/expose the patient to fewer infections/etc?
   - For example - are babies who undergo surgery at 2 days of age have a more successful recovery or less successful recovery than babies whose parents opt for a more conservative treatment option (watchful waiting/pharmaceutical interventions, etc)?

3. Does prescribed bed rest for a pregnant mother who is experiencing early labor signs serve halting labor as well as, better, or worse than pharmaceutical interventions when past 28 weeks of pregnancy?
Ongoing Research:
CMMI Strong Start for Mothers and Newborns Initiative

Caitlin Cross-Barnet, PhD
Center for Medicare and Medicaid Innovation
What is Strong Start?

• **Strong Start I**
  – A nationwide public awareness campaign

  **Goal**: Reduce incidence of early elective deliveries (scheduled induction or cesarean without medical indication before 39 weeks)

• **Strong Start II**
  – MIHOPE-SS (home visiting)
    • HRSA project with ACA mandate; evaluation funds from CMMI
  – Three approaches to enhanced prenatal care: CMMI based initiative

  **Goal**: Reduce incidence of preterm birth among high risk Medicaid beneficiaries
Strong Start II at CMMI

• Preventing preterm birth among high-risk (based on IOM) Medicaid beneficiaries

• Three enhanced approaches to care
  – Birth Centers
  – Group Care/Centering Pregnancy
  – Maternity Care Homes

• Awardees estimate serving more than 80,000 women at 182 sites in 32 states, DC, and PR.
CMMI Strong Start Specific Outcomes

• Better Care, Better Health, Lower Cost
• Preterm Birth
  – Gestational Age
  – Birthweight
• Cost of care
  – Woman: pregnancy, delivery, postpartum 60 days (through a year if Medicaid eligibility continues)
  – Infant: Birth through one year

  • Length of stay for delivery
  • NICU admission and length of stay
  • Unplanned maternal ICU admission
Other Outcomes of Interest

- Frequency of ongoing prenatal care
- Timing of prenatal care
- Appropriate use of progesterone and antenatal steroids
- Delivery (vaginal, cesarean)
- Elective delivery before 39 weeks and up to 41 weeks
- Appropriately timed postpartum care
- Patient experience of care
Evaluation Methods

• Baseline comparison
• Contemporaneous comparison group
• Site visits
• Interviews
• State Medicaid and Vital Records data
Providers

• Maternity Care Home
  – May see a number of service providers through care coordination
  – Primary prenatal care provider may or may not attend delivery

• Centering Pregnancy
  – Facilitators may have varying qualifications
  – Group facilitators are consistent throughout prenatal care
  – Peer group is consistent
  – Facilitators may or may not attend deliveries

• Birth Center
  – Prenatal care providers are usually midwives (CNM, CM, CPM)
  – Prenatal care providers attend deliveries
Birth Settings

• Maternity Care Home
  – No requirement for setting, but usually hospital
  – May be affiliated with care provider setting or not

• Centering Pregnancy
  – No requirement for setting, but usually hospital
  – May be affiliated with care provider setting or not

• Birth Center
  – All awardees are freestanding birth centers; some offer homebirth
Participants

• Many states and geographic regions (urban and rural) will be served.
• Level and type of risk for preterm birth varies among and within states.
• Demographic composition of intervention participants may vary by site/region.
Overcoming Obstacles

- A combination of strategies (triangulation)
- Judicious use of state data
- Standardized measurement tools (e.g. intake)
- Qualitative inquiry
The National Children’s Study: Vanguard 2.0

Patient Centered Outcomes Research Institute Perinatal Care and Outcomes Workgroup

Washington, D.C. October 24, 2013
WHAT IS THE National Children’s Study (NCS)?

- Largest, long-term study of environmental influences on children’s health and development ever to be conducted in the United States that will:
  - Enrolment of ~100,000 women (preconception and pregnant)
  - Follow the cohort of children and their families from before birth to age 21
- Environment is broadly defined to include factors such as:
  - Environmental: air, water, sound, chemicals in home, schools, and communities
  - Genetics: DNA sequencing, epigenetics, metabolomics, lipidomics
  - Nutritional: composition of food, caloric intake, eating behaviors
  - Social: family dynamics, community, cultural influences
GOALS OF THE NCS

OVERALL: To improve the health and well-being of children

• Identify both harmful and beneficial contributors to children’s health

• Provide a national dataset linking source-exposure-effect:
  • Evidence for practice and policy decisions
  • Evaluation of the consequences/effectiveness of health and environmental policy

• Serve as resource for future research

• Produce economic benefits through knowledge gained about disease prevention
• Data from the NCS will:
  • Be representative of US births
  • Benefit from a robust logistics infrastructure: NU team is pilot-testing customized vans with freezers and refrigerators and capacity for computer adaptive assessment in 3 Study Locations
  • Include 100,000 children and their parents
  • Be longitudinal and include
    - Phenotypic
    - Biological specimens
    - Environmental specimens
    - Social and familial contexts

• NCS will generate substantial data for predictive modeling
Child health has improved over the past 50 years

- Mainly because of improved treatments
- Intensification of disease prevention is the only way to continue to improve health and reduce long-term healthcare costs
- Disease prevention will only result from improved understanding of the underlying causes

NCS focuses on exposure-outcome link
PARTICIPATORY
NCS SAMPLING STRATEGY

All Births in the United States

Sample of Study Locations

Sample of Study Segments

Study Households or Prenatal Care Sites

Study Women

~4 million births in the 50 states (3,141 counties)

105 “Locations” (county or counties)

Selection of communities in the Study Location

All or a sample of households or prenatal care sites within the communities

All eligible women in the households or prenatal care sites
Active Vanguard Study Locations
NCS TO DATE

- Oct-00 Legislation Signed
- Feb-04 105 Study Locations (SLs) Selected
- Aug-05 Original Vanguard Centers Funded
- Jan-07 NCS Funding Appropriated
- Aug-07 Original Vanguard Centers Recruitment
- Aug-08 17 Additional SLs Funded
- Sep-10 - Apr-12 Vanguard 1.0 (17 SLs) Recruitment
- Sep-12 4 Regional Operations Centers (ROC) Funded
- May-12 Provider-based SLs Recruitment
- Mar-13 Vanguard 2.0 Field Work
- Aug-13 68% Reconsent in 7 SLs

Timeline:
- Jan-01 to Jan-13

Oct-00 to Aug-13
NCS VANGUARD
DATA COLLECTION

Current Visit Protocol | Future Visit Protocol*
---|---
Birth | 3 m | 6m | 9m | 12m | 18m | 24m | 30m | 36m | 4y | 5y | 6y

- Telephone, in-person, and self-administered surveys
- Biological specimens
- Anthropometric measures
- Environmental samples
- Parent/guardian and child CAT assessments* to begin in 2014

* Initially using NIH Toolbox Instruments (neuro-psycho-social)
**BIOLOGICAL AND ENVIRONMENTAL SPECIMENS AND SAMPLES**

<table>
<thead>
<tr>
<th>Original Vanguard</th>
<th>Vanguard 2.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal blood</td>
<td>✔</td>
</tr>
<tr>
<td>Maternal urine</td>
<td>✔</td>
</tr>
<tr>
<td>Maternal saliva</td>
<td>✔</td>
</tr>
<tr>
<td>Placenta</td>
<td>✔</td>
</tr>
<tr>
<td>Cord blood</td>
<td>✔</td>
</tr>
<tr>
<td>Meconium</td>
<td>✔</td>
</tr>
<tr>
<td>Breast milk</td>
<td>✔</td>
</tr>
<tr>
<td>Child blood</td>
<td>✔</td>
</tr>
<tr>
<td><strong>DUST</strong></td>
<td></td>
</tr>
<tr>
<td>Wipes</td>
<td>✔</td>
</tr>
<tr>
<td>Vacuum</td>
<td>✔</td>
</tr>
<tr>
<td>Plate</td>
<td>✔</td>
</tr>
<tr>
<td><strong>WATER</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>✔</td>
</tr>
</tbody>
</table>
## NCS Vanguard 1.0

*All numbers rounded = minor inconsistencies in totals*

<table>
<thead>
<tr>
<th></th>
<th>Initial Household (2008 cohort)</th>
<th>Alternate Recruitment (2010 cohort)</th>
<th>All Vanguard to date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Study Locations</td>
<td>7</td>
<td>30</td>
<td>37</td>
</tr>
<tr>
<td>Recruitment Duration (months)</td>
<td>34</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>A. Women eligible for contact</td>
<td>35,000</td>
<td>50,700</td>
<td>85,650</td>
</tr>
<tr>
<td>B. Eligible for Pregnancy Screen (%)</td>
<td>34,350 (98%)</td>
<td>44,600 (88%)</td>
<td>78,950 (93%)</td>
</tr>
<tr>
<td>C. Completed Screen (% of contacted)</td>
<td>30,900 (90%)</td>
<td>38,350 (86%)</td>
<td>69,250 (88%)</td>
</tr>
<tr>
<td>D. Pregnant or Trying (% of screened)</td>
<td>3,100 (10%)</td>
<td>7,000 (18%)</td>
<td>10,100 (15%)</td>
</tr>
<tr>
<td>E. Enrolled (% of pregnant or trying)</td>
<td>2,000 (64%)</td>
<td>5,100 (74%)</td>
<td>7,100 (71%)</td>
</tr>
<tr>
<td>F. Babies Born and Enrolled</td>
<td>1,200</td>
<td>2,450</td>
<td>3,650</td>
</tr>
<tr>
<td>G. Provider-based Sample</td>
<td></td>
<td></td>
<td>1,400</td>
</tr>
<tr>
<td>H. Total Child Sample</td>
<td></td>
<td></td>
<td>≈5,050</td>
</tr>
</tbody>
</table>
THE FUTURE

- MAIN STUDY design and protocol
- CONCEPTUAL MODEL OF CHILD HEALTH on which to base instrument/tool development and selection
- LEVERAGING TECHNOLOGY for informatics systems and protocol implementation.
Major Debate!

American Journal of Epidemiology Advance Access published March 12, 2012

New Models for Large Prospective Studies: Is There a Better Way?


Large prospective cohort studies are critical for identifying etiologic factors for disease, but they require substantial long-term research investment. Such studies can be conducted as multisite consortia of academic medical centers, combinations of smaller ongoing studies, or a single large site such as a dominant regional health-care provider. Still another strategy relies upon centralized conduct of most or all aspects, recruiting through multiple temporary assessment centers. This is the approach used by a large-scale national resource in the United Kingdom known

Vehement Agreement on New Models?

Teri A. Manolio¹, Rory Collins, for the National Institutes of Health New Models Workshop Participants

¹Correspondence to Dr. Teri Manolio, Director, Division of Genomic Medicine, National Human Genome Research Institute, 5635 Fishers Lane, Room 4113, MSC 9305, Rockville, MD 20892-9305 (e-mail: manolio@nih.gov).

Received October 1, 2012.
Accepted October 8, 2012.

Dr. Bracken et al. (1) raise several issues in their interpretation of our recent commentary, “New models for large prospective studies: Is there a better way?” (2). Although the 12 points raised by Bracken et al., all of whom are described as associated with the US National Children’s Study, begin with issues related to our commentary, their later points stray into criticisms of the National Children’s Study with which we were not directly
DEFINITIONS OF HEALTH

• Institute of Medicine:
  • **Health conditions**: disorders or illnesses
  • **Function**: execution of tasks and participation in desired activities
  • **Health potential**: development of assets and positive aspects of health (e.g., competence, capacity, developmental potential)

• **International Classification of Function (ICF)**
  • Body structures
  • Functions
  • “Self” functioning
DEFINITIONS OF HEALTH

- NIH PROMIS
  - Experiences of health

Diagram:
- Self-Reported Health
  - Physical Health
    - Symptoms
    - Function
  - Mental Health
    - Affect
    - Behavior
    - Cognition
  - Social Health
    - Relationships
    - Function
DEFINITIONS OF HEALTH

• NIH Toolbox
  • Assessments of four domain:
LIFE COURSE MODEL

Integrates concepts of both Barker and Geronimus:

- Maternal health status (e.g., chronic illnesses, obesity) affects fetal/infant outcomes
- Fetal and infant outcomes are associated with child, adolescent, and adult well-being, and
- Adult health status, in turn, affects fertility and infant health status

Halfon, Inkelas, and Hochstein, 2000
CHALLENGES IN MEASURING HEALTH POTENTIAL

- Conceptual frameworks poorly developed
- Developmental modulation is difficult to capture and account for
- Existing measures have “ceiling” effect
- Domain definitions: reductionist legacy
  - Mechanistic models of body function
  - Capacity-based concepts
HEALTH MEASUREMENT NETWORK
VISION

Health Dimensions

- Biological Function
- Self Functioning
- Experiential
- Potential

Typology

- Visual Acuity
- Visual Function: Reading level*
- Retinal Adaptability**

Measures

- Tool box Vision
- Tool box Cognition + Reading Test
- To be developed

* Confounded by cognition
** Measure of potential for retinal regeneration
Questions are selected from an item-bank that is calibrated using Item Response Theory (IRT).

Next question in the test is selected based on responses to previously administered questions.

Iteratively estimate a person’s ability.

Desired level of precision can be obtained using the minimal possible number of questions.
In the past 7 days...
I could stand up by myself.  
YES

In the past 7 days...
I could keep up when I played with other kids.  
NO
In the past 7 days, I could walk by myself. YES
In the past 7 days...
I could stand up by myself.

In the past 7 days...
I could walk by myself.

In the past 7 days...
I could keep up when I played with other kids.
THANK YOU!

Jane L. Holl, MD MPH
j-holl@northwestern.edu
Ongoing Initiatives

- Collaborative Improvement & Innovation Network to Reduce Infant Mortality (CoIIN)
- CMCS Expert Panel on Improving Maternal and Infant Outcomes in Medicaid and CHIP
- Medicaid Medical Directors Learning Network Perinatal Project
LUNCH

• Visit us at www.pcori.org
• PCORI has launched the “Pipeline to Proposal” awards, it is being piloted in 13 western states - Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming. Proposals are due Monday, Dec. 2. For more information please visit - http://www.pcori.org/funding-opportunities/pipeline-to-proposal-awards/
Recap of Proposed Research Questions in Perinatal Care

Moderated by: Jeff Schiff, MD, MBA
Medical Director, MN Health Care Programs, Dept. of Human Services
Discussion & Narrowing Down: Comparative Research Questions
Workgroup Objective:
Achieve Consensus on Set of Research Questions

- Perinatal care is a very broad concept
- The goals of the discussion today are to:
  - Discuss all proposed research questions and topics
  - Determine which questions are the most important via group consensus
  - Identify 10-12 priority research topics for further consideration by PCORI staff
Collaborative Workgroup Discussion

**Focus:** Provide targeted input without scientific jargon

**Honor timelines:** Provide brief and concise presentations and comments

**Participate:** Encourage exchange of ideas among diverse perspectives that are present today:
- Researchers
- Clinicians
- Patients
- Other stakeholders
BREAK

• Visit us at www.pcori.org
PCORI Criteria for Research Questions

Questions should:

- **Be patient-centered**: Is the proposed knowledge gap of specific interest to patients, their caregivers, and clinicians?

- **Assess current options**: What current guidance is available on the topic and is there ongoing research? How does this help determine whether further research is valuable?

- **Have potential to improve care and patient-centered outcomes**: Would new knowledge generated by research be likely to have an impact in practice?

- **Provide knowledge that is durable**: Would new knowledge on this topic remain current for several years, or would it be rendered obsolete quickly by subsequent studies?

- **Compare among care options**: Which of two or more approaches to perinatal care lead to better outcomes for particular groups of patients?
Recap and Next Steps
We Still Want to Hear from You

- We welcome your input on today’s discussions
- We are accepting comments and questions for consideration on this topic through November 1, 2013 via:
  - info@pcori.org
- We will take all feedback into consideration
Thank You for Your Participation