Evidenced-Based Practice Update:
Strategies to Prevent Preterm Birth

Prematurity Prevention Summit 2016
Utah Women and Newborn Quality Collaborative
Maternal Intervention Committee
Frank Powers, MD, Sean Esplin, MD, Julia Johnson, MPH
Prematurity Prevention Summit
LDS Hospital
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Acknowledgments
- Sean Esplin, MFM
- Erin Clark, MFM
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Utah Women and Newborn Quality Collaborative (UWNQC)
- Statewide multi-stakeholder network designed to improve perinatal outcomes in Utah
- Mission: "Improve maternal and neonatal outcomes through collaborative efforts centered around quality improvement methodology and data sharing"
Preterm Birth

- 1 in 8 births in US (12%)
- Utah singleton PTB rate 9.5% (in 2010)
- Estimate cost in US $26 billion per year ($51,000 per infant)
- Leading cause responsible for 85% of all perinatal morbidity and mortality

Risk Factors for Preterm Birth

- Personal history of preterm birth — Strongest
- Incidental Short Cervix
- Unintended pregnancy
- Short inter-pregnancy interval

Impact of Recurrent Preterm Birth

- 15% of all preterm births are recurrent preterm births
  - 75,000 of the 500,000 PTB in the US annually
- Interventions including progesterone reduce rate by up to 30%
  - Estimated that 10,000 PTB prevented annually*
- The only type of PTB that can be accurately predicted

**Progesterone Therapy**

- Meta-analysis of randomized trials
  - 7 trials of 17OHP to prevent recurrent PTB
  - Use 17 OHP 250 mg IM weekly beginning at 16-20 weeks
  - Risk for PTB < 37 wks - 1020 women enrolled
    - RR = 0.58, 95% CI = 0.48-0.70
  - Risk for infant with birth weight of < or =2.5 kg - 872 infants
    - RR = 0.62, 95% CI = 0.49-0.78
  - Risk of an infant diagnosed with intraventricular hemorrhage - 458 infants
    - RR = 0.25, 95% CI = 0.08-0.82

**Vag P vs. 17 OHPC**

- Prospective randomized trial for women with history of SPTB
  - 90 mg vaginal progesterone gel daily (n=253)
  - 250 mg 17 OHPC weekly (n=249)
  - Started at 14-18 weeks
- Inclusion
  - Singleton between 14 and 18 weeks gestation
  - History of previous SPTB
    - Included women who had cerclage in previous pregnancy

**Vag P vs. 17 OHPC**

- Primary outcome GA at < 34 weeks gestation
  - Vag P 42/253 (16%)
  - 17 OHPC 64/249 (25.7%)
  - P = 0.02
  - OR 0.58 (95%CI 0.37-0.89)

**17 P**

**The Bottom Line**

- Screen all patients for history of SPTB
  - Live birth between 20 weeks 0 days and 36 weeks 6 days
  - Any type of delivery after spontaneous labor, PPROM, Abruption or Silent cervical dilation
- For previous deliveries between 16 -24 weeks
  - Consider prophylactic cerclage
17P
The Bottom Line

• Progesterone therapy
  – 1st Line 17 OHPC
    • Dose is 250 mg IM weekly
    • Start at 16 weeks if possible but still some affect as late as 24 weeks
    • Use Makena if possible but may use compounded if insurance issue or allergy documented
  – 2nd Line Vaginal Progesterone
    • Natural progesterone 200 mg suppository
    • Crinone gel 90 mg nightly

How to get 17P

• Rx for 17-OH progesterone 250mg/ml
  – 250mg IM weekly 16-36 weeks
• ICD 10 “Supervision of pregnancy with history of preterm labor” (second, third, unspecified trimester)
  – 009.212, 009.213, 009.219
• Makena only FDA-approved formulation

Progesterone Therapy and...

• Not for twins or triplets
• Not for women with symptomatic labor unless previous history of PTB
• Still offer 17 OHPC even if last delivery was at term
• Progesterone and cervical shortening
  – Start treatment if not previously initiated
  – 17 OHPC vs vaginal progesterone

How to get 17P

• Cost $15,000 per pregnancy ($690 per injection)
• Co-pay and insurance coverage varies
• Patient assistance programs
  – Free for unfunded patients who meet eligibility
  – Co-pay assistance (Medicaid, Tricare not eligible)
• UWNQC recommends facility establishes protocol
The role of cerclage

Which patient and when

**History of SPTB and Short Cervix**

- Meta-analysis of 5 trials
- Women with a history of SPTB and short cervix (<2.5 cm) n=504
- Rate of PTB < 35 weeks
  - 28.4% (71/250) in the cerclage compared with 41.3% (105/254) in the no cerclage groups
  - (relative risk 0.70, 95% confidence interval 0.55–0.89)
- Cerclage also significantly reduced
  - PTB < 37, 32, 28, and 24 weeks of gestation.
  - Composite perinatal mortality and morbidity (15.6% in cerclage compared with 24.8% in no cerclage groups; relative risk 0.64, 95% confidence interval 0.45–0.91).

Berghella et al. Obstet Gynecol 2011; 117:663

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### Evaluation and Treatment of Short Cervix

#### Gestational Age < 24 weeks

- **Evaluation and treatment of short cervix**
  - Cervical Length < 1.5 cm or visible membranes
    - Tocometry
    - Rule Out Contractions
  - Positive contractions
    - Offer Cerclage
    - Admit to hospital for active tocolysis with Indocin
    - Follow-up in 1-2 weeks
  - Negative contractions
    - Initiate progesterone if not previously done
    - Follow-up in 1-2 weeks

#### Gestational Age > 24 weeks

- **Evaluation and treatment of short cervix**
  - Cervical Length 1.0-2.5 cm
    - Tocometry
    - Rule Out Contractions
  - Positive contractions +/− Cervical change
    - Admit to hospital for active tocolysis with Indocin
    - Treat with steroids if not done previously
    - Reevaluate cervical length in 48 hours
  - Negative contractions
    - Initiate progesterone if not already done
    - Follow-up in 1-2 weeks

- **Cervical Length < 1.0 cm**
  - Admit to hospital for active tocolysis with Indocin
  - Treat with steroids if not done previously
  - Reevaluate cervical length in 48 hours

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Berghella et al. Obstet Gynecol 2011; 117:663
Screen for risk

At first prenatal visit:
• Does the patient have a history of any preterm birth (PTB)?
  • Confirm EDC
  • Confirm singleton pregnancy

Does the patient have:
• A history of spontaneous PTB?
  • Singleton live birth between 16 and 36 weeks gestation?
  • Includes presentation as labor, PPROM, or advanced cervical dilation

Yes
  No

Was PTB between 16 and 24 6/7 weeks?

Cervical length < 25 mm?

Start vaginal progesterone 200 mg per vagina QHS
• May substitute Crinone Gel

Yes
  No

Cervical length < 15 mm?

• Consider ultrasound indicated cerclage placement
  • Continue 17P or switch to Vag P

Yes
  No

Consider evaluation of cervical length
At time of anatomic survey (Ultrasound)

How to get 17P

• Rx for 17-OH progesterone 250mg/ml
  – 250mg IM weekly 16-36 weeks
• ICD 10 “Supervision of pregnancy with history of preterm labor” (second, third, unspecified trimester)
  – O09.212, O09.213, O09.219
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Thank You
Transferring Smoothly: The State of Out-of-Hospital Birth Transfers in Utah

Disclosure

◦ I am an obstetrician...
◦ ...An obstetrician sympathetic to a woman’s right to choose where and how to deliver

Transitioning Smoothly

Acknowledgement of two truths is necessary in order to have this conversation:

◦ 1. Women are going to continue to choose to deliver at birth centers and at home.
◦ 2. Women are occasionally going to need transfer to a hospital for management of complications / concerns.

Transitioning Smoothly

◦ The relative rarity of the event only makes the topic more relevant, because it is hard to do something really well, when we only do it occasionally.
Objectives

- Introduce UWNQC Out-of-Hospital Birth Subcommittee
- Mission, members, work-to-date
- Tools derived from the collaborative
- Opportunities for future work

Out-of-Hospital Birth Subcommittee: Mission

First convened, November 2013

1) Analysis of the current state of out-of-hospital births in Utah
2) Identification of maternal and neonatal safety issues related to out-of-hospital birth and transfers
3) Creation of statewide action items

Out-of-Hospital Birth Subcommittee: Members

- Multi-disciplinary team of stakeholders:
  - Obstetricians, pediatricians, nurses, CNMs, community midwives, hospital and public health administrators
- Open meeting (everyone welcome)
  - Second Tuesday, 3:00-4:30 pm, Dept. of Health (Highland)
First Report on Planned Out-of-Hospital Births in Utah

Planned Out-of-Hospital Births in Utah, 2010-2012: A Descriptive Review
Utah Department of Health, Maternal Child Health Bureau
January 6, 2016

Background:
The U.S. Department of Health and Human Services recently published a data brief indicating that large changes in birthing patterns in the United States have occurred over the past century. In 1988, almost all births occurred inside a hospital, most of which occurred at home. This proportion fell to 49% by 2004 (1). Planned out-of-hospital (OOH) births are still relatively uncommon in Utah, but the trend is increasing (see Figure 1).


Out-of-Hospital Birth Report, 2010-2012

- Descriptive statistics
- Notable limitations
  - Unable to identify intended out-of-hospital births who ultimately delivered in the hospital
  - Unable to identify intrapartum fetal deaths that occur in an out-of-hospital setting

Changes in the birth and fetal death certificates
Changes in Birth & Death Certificates

- Allows capture of intended out-of-hospital births that ultimately deliver in the hospital
- Oregon is the only other state to capture this information (unable to differentiate home vs. birth center)

<table>
<thead>
<tr>
<th>Situation, Background, Assessment, Recommendation</th>
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<tbody>
<tr>
<td>Field-tested in an iterative process</td>
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Transfer Forms: Maternal and Neonatal

- Communication tools
- Based on Home Birth Summit and work from other states
- SBAR format
  - Situation, Background, Assessment, Recommendation
- Field-tested in an iterative process

Transfer Forms: Maternal and Neonatal

- How should we use these?
  - Encouraged communication tool
  - Facilitates SBAR oral communication
  - Option to fill out prior to transport as a concise summary
  - Option to fill out after arrival with the accepting medical team in the case of urgent transfers
  - Ensures correct information re: the transferring midwife
Helping Hospitals: A Transfer Algorithm

- Hospitals need to identify their transfer process
  - What number should a transferring provider call?
    - Maternal: Antepartum / Intrapartum / Postpartum
    - Neonatal
    - Non-urgent vs. urgent
- Our goal is to help each hospital define their process and post on the UWNQC website for easy reference.
Feedback: Transfer Process & Forms

- We need a forum to collect feedback on:
  - What is working
  - What isn’t working
  - General concerns and observations
  - Use of the transfer forms and other tools
- Need to collect de-identified information
- Goal of identifying key themes

Midwife Infographic

- Educational reference regarding midwives in Utah
  - Types
  - Statistics
  - Similarities & differences

Midwife Statistics in Utah

Location of Midwife Attended Births

- CNM 4,145 Total Births
  - Hospital 8,580
  - Birth Center 120
  - Planned Home 98
- LDEM 521 Total Births
  - Hospital 20
  - Birth Center 264
  - Planned Home 251
- Other Midwife 785 Total Births
  - Hospital 4
  - Birth Center 70
  - Planned Home 709

2014 - 51,164 Total Live Births in Utah
Future Directions

* New Out-of-Hospital Birth Report to be published 2017
  * Eye toward future publication opportunities
* Transfer algorithms for all facilities
* Internal Quality Measures
  * E.g., Can we accurately identify intended OOH Birth Transfers?

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Prevention of Preterm Birth: The Role of Highly Effective Reversible Contraception

David Turok, MD, MPH
October 24, 2016
Contraception is currently too hard &
It’s too important for us to not do a better job

- **The Big Goal** → Decrease PTB
- **The Goal** → Meeting contraceptive needs
- **The Path** → Improving access to all contraceptive methods, especially HERC

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Unintended Pregnancy in the U.S.

- **Unintended**: 45%
- **Intended**: 55%

- Elective abortions: 23%
- 1.1 million abortions/yr
- Unintended births: 22%

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Finer and Zolna. NEJM 2016;374:843-52.

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Contraception is highly effective

Among U.S. women at risk of unintended pregnancy...

- 10% who use contraception consistently and correctly
- Only 5% of unintended pregnancies

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U.S. women's use of long-acting reversible contraceptive (LARC) methods, like the IUD, has increased over the past decade

<table>
<thead>
<tr>
<th>Year</th>
<th>Implant</th>
<th>IUD</th>
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</thead>
<tbody>
<tr>
<td>2002</td>
<td>2.4%</td>
<td></td>
</tr>
<tr>
<td>2007</td>
<td>3.7%</td>
<td></td>
</tr>
<tr>
<td>2009</td>
<td>8.5%</td>
<td>0.8</td>
</tr>
<tr>
<td>2012</td>
<td>11.6%</td>
<td>10.3</td>
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www.guttmacher.org  **Numbers do not add to total due to rounding.**
Highly Effective Contraception Can Play an Important Role in Reducing PTB

Contraception Can Prevent PTB

Hx of PTB (High Risk)

Unintended Preg (Lower risk)

PTB

Unintended Pregnancy Challenges Children

- Increased rates of preterm birth
- More NICU stays
- More likely to die in the first year of life
- Less likely to graduate high school

Family Planning = Big Time Cost Savings

$7.09 BIGGER FOR HIGH RISK WOMEN

Societal cost of prematurity = $26.2 Billion

Brown & Eisenberg
The Best Intentions: Unintended Pregnancy and the Well-Being of Children and Families. Institute of Medicine, 1995

Preterm Birth: Causes, Consequences, and Prevention. Nationalacademies.org
An Experiment in St. Louis

CHOICE: Probability of UIP


Set It and Forget It
Highly Effective Reversible Contraception

- Copper T380A
  - Hormone Free
  - 12 yrs use

- Mirena or Liletta IUD
  - levonorgestrel released daily
  - 5 years use

- Implanon
  - Etonorgestrel
  - 3 years use

HOW WELL DOES BIRTH CONTROL WORK?
Two Utah Examples of Increasing HERC Access

#1) Increasing Overall Contraceptive Access in SLC

The HER Salt Lake Contraceptive Initiative

Study Approach
#2) Increasing Postpartum HERC Access in SLC

Requested LARC, n = 629

Enrolled, n = 351

Did not receive LARC in hospital, n = 33

Received LARC, n = 318

LNG IUD, n = 123

Cu IUD, n = 87

Implant, n = 108

In-hospital Postpartum IUD & Implants 6 Month Continuation

Eggebrotten ACOG Annual Meeting, 2016
Already Saving Utah Money

- LARC Program & other research projects
- 5,000 IUDs and Implanon devices have been inserted
- 1210 unintended pregnancies prevented
- Saved the state $15.4 million in Medicaid expenditures

US Medical Eligibility Criteria (US-MEC) for contraceptive use

- CDC coordinated, evidence based contraceptive
  - Characteristics
    - Age
    - Parity
    - Postpartum
  - Diseases
    - Diabetes
    - Migraines
US MEC Categories

Category 1
Use!

Category 2
Consider & Use!

Category 3
Consider & maybe
Don’t use!

Category 4
Don’t use!

CDC MEC for the Postpartum Period

CDC MEC for Breastfeeding
Let’s slay the 6 week postpartum visit myth forever

Have a plan in place before birth and execute it within 4 weeks

*43% of women resume sex before 6 weeks

RCT of PP Implant In-Hospital vs. Delayed


Proportion of participants with any breastfeeding at each follow-up time period (p=NS)

Proportion of participants fully breastfeeding at each follow-up time period (p=NS)

Conclusion

• **In order to** Decrease PTB
• **We need to** Meet contraceptive needs
• **Via** Improving access to all contraceptive methods, especially IUDs and implants
Questions?

Thank You