School of Medicine

Infant Mortality Summit

Valerie M. Parisi, M.D., M.P.H., M.B.A.
Dean, School of Medicine
Wayne State University
October 17, 2011

70% of Infant Mortality is Attributable to Premature Birth

School of Medicine

Overview

- Medical Research Background
- Recommended Clinical Interventions
  - Universal Cervical Length Screening and Progesterone Gel for the Prevention of Preterm birth
  - Planned Delivery
  - Back to Sleep
- Impact on State
  - Economic Impact/Cost Savings
  - Lives Saved/Improved Quality of Life

School of Medicine

The Prognosis of Preterm Neonates is a Function of Gestational Age at Birth

School of Medicine

Born Too Soon

Preterm Birth -
Leading cause of infant mortality

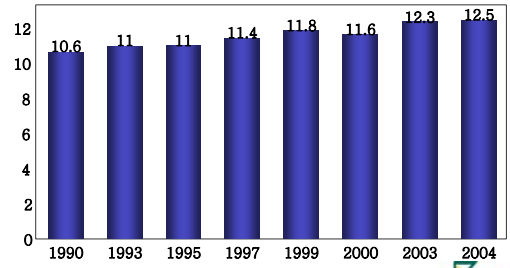
IOM Report – July 2006

"Babies born before 32 weeks have the greatest risk for death and poor health outcomes, however, infants born between 32 and 36 weeks, which make up the greatest number of preterm births, ***are still at higher risk for health and developmental problems compared to those infants born full term***"

IOM Report page 72

School of Medicine

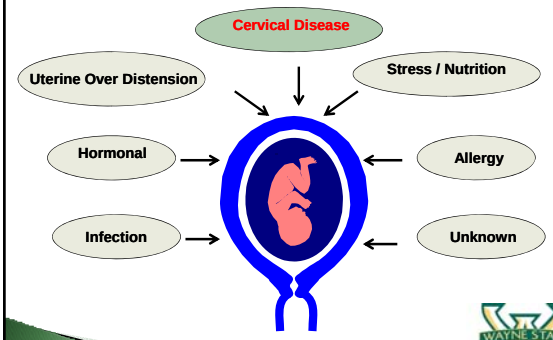
Preterm Births as a Percentage of Live Births in the United States,1990 to 2004



Institute of Medicine. PRETERM BIRTH: CAUSES, CONSEQUENCES, AND PREVENTION. 2006.

School of Medicine

Factors Contributing to Preterm Birth



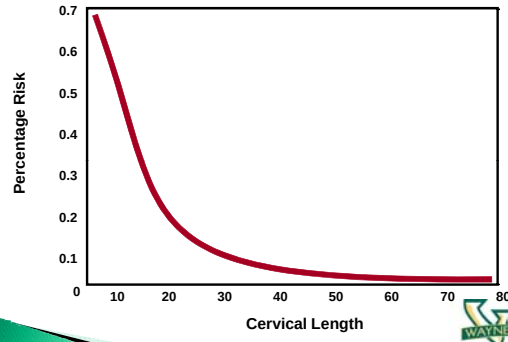
School of Medicine

Academic Medicine Sub-Committee

- **Goal: Identify key clinical interventions that can make the largest impact in the shortest amount of time.**
- **Committee members**:
  - Valerie M. Parisi, M.D., M.P.H., M.B.A. – Dean, WSU School of Medicine
  - Sonia Hassan, M.D. – Director, Center for Advanced Obstetrical Care & Research Perinatology Research Branch, NICHD; Professor, OBGYN, WSU School of Medicine
  - Timothy Robert B. Johnson, M.D. – Chair, Department of OB-GYN, University of Michigan
  - Richard E. Leach, M.D. – Chair, Department of OB-GYN, Michigan State University
  - Robert Lorenz, M.D. – Chair, Department of OB-GYN, Beaumont/ACOG Rep
  - Jean Chabut – Deputy Director, Public Health Administration, MDCH
  - Alethia Carr - Director, Bureau of Family and Maternal and Fetal Health, MDCH
  - Douglas Skrzyniarz – Senior Director of External Affairs, WSU School of Medicine
  - Sandra Frank - Chief Executive Officer, Tomorrow's Child
  - Lynne C. Smitherman, M.D. – Residency Program Director, Children's Hospital of Michigan

School of Medicine

Risk of Spontaneous Preterm Delivery at ≤32 Weeks Among Women with Measured Cervical Length Between 14-24 Weeks



School of Medicine

Hassan SS, Romero R, Berry SM, Dang K, Blackwell SC, Treadwell MC, Wolfe HM. Am J Obstet Gynecol 2000;182:1458

Prioritizing Clinical Interventions

- Submission of position papers for interventions
- Peer review and discussion by committee
- Decision based on scientific evidence of potential impact on infant mortality, subsequent child, adolescent and adult health, and Michigan economy
  1. Identifying & treating women with a short cervix – Progesterone Study
  2. Eliminate planned deliveries prior to 39 weeks
  3. Comprehensive Back to Sleep programming

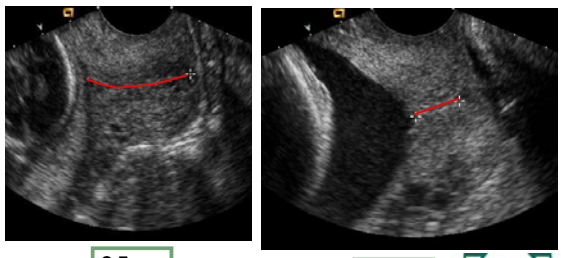
School of Medicine

A sonographic short cervix is a powerful predictor of spontaneous preterm birth

Anderson et al 1990, Kushnir et al 1990, Okitsu et al 1992, Iams et al 1994, 1995, 1996, Hasegawa et al 1996, Berghella et al 1997, Goldenberg et al 1998, Guzman et al 1998, Heath et al 1998, Taipale et al 1998, Watson et al 1999, Andrews et al 2000, Hibbard et al 2000, Hassan et al 2000, To et al 2001, Owen et al 2001, Durnwald et al 2005, Matijevic et al 2006

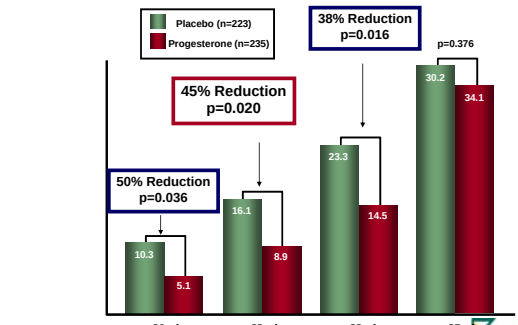
School of Medicine

A short cervix can be diagnosed by ultrasound



School of Medicine

Gestational Age at Delivery



Perinatology Research Branch

Hassan S, Romero R, Vidyadhari D, et al Ultrasound Obstet Gynecol. 2011 Apr 6

School of Medicine

School of Medicine

Progesterone reduced the rate of Respiratory Distress Syndrome by 61%

placebo 7.6% vs. progesterone 3% vs. p=0.03

Hassan S, Romero R, Vidyadhari D, et al Ultrasound Obstet Gynecol. 2011 Apr 6

School of Medicine

Methods of Study

- Double blind, randomized clinical trial
- Patients 19 – 23 6/7 weeks
- Short cervix (10 – 20 mm)
- Vaginal progesterone gel vs. placebo
- Primary outcome: delivery < 33 weeks

School of Medicine

Summary

- Reduced the rate of preterm birth
- Reduced the rate of neonatal morbidity
- Safe for use in pregnancy
- Easy use and well-tolerated by patients

School of Medicine

Progesterone Gel

- If women are found to have a cervical length 10 – 20 mm, treatment with vaginal progesterone gel is indicated
- The vaginal progesterone gel is available by prescription as Prochieve 8% or Crinone 8%
- Self-administered as a once daily dose of one applicator (90 mg)
- There was no safety signal in the multi-center trial and over past 12 years of use in first trimester

School of Medicine

Clinical Recommendation Prevention of Preterm Birth

- Universal Cervical Length Screening
  - Access to Vaginal Ultrasound at 19th week
  - Ensure regional access to equipment
  - Provide diagnostic training
  - Provide insurance coverage
- Treatment Standard with Vaginal Progesterone Gel
  - Ensure affordability, insurance coverage, product availability on formularies
- Collect statewide patient data on 19th week cervical length screening

School of Medicine

Prochieve® 8% (progesterone gel)

- FDA Approved for use in the first trimester – 12 years
- Adheres to vaginal tissue, helping to reduce leakage and eliminate messiness of other vaginal deliveries
- Eliminates injection-site pain of IM administration

Source: Columbia Laboratories

School of Medicine

Planned Delivery

Eliminating Non-Medically Indicated Deliveries

Economic Impact

- Premature births costs U.S. nearly $26 billion per year
- Universal Screening of cervical length is cost-effective if cervical ultrasound is < or = $186/scan*
  - Assuming an effect size of 45% and no improvement in infant outcome
  - Cost savings $19,603,380 (in 2010 dollars) for every 100,000 women screened
  - Michigan has ~ 110,000 births annually

** Werner EF, Han CS, Pettker CM, et al. Ultrasound Obstet Gynecol. 2011 Jul;38(1):18-31*

School of Medicine

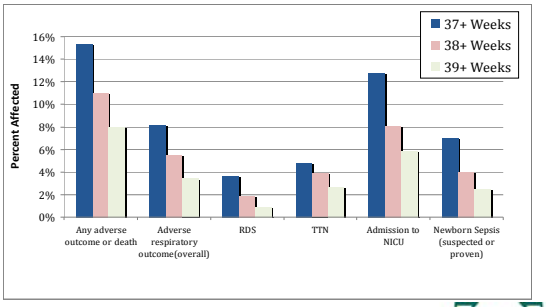
Planned Delivery

- Non-medically indicated (Elective) deliveries before 39 weeks are associated with significant neonatal morbidities
- Applies to both induction of labor and elective caesarean deliveries

Tita ATN, Landon MB, Spong CY, Lai Y, Leveno KJ, Varner MW, et al. Timing of elective cesarean delivery at term and neonatal outcomes. The New England Journal of Medicine 2009 January;360:111-20.

School of Medicine

Adverse Neonatal Outcomes According to Completed Week of Gestation at Delivery: Absolute Risk



Tita AT, et al, NEJM 2009;360:111
www.acog.org

School of Medicine

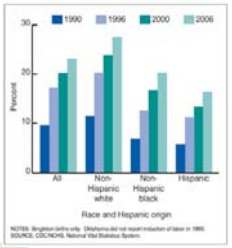
Risks (continued)

- Late preterm and possibly early term deliveries may increase neonatal risk of brain injury and long-term neurodevelopmental abnormalities
  - Approximately 50% of cortical volume growth occurs between 34 and 40 weeks
  - At 37 weeks, the brain weighs only 80% of the weight at 40 weeks and gray matter volume increases at a rate of 1.4% per week between 36 and 40 weeks

School of Medicine

Demographics

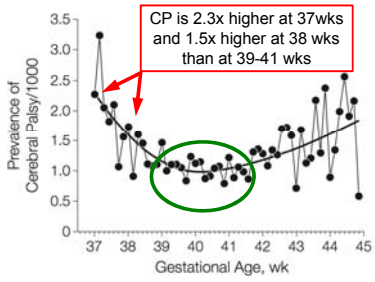
- The rise of induction of labor is present in **all** racial groups with the highest increase in Non-Hispanic whites



Rise in Induction of Labor by Racial Groups in the U.S.

School of Medicine

Cerebral Palsy among Term and Postterm Births



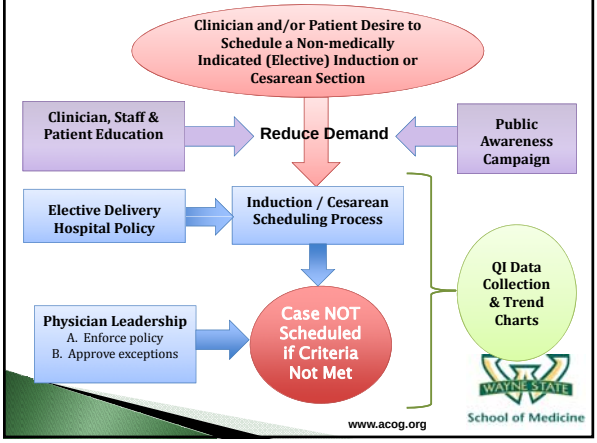
Norwegian birth cohort of 1,682,441 singleton term births without congenital anomalies followed for a minimum of 4 years (maximum of 20 years) with identified CP in the National Health Insurance Registry.
Moster et al. JAMA 2010;304:976-982.

School of Medicine

Risks of Deliveries Before 39 Weeks

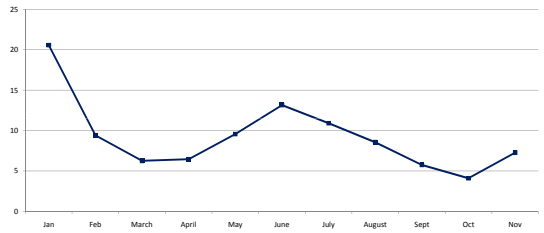
- Increased NICU admissions
- Increased transient tachypnea of the newborn (TTN)
- Increased respiratory distress syndrome (RDS)
- Increased ventilator support
- Increased suspected or proven sepsis
- Increased newborn feeding problems and other transition issues

School of Medicine



School of Medicine

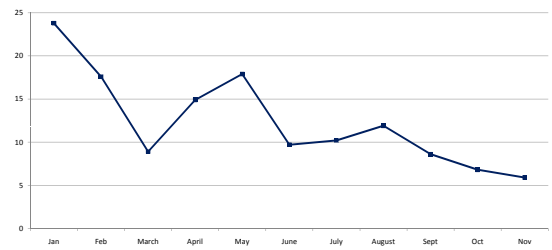
% Elective Inductions < 39 wks



Back to Sleep

Reduce Incident of
Sudden Unexpected Infant Death (SUID)

% Elective Cesarean Births < 39 wks



Sudden Unexpected Infant Death (SUID)

WAYNE STATE
School of Medicine

Clinical Recommendation
Planned Delivery

- Develop a consensus on standard of practice across all providers and hospitals in the state on risks of delivery before 39 weeks
- Work with medical schools and other health science programs in the state to include in curriculum
- Educate providers, payors, hospitals and patients
- Review annually number of deliveries at each week of gestation 34, 35, 36, 37, 38 to assess effectiveness of intervention
- Best outcomes occur at 39 and 40 weeks!

WAYNE STATE
School of Medicine

Sudden Unexpected Infant Death

Major Risk Factors

- Bed sharing
- Overheating
- Preterm birth
- Low Birth Weight

WAYNE STATE
School of Medicine

Back to Sleep

- History
  - *Back to Sleep* and *Safe Sleep*
  - Back to Sleep was recommended in 1992 by the American Academy of Pediatrics
  - 1994 – National *Back to Sleep* – Public health campaign
  - 2006 – NIH *Back to Sleep*: *Safe Sleep for your Baby*

School of Medicine

Michigan Post-neonatal Deaths

POSTNEONATAL DEATHS BY SPECIFIC CAUSE, MICHIGAN RESIDENTS 2007-2009

CAUSE OF DEATH	2007	2008	2009
SUDDEN INFANT DEATH SYNDROME (R95)	42	44	37
OTHER SUDDEN DEATH, CAUSE UNKNOWN (R96)	1	0	0
UNKNOWN CAUSE OF DEATH (R97)	0	0	1
UNATTENDED DEATH (R98)	1	1	2
OTHER ILL-DEFINED AND UNSPECIFIED CAUSE OF DEATH (R99)	6	1	3
ACCIDENTAL SUFFOCATION AND STRANGULATION IN BED (W75)	50	51	57
UNSPECIFIED THREAT TO BREATHING (W84)	5	4	1
HANGING, STRANGULATION AND SUFFOCATION, UNDETERMINIED INTENT (Y20)	2	4	5
UNSPECIFIED EVENT, UNDETERMINED INTENT (Y34)	0	0	1
TOTAL	107	105	107

SOURCE: 2007-2009 INFANT DEATH FILE, VITAL RECORDS AND HEALTH DATA DEVELOPMENT SECTION, MDCH

School of Medicine

AAP Guidelines

- Infants should be on BACKS for every sleep
- Firm sleep surface with fitted sheet
- Soft objects and loose bedding out of the crib
- Do not smoke or let others smoke
- Do not share a bed with your baby
- Avoid overheating baby
- Encourage "tummy time" when baby is awake
- Make sure everyone caring for your baby knows these guidelines

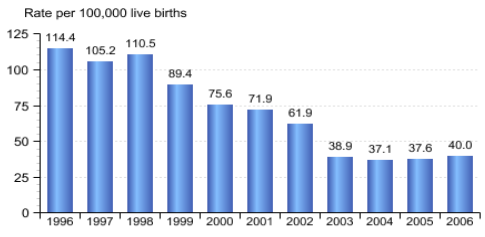
School of Medicine

Causation & Impact Data

- Well-designed epidemiologic studies
  - Plausible causal associations between modifiable risk factors and increased odds ratio of SUID
    - Prone sleep
    - Soft sleep surface/bedding
    - Maternal smoking during pregnancy
- Meta-analyses suggest additional modifiable risk factors
  - Increase the risk of SUID
    - Bed sharing
    - Overheating
    - Preterm birth
    - LBW
  - Reduce the risk of SUID
    - Pacifier use

School of Medicine

Infant deaths due to Sudden Infant Death Syndrome: Michigan, 1996-2006



School of Medicine

Disparity Data

2008 Michigan Pregnancy Risk Assessment and Monitoring (PRAMS)

- Infant back sleep position
  - 75% of white mothers report back sleep
  - 56.1% of African American mothers report back sleep
- Bed sharing with infant
  - 45% of white mothers report never bed sharing
  - 19.3% of African American mothers report never bed sharing

School of Medicine

Interventions

- Evidence-based risk reduction strategies
  - 2011 AAP recommendations
- Focus - Communities with highest disparity rates in Michigan
- Institutionalize the interventions
- Across systems within communities
  - Measurable outcomes
  - Consistent message/intervention across systems

School of Medicine

Clinical Recommendation
Back to Sleep

- Use 2011 AAP recommendations as guidelines for all Infant Safe Sleep efforts in Michigan
- Integrate Infant Safe Sleep education into Michigan medical and nursing school curricula
- Provide distance learning and electronic education resources for providers, hospitals and patients
- Initiate media and social media efforts
- Continue current safe sleep education efforts

School of Medicine

Interventions
Individuals and Communities

- Dose dependent, i.e., more advice = more likely to follow
- Target highest risk populations and communities; those who influence them
- Address social determinants influencing behavior and practice
- Address parental concerns
- Communication strategies modified from 'lecture' to conversation

School of Medicine

Preventing Infant Mortality in Michigan

- We have effective, evidence-based medical interventions
- Implementation of progesterone treatment for women with short cervix
- Eliminate planned deliveries less than 39 weeks
- Fully implement safe sleep practices
- Data tracking
- Annual Infant Mortality Symposium

School of Medicine

Evidence-Based Interventions

- Not well-established for SUID prevention
- Cross-sectional interviews and random sample interview studies on effects of beliefs and advice
  - Advice from physician or nurse = more likely to report behaviors reducing risks
- National studies on back sleep
  - Mothers report 56% of doctors/44% of nurse exclusively recommend back sleep
  - 77% of physicians report exclusively recommending back sleep

School of Medicine

THANK YOU FOR MAKING A DIFFERENCE!