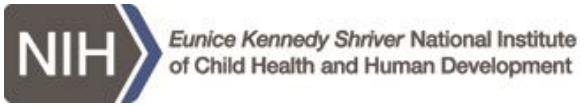
NICHD ACTIVITIES TO ADDRESS INFANT MORTALITY AND HEALTH DISPARITIES

Catherine Y. Spong, M.D.
Deputy Director

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

March 26, 2015



Overview of Today's Topics

- NICHD Research on Infant Mortality and Preterm Birth
  - Stillbirth and SIDS
  - Preterm Birth
- NICHD Health Education and Outreach
  - Safe to Sleep Campaign
  - National Child & Maternal Health Education Program (NCMHEP)
- Future NICHD Research Projects
  - The Human Placenta Project
  - MyPregnancy Project

NICHD Research on Infant Mortality and Preterm Birth

NICHD Research

- NICHD's research focuses on improving health, including:
  - Understanding and reducing sudden unexplained infant death – stillbirth and SIDS
  - Improving pregnancy outcomes, with a special emphasis on reducing preterm birth

Disparities in Perinatal Medicine

Preterm Birth, Stillbirth, and Infant Mortality

Catherine Y. Spong, MD, Jay Iams, MD, Robert Goldenberg, MD, Fern R. Hauck, MD, MS, and Marian Willinger, PhD

Infant mortality, stillbirths, and preterm births are major public health priorities with significant disparities based on race and ethnicity. Interestingly, when evaluating the rates over the past 30 to 50 years, the disparity persists in all three and is remarkably consistent. In the United States, the infant mortality rate is 6.7 deaths per 1,000 live births, the stillbirth rate is 6.2 per 1,000 deliveries, and the preterm birth rate is 12.8% of live births. The rates among non-Hispanic African Americans are dramatically higher, nearly double the infant mortality at 13.4 infant deaths per 1,000 live births, nearly double the stillbirth rate at 11.1 stillbirths per 1,000 deliveries, and one third higher with preterm births at 18.4% of live births. Despite numerous conferences, workshops, articles, and investigators focusing on this line of work, the disparities persist and, in some cases, are growing. In this article, we summarize a *Eunice Kennedy Shriver* National Institute of Child Health and Human Development workshop that focused on these disparities to identify the associated factors to determine their relative contributions, identify gaps in knowledge, and develop specific strategies to address the disparities in the short-term and long-term.

(Obstet Gynecol 2011;117:948–55)
DOI: 10.1097/AOG.0b013e318211726f

See related articles on pages 828, 837, and 850.

From the Pregnancy and Perinatology Branch, Eunice Kennedy Shriver *National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland; the Departments of Obstetrics and Gynecology, The Ohio State University, Columbus, Ohio, and Drexel University College of Medicine, Philadelphia, Pennsylvania; and Family Medicine and Public Health Sciences, University of Virginia, Charlottesville, Virginia.*

Dr. Spong, Associate Editor of Obstetrics & Gynecology, *was not involved in the review or decision to publish this article.*

Corresponding author: Catherine Y. Spong, MD, Chief, Pregnancy and Perinatology Branch, Eunice Kennedy Shriver *National Institute of Child Health and Human Development, National Institutes of Health, 6100 Executive Blvd, Room 4B03, MSC 7510, Bethesda MD 20892; e-mail spongc@mail.nih.gov.*

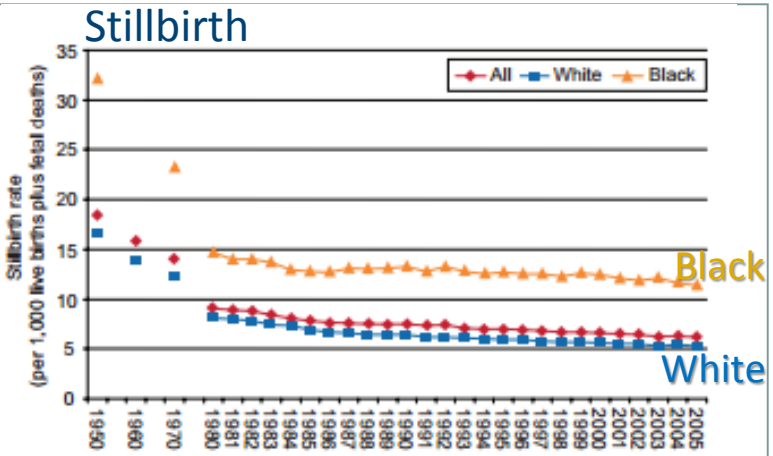
Financial Disclosure
The authors did not report any potential conflicts of interest.

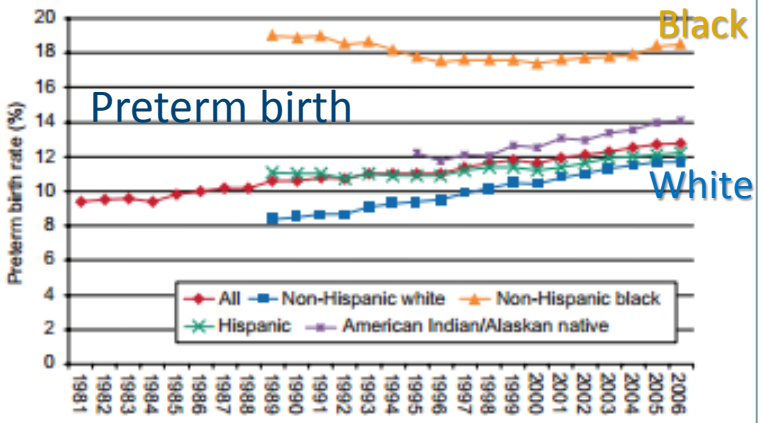
ISSN: 0029-7844/11

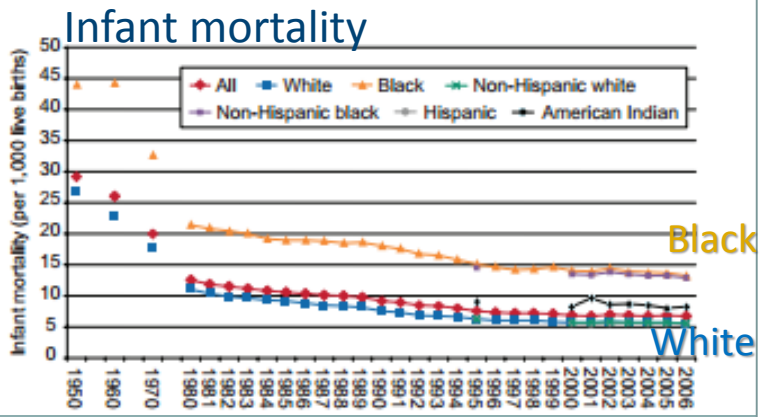
When analyzing the health conditions of a nation, one of the most important indicators is infant mortality. Because of strong efforts, the rate of infant mortality is decreasing worldwide; however, there are significant disparities between countries, regions, and ethnicities. Infant mortality in the United States has declined in the past century from 100 infant deaths per 1,000 live births in 1900 to 6.89 in 2000.[1] However, after 2000, the decline has stagnated and is far from the Healthy People 2010 target, which is 4.5 infant deaths per 1,000 live births. Other countries have been more successful in reducing infant mortality and, as a result, the United States' international ranking fell from 12th in 1960 to 29th in 2004.[2]

Infant mortality, stillbirths, and preterm births are major public health priorities, affecting 28,527 infants in 2006,[3] 25,894 fetuses in 2005,[4] and 542,893 pregnancies in 2006,[5] respectively. This translates to an infant mortality rate of 6.7 deaths per 1,000 live births, a stillbirth rate of 6.2 per 1,000 deliveries, and preterm births comprising 12.8% of live births in the United States. The rate of preterm birth has been increasing each year, with a 20% increase since 1990, and accounts for more than half a million preterm births in the United States annually.[5]

In addition to the significant burden, all three have significant disparities based on race and ethnicity, with higher rates in African Americans and Native American or Alaskan Native women. The rates among non-Hispanic African Americans are dramatically higher, nearly double the infant mortality at 13.4 infant deaths per 1,000 live births,[3] nearly double the stillbirth rate at 11.1 stillbirths per 1,000 deliveries,[4] and one third higher with preterm births at 18.4% of live births.[5] Remarkable is the consistency in the disparities in these three perinatal areas and, despite numerous conferences, workshops, articles, and investigators focusing on this line of work, the disparities persist and, in some cases, are growing.







Stillbirth Collaborative Research Network (SCRN)

- SCRN established in 2003 to examine the etiology and epidemiology of stillbirth, fetal death at ≥20 wks
  - surveillance, case-control, and follow-up studies
  - 5 geographic catchment areas
  - 59 hospitals enrolled stillbirths and livebirths (2006-2008)
- Case-by-case analyses: clinical history, postmortem examination of the fetus, and placental pathology
- Enrollment of 668 stillbirths and 1768 live births completed August 31, 2008

Stillbirth Risk

- 50% of stillbirths result from pregnancy disorders and conditions affecting the placenta
- Most stillbirths could not be accounted for by pregnancy history and other maternal characteristics at the time women learned they were pregnant
- Characteristics associated with increased stillbirth risk:
  - previous stillbirth
  - first-time mother
  - history of miscarriage
  - gestational diabetes
  - AB blood type
  - drug addiction
  - smoking 3 mo before pregnancy
  - maternal overweight and obesity

JAMA, Dec. 14, 2011 – Vol 306, No.22

Stillbirth Risk and Stress

- Two stressful events increased odds of stillbirth by ~40%
- Five or more stressful events increased stillbirth by nearly 2.5 times more than no stressful events
- Women reporting three or four significant life event factors (financial, emotional, traumatic or partner-related) remained at increased risk for stillbirth after accounting for other risk factors
- Black women reported experiencing more stressful events than non-Hispanic white and Hispanic women

Hogue et al. *Am J Epidemiol* 2013;177:755-767

Prenatal Alcohol and SIDS and Stillbirth (PASS) Network

- Established in 2003
- NICHD & National Institute on Alcohol Abuse and Alcoholism; National Institute on Deafness and Other Communication Disorders joined in 2009
- Community-linked studies to investigate the role of prenatal exposure to alcohol in SIDS and adverse pregnancy outcomes, such as stillbirth and fetal alcohol spectrum disorders (FASDs), and how SIDS and these other outcomes may be interrelated

PASS Safe Passage Study

- Two clinical sites:
  - Northern Plains of North America (South Dakota and North Dakota)
  - Western Cape of South Africa
- High rates of maternal alcohol consumption in pregnancy
- 12,000 pregnant women enrolled
  - Assessment during pregnancy
  - Fetal physiology
  - Infant follow-up through first year
- Follow up will be completed in 2016

Maternal Fetal Medicine Units (MFMUs) Network

- Obstetrical management, especially for high-risk patients, has often adopted practices without objective evaluation
- To respond to the need for well-designed clinical trials in maternal fetal medicine, NICHD established the MFMU Network in 1986
- Aim: Perform clinical trials to improve pregnancy outcomes, with emphasis on reducing preterm birth
- Has undertaken >40 studies and trials

Progesterone to Prevent Preterm Birth

- Weekly progesterone injections helped prevent recurrent preterm birth in specific women (those with a prior spontaneous birth at <37 weeks) and improved the neonatal outcome for pregnancies at risk
- Effective in both Black and White women

Meis *et al., N Engl J Med* 2003

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

ACOG COMMITTEE OPINION

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

Use of Progesterone to Reduce Preterm Birth

Committee on Obstetric Practice

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.

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

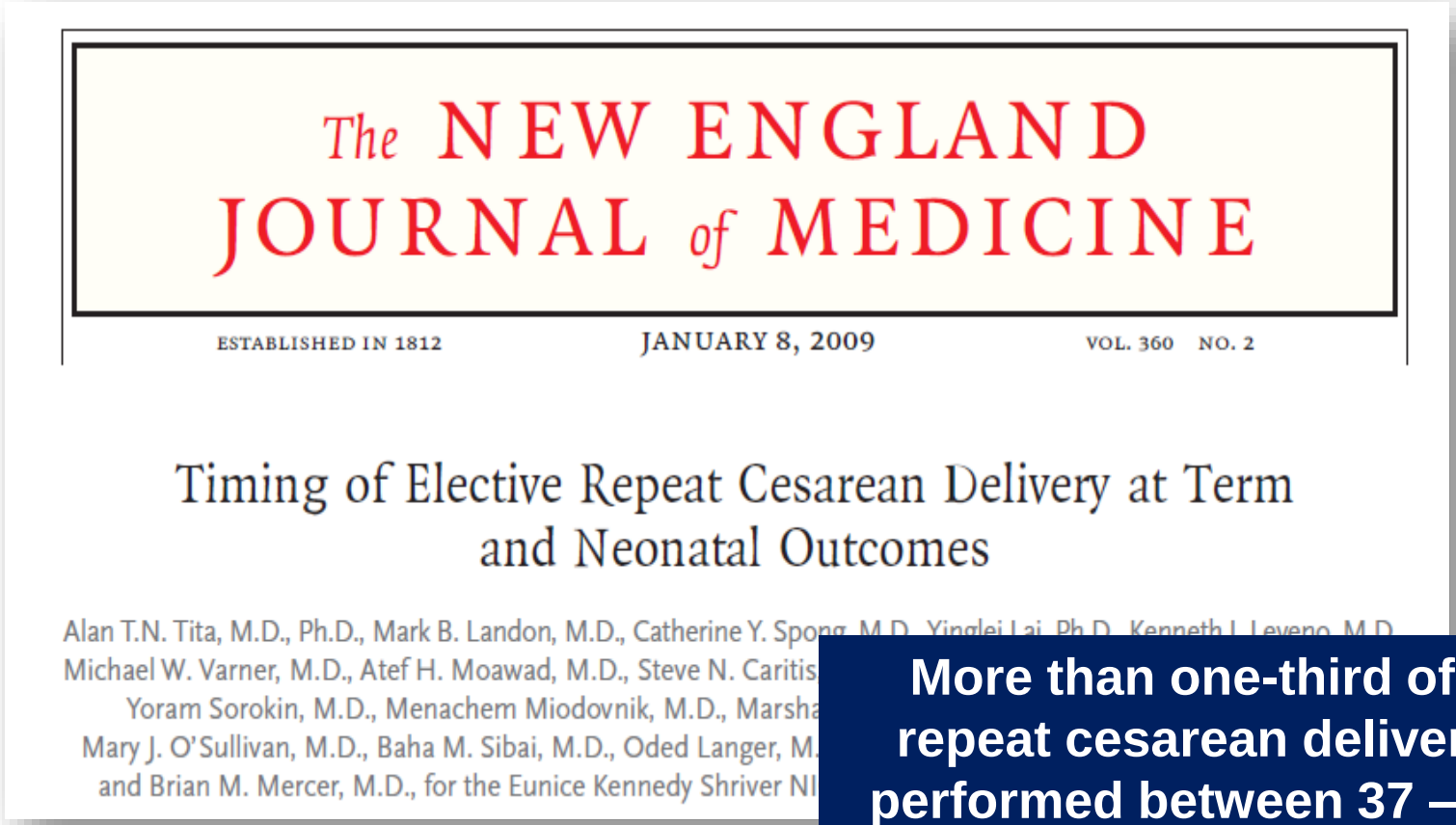
Impact on Practice: ACOG recommends use of progesterone to reduce preterm birth for women with prior spontaneous preterm birth

Obstet Gynecol 2008;112:963-5

ACOG

THE AMERICAN CONGRESS OF OBSTETRICIANS AND GYNECOLOGISTS

1982: Elective deliveries should not occur prior to 39 weeks' gestation



The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JANUARY 8, 2009 VOL. 360 NO. 2

Timing of Elective Repeat Cesarean Delivery at Term and Neonatal Outcomes

Alan T.N. Tita, M.D., Ph.D., Mark B. Landon, M.D., Catherine Y. Spong, M.D., Yinglei Lai, Ph.D., Kenneth J. Leveno, M.D., Michael W. Varner, M.D., Atef H. Moawad, M.D., Steve N. Caritis, Yoram Sorokin, M.D., Menachem Miodovnik, M.D., Marsha, Mary J. O'Sullivan, M.D., Baha M. Sibai, M.D., Oded Langer, M., and Brian M. Mercer, M.D., for the Eunice Kennedy Shriver NI

More than one-third of elective repeat cesarean deliveries were performed between 37 – 38 weeks

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 optimal timing of delivery in the late-preterm or early-term period for improved neonatal and infant outcomes. However, for nonmedically

"…a nonmedically indicated early term birth is *not appropriate*."

Nonmedically indicated early-term deliveries. CO No. 561. Obstet Gynecol 2013;121:911–5

VIEWPOINT

ONLINE FIRST

Defining "Term" Pregnancy

Recommendations From the Defining "Term" Pregnancy Workgroup

Catherine Y. Spong, MD

THE NATIONAL EMPHASIS ON REDUCING PRETERM BIRTH, and the increase in scheduled deliveries, has created confusion around the definition of term gestation. The concept of "term" gestation provides guidance to clinicians and influences the public's perception. In response to this confusion, the National Institute of Child Health and Human Development, the American Congress of Obstetricians and Gynecologists (formerly the American College of Obstetricians and Gynecologists), the American Academy of Pediatrics, the Society for Maternal-Fetal Medicine, the March of Dimes, and the World Health Organization (WHO) convened a meeting of experts and stakeholders on December 17, 2012, in Bethesda, Maryland, and this article reports recommendations from that workshop.

Workshop held at NICHD December 2012

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.

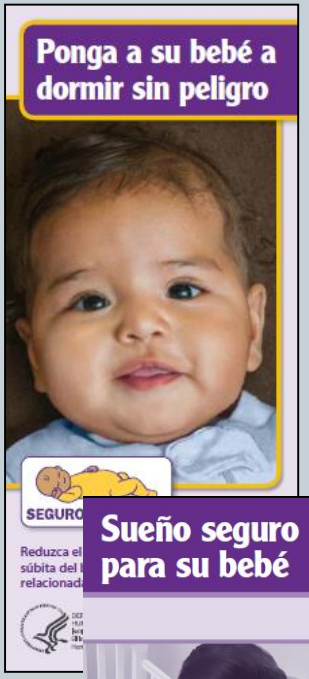
Then

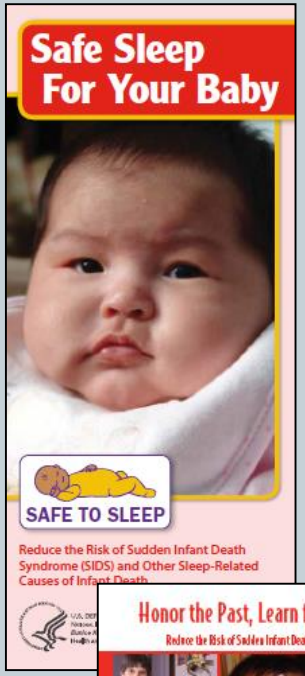
Now

Campaign Outreach Audiences

- General
- African Americans
- American Indians/Alaska Natives
- Spanish-speaking communities
- Health professionals (Nurses & Pharmacists)
- Statewide efforts (Mississippi, Arkansas)

Safe to Sleep® Campaign Materials





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

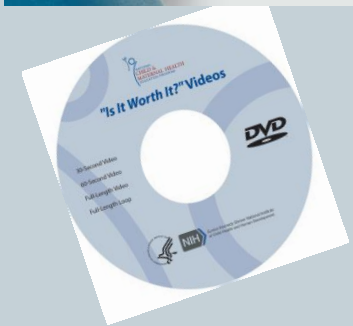
National Child & Maternal Health Education Program (NCMHEP)

- 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

NATIONAL CHILD & MATERNAL HEALTH EDUCATION PROGRAM

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
- Shipped 56,625 infocards that direct women to the video and the landing page on the NICHD website since August 2013



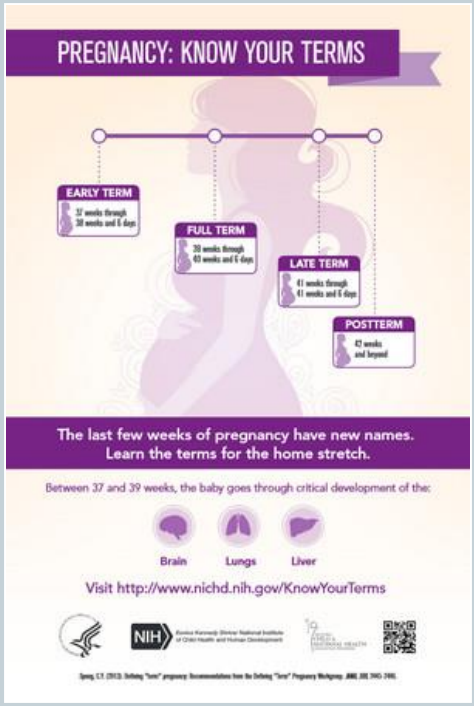
New Definition of Full-Term Pregnancy: Know Your Terms Initiative

- In response to new, more 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, NICHD created Know Your Terms Initiative
- 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

Outreach Success Stories

- All Blue Shield of California members who enroll in their prenatal education program (~9,500 to 10,000 women per year) will receive an educational packet in the mail with Know Your Terms and Is It Worth It? materials.
- Carilion Clinic in Virginia shares the Is It Worth It? postcard with each expectant mother during her 36 week visit (~3,000 women per year)
- Is It Worth It? videos has been shown in 141 OB clinic waiting rooms in 2013 and 212 OB clinic waiting rooms in 2014

Available NCMHEP Materials



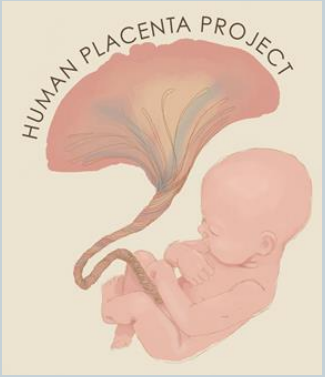
Visit
http://www.nichd.nih.gov/ncmhep/terms/ordermaterials
or call 1-800-370-2943

Future NICHD Research Projects

Human Placenta Project

Overarching goal:

Understanding human placental structure and function in real time



Why A Human Placenta Project?

- The least understood human organ
- One of the most important, for
  - Maternal health
  - Fetal health and development
  - Lifelong health of the mother
  - Lifelong health of the resulting child

What An Organ...

- Only organ grown and discarded (more than once)
- Functions as many organs: liver, lungs, kidney, etc.
- Functions via many pathways: endocrine, immune, etc.
- Impacts not only maternal and fetal health but also lifelong health of mother and child
- A model organ(ism)
  - Programmed vascular growth
  - Programmed cell death
  - Symbiotic immune function
  - Placenta as tumor

But…

- Vast majority of analyses of the post-functional state; and often histological only
- Animal models helpful, but with limited applicability to humans
- *In vivo* human assessment difficult due to inaccessibility and issues of fetal safety
- Increased knowledge of structure, function, and development in the human would enhance pregnancy management and inform other aspects of science and medicine

THE PLACENTA

A VITAL ORGAN FOR BABY, MOM, AND SCIENCE

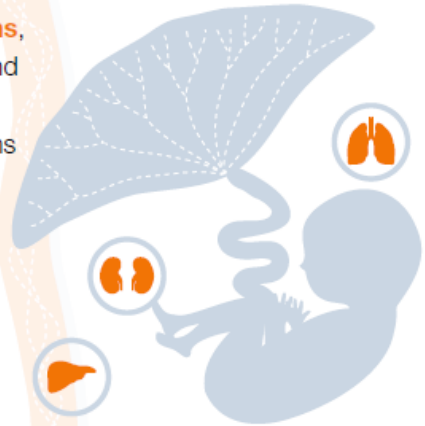
What is the placenta?

A temporary organ linking mother and fetus—brings nutrients and oxygen to and moves harmful waste and materials away from the fetus.

Oxygen | Nutrients | Protection

What does the placenta do?

- **It performs multiple functions**, acting as the lungs, kidneys, and liver, and the gastrointestinal, endocrine, and immune systems for the fetus.
- **It produces hormones** to help maintain pregnancy and support fetal development.
- **It protects** the fetus from the mother's immune system.



Why is the placenta so important?

- **Vital for pregnancy, it plays a big role in pregnancy outcomes.** Problems with the placenta can result in conditions like preeclampsia, gestational diabetes, prematurity, and stillbirth.
- **It can influence lifelong health.** Problems with the placenta can be a marker, maybe even a cause, of later disease of mother and child.

What does science say?

Scientists are still learning what a "normal" placenta is and how it functions.

Many past studies were limited to analyzing the placenta **after** delivery.

New technologies may allow scientists to safely study the placenta **during** pregnancy.

Learning more about the placenta could:

- Pave the way for **new treatments to improve the health of mom and baby**, during pregnancy and throughout their lives.
- Provide **insights into other important health issues** like organ transplantation and cancer treatment.

Human Placenta Project (HPP)
http://go.usa.gov/5J3z

Human Placenta Project Goals

- Improve current methods, and develop new technologies, for real-time assessment of human placental structure and function across gestation
- Apply these technologies to understand and monitor, in real time, placental development and function in normal and abnormal human pregnancies
- Develop and evaluate non-invasive markers of placental dysfunction for prediction of adverse human pregnancy outcomes
- Understand the contributions of placental development to long-term human health and disease
- Develop interventions to prevent abnormal human placental development, and hence improve pregnancy outcome

HPP Timeline

Workshop 1
May 2014

R01/R21 RFA for
novel tool development
Due Feb 19, 2015

Workshop 2
April 27-28 2015
Omics/Imaging

U01 RFA for innovations
for in vivo human
placental assessment
Due June 1, 2015

New RFAs
FY 2016

First RFA
Awards FY16

Workshop 3
2016

Goal: understand human placental structure & function in real time

MyPregnancy: Another Aid for Research?

- A crowd-sourced, interactive, mobile app to:
  - Detail the natural history – and variations - of human pregnancy
  - Provide accurate information about pregnancy from trusted sources
  - Let targeted pregnant women know about opportunities to participate in research
- In early stages of development

Now it’s your turn…

Comments, questions?