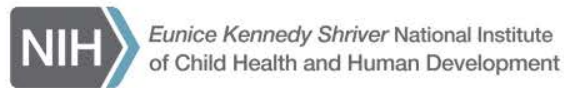


NIH/NICHD ACTIVITIES RELATED TO PREVENTING PRETERM BIRTH

Catherine Y. Spong, M.D.
Deputy Director





Overview of Today's Topics

- NICHD Research on Infant Mortality and Preterm Birth
- NICHD Health Education and Outreach
- Future NICHD Research Projects



NICHD Research on Infant Mortality and Preterm Birth



Our Research Portfolio on Preterm Birth

- Vast majority are researcher-initiated, spanning the spectrum from basic to clinical
- We also fund targeted clinical studies conducted by transdisciplinary networks
- Projects are wide-ranging in aim, e.g.:
 - Identifying mechanisms of preterm birth
 - Developing potential preventive measures
 - Improving care for preterm infants
 - Training young investigators





Preterm Birth and Maternal-Newborn Research Areas

Discovery

- Risk Factors
- Mechanisms and Pathways
- Therapeutic & biomarker target identification/validation

Key emphasis areas

- risk factors for preterm birth
- normative and atypical fetal development
- placental research (e.g., nutrition, microbiome)
- genetic/epigenetic factors and:
 - structural birth defects
 - IDD's
 - other conditions
- basic research supporting obstetric pharmacology
- understanding mechanisms of:
 - birth injury
 - NEC
 - other conditions
- basic biology of breastfeeding

Policy / Advocacy Communications

Key emphasis areas

- Understanding mechanism of labor
- Understanding basic science of normal and abnormal development

Development

- Biomarkers / Diagnostics
- Therapeutics / Interventions

Key emphasis areas

- clinical research in maternal-fetal medicine
- obstetric pharmacology
- effect of maternal illness and treatment during pregnancy
 - asthma
 - gestational diabetes
 - metabolic diseases
 - maternal obesity
 - infectious diseases
 - many others
- interventions to prevent preterm birth
- preeclampsia
- stillbirth
- medical devices for NICUs

Key emphasis areas

- Identifying interventions to improve outcome
- Identifying markers for normal and abnormal development

Delivery

- Implementation science / Operations research
- Health services
- Quality improvement

Key emphasis areas

- maternal safety interventions
- newborn screening, and prompt treatment of conditions detected via newborn screening
- supporting breastfeeding
- resuscitation interventions
- care and decision making for critically ill infants
- preventing HIV transmission to newborns
- optimizing treatment for HIV-infected mothers and infants
- research in international settings, especially in countries with limited resources

Key emphasis areas

- Safe Sleep for Infants (Safe to Sleep)
- Preventing Elective Preterm and Early Term Delivery



Maternal-Fetal Medicine Units (MFMU) Network

- Established to perform clinical trials to improve pregnancy outcomes, with emphasis on reducing preterm birth
- Undertaken >40 studies and trials; findings include:
 - Fetal fibronectin in early 2nd trimester associated with preterm birth
 - Progesterone prevents preterm birth in women with prior PTB
 - Vitamins C and E do not prevent preeclampsia
 - Broad spectrum antibiotics improve neonatal outcomes in women with premature rupture of membranes
 - Mag sulfate reduces risk of CP for women at risk of preterm delivery



Neonatal Research Network (NRN)

- Established to conduct observational and interventional studies to improve neonatal health outcomes
- Undertaken 18 observational studies and 31 interventional trials, some examples include:
 - CPAP shown to be as effective as traditional ventilator/surfactant therapy, but with fewer complications
 - The Necrotizing Enterocolitis Surgical Trial is testing different treatment strategies to find which increase survival rates without neurodevelopmental impairment at 18-22 months
 - ALPS aEEG – a study to determine if antenatal steroids affect maturation of the amplitude integrated electroencephalogram in late preterm infants



Nulliparous Pregnancy Outcomes Study: Monitoring Mothers-to-be (NuMOM2b)

- Aims to identify mechanisms and early predictors of adverse pregnancy outcomes (i.e., preterm birth, preeclampsia, fetal growth restriction, and stillbirth)
- Study pool: 10,000 racially, ethnically, and geographically diverse women in their first pregnancies; recruitment is ongoing





Intramural Perinatology Research Branch

- Conducts laboratory and clinical research on maternal and fetal diseases responsible for infant mortality; focused on mechanisms of premature labor and delivery, with emphasis on the role of subclinical intrauterine infection and inflammation
- Recent key finding: Multinational study showed vaginal progesterone for women with a short cervix reduced PTB <33 weeks by 45% and RDS by 61%
- Currently working to find biomarkers to identify patients at risk and to select strategies for prevention



Roberto Romero



Other Key Research Initiatives

- Genomics & Proteomics Network for Preterm Birth Research (GPN) – Uses genomic and proteomic strategies to uncover mechanisms of spontaneous premature birth; designed to be a resource to the scientific community with data readily available for secondary analysis
- And...




**Vaginal
Ultrasound
Cerclage Trial**




**Perinatal Alcohol and
SIDS and Stillbirth
Network**



Research findings impact clinical practice, leading to medical recommendations and treatments that improve patient outcomes



The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS



The Society for Maternal-Fetal Medicine

COMMITTEE OPINION

Number 561 • April 2013

The American College of Obstetricians and Gynecologists Committee on Obstetric Practice
The Society for Maternal-Fetal Medicine

This document reflects emerging clinical and scientific advances as of the date issued and is subject to change. The information should not be construed as dictating an exclusive course of treatment or procedure to be followed.

Nonmedically Indicated Early-Term Deliveries

ABSTRACT: For certain medical conditions, available data and expert opinion support opti-
ery in the late-preterm or early-term period for improved neonatal and infant outcomes. Howeve
indicated early-term deliveries such an improvement has not been demonstrated. Morbidity
are greater among neonates and infants delivered during the early-term period compared w
between 39 weeks and 40 weeks of gestation. Nevertheless, the rate of nonmedically indicat
erice continue to increase in the United States. Implementation of a policy to decrease the



The American College of Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS



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Medically Indicated Late-Preterm and Early-Term Deliveries

ABSTRACT: The neonatal risks of late preterm (34 0/7–36 6/7 weeks of gestation) and early-term (37 0/7–38 6/7 weeks of gestation) births are well established. However, there are a number of maternal, fetal, and placental complications in which either a late-preterm or early-term delivery is warranted. The timing of delivery in such cases must balance the maternal and newborn risks of late-preterm and early-term delivery with the risks of further

ACOG COMMITTEE OPINION

Number 419 • October 2008
(Replaces No. 291, November 2003)

Use of Progesterone to Reduce Preterm Birth

Committee on Obstetric Practice

ABSTRACT: Preterm birth affects 12% of all births in the United States. Recent
support the hypothesis that progesterone supplementation reduces preterm
select group of women. Despite the apparent benefits of progesterone, the
terone formulation is unknown. The American College of Obstetricians and
ts' Committee on Obstetric Practice and the Society for Maternal-Fetal
lieve that further studies are needed to evaluate the optimal preparation,
e of administration, and other indications for the use of progesterone for
n of preterm delivery. Based on current knowledge, it is important to offer
for pregnancy prolongation to only women with a documented history of a
taneous birth at less than 37 weeks of gestation.

ffects 12% of all births in the ... domly assigned to receive weekly intramus.



NICHD Health Education and Outreach



Safe to Sleep Campaign



- Since the campaign launched in 1994, overall U.S. SIDS rate declined by 50% across all racial/ethnic groups.
- The rate of back sleeping among infants has increased almost 200% since 1994.
- Data show risk factors for SIDS and infant mortality go beyond back sleeping.
- Risk factors include features in the sleep environment.



Recent Safe to Sleep® Outreach Efforts

- Developing a video for grandparents
- Improving the promotion of breastfeeding with safe sleep messaging
- Partnering with colleges/universities, community groups, and male-based organizations to conduct fatherhood outreach trainings
- Engaging with state health departments to spread word about campaign resources and outreach strategies
- More information: 1-800-505-CRIB (2742) or <http://safetosleep.nichd.nih.gov>



National Child & Maternal Health Education Program (NCMHEP)

- Uses a coalition of the nation's most prominent health care provider associations, federal agencies, nonprofit maternal and child health organizations, and other partners to review, translate, and disseminate new research in the field of maternal and child health
- First topic: late preterm birth and reducing elective deliveries before 39 weeks of pregnancy



Is It Worth It? Initiative to Reduce Elective Deliveries Before 39 Weeks

- Created 30-second, 60-second, and 4-minute versions of educational video for pregnant women and their families
- Produced a continuing education course with Medscape entitled Raising Awareness: Late Preterm Birth and Non-Medically Indicated Inductions Prior to 39 Weeks for physicians and nurses

Let that baby grow!

Why wait until at least 39 weeks?

WATCH THE VIDEO

nichd.nih.gov/ncmhiep/isitworthit



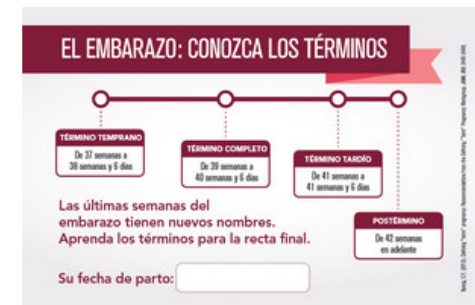
NATIONAL CHILD & MATERNAL HEALTH EDUCATION PROGRAM

 **NIH** Eunice Kennedy Shriver National Institute of Child Health and Human Development



Know Your Terms Initiative

- Educates about the precise definitions for the period between 37 weeks and 42 weeks gestation and to reflect the increased health risks to babies born before 39 weeks
- Produced an expert column continuing education course with Medscape for physicians and nurses
 - 18,227 total learners to date (5,490 doctors and 12,212 nurses and nurse practitioners)
 - 6,043 total earned credit to date (1,480 doctors and 4,563 nurses and nurse practitioners)
- 26,025 educational materials including posters, infocards and tear pads that are available in Spanish and English that have been shipped since October 2014



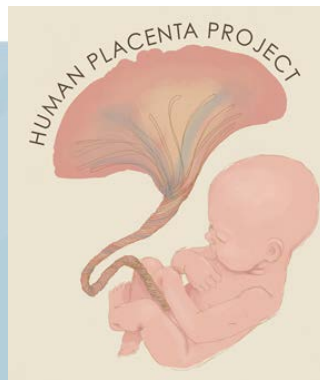
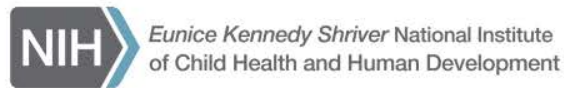


Future NICHD Research Projects

Human Placenta Project

Overarching goal:

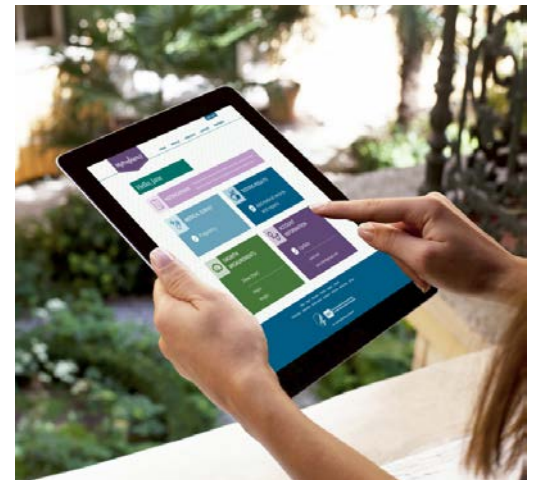
Understanding human placental development and function in real time





PregSource: Crowdsourcing to Understand Pregnancy

- A crowd-sourced, interactive, mobile app to:
 - Detail the natural history – and variations - of human pregnancy
 - Provide accurate info about pregnancy from trusted sources
 - Let pregnant women know about opportunities to participate in targeted research
- In early developmental stage with >15 partner organizations





Questions?