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October 17, 2011

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

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

Born Too Soon

Preterm Birth - Leading cause of infant mortality

70% of Infant Mortality is Attributable to Premature Birth

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
Goal: Identify key clinical interventions that can make the largest impact in the shortest amount of time.

Committee members:
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- Sandra Frank – Chief Executive Officer, Tomorrow’s Child
- Lynna C. Smitherman, M.D. – Residency Program Director, Children’s Hospital of Michigan

Factors Contributing to Preterm Birth

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

A short cervix can be diagnosed by ultrasound

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

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
**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.

**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.

**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

**Planned Delivery**

**Eliminating Non-Medically Indicated Deliveries**

**Economic Impact**

- Premature births cost 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.


**Planned Delivery**

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

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

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

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

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

Cerebral Palsy among Term and Postterm Births
- CP is 2.3x higher at 37wks and 1.5x higher at 38 wks than at 39-41 wks

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.

Clinician and/or Patient Desire to Schedule a Non-medically Indicated (Elective) Induction or Cesarean Section
- Physician Leadership
  A. Enforce policy
  B. Approve exceptions
- Case NOT Scheduled if Criteria Not Met
- Reduce Demand
- Public Awareness Campaign
- QI Data Collection & Trend Charts
**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!

**Sudden Unexpected Infant Death (SUID)**

- Major Risk Factors
  - Bed sharing
  - Overheating
  - Preterm birth
  - Low Birth Weight
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

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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

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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

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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
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

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

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

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

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

THANK YOU FOR MAKING A DIFFERENCE!