Systematic Review: Cervical Ripening in the Outpatient Setting

A PCORI Virtual Multi-Stakeholder Workshop

August 22nd, 2019

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PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE

Housekeeping

- Participants' lines are live
  - Please mute your line when you are not speaking to reduce background noise
- Today's conversation is being recorded and will be posted to the PCORI website
- We will take stakeholder comments in the order indicated
- If you wish to speak during the open comments/questions period, please indicate this by typing using the "raise hand" function or you can type "permission to speak" in the chat box
- Comments and questions from participants may be submitted via the chat window
  - We cannot guarantee a question will be addressed

Agenda

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- Welcome
- Background and goals for the webinar:
  - Background
  - Proposed Systematic Review Key Questions (KQs)
    - PICOTS
- Moderated discussion
- Summary and closing remarks
- Adjourn

Welcome and Introductions

Welcome!

Today's PCORI Representatives:

- **Bill Lawrence, MD, MS,** Senior Clinical Advisor, Office of the Chief Engagement and Dissemination Officer, PCORI

- **Michelle Althuis, PhD, MA,** Program Officer, Research Synthesis, Office of the Chief Science Officer, PCORI

Order of Comments
Representatives

- **National Partnership for Women & Families**
  - **Carol Sakala, PhD, MSPH,** Director of Childbirth Connection Programs
- **Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN)**
  - **Kathleen Rice Simpson, PhD, RN, CNS-BC, FAAN**
- **University of California San Diego (UCSD)**
  - **Maryam Tarsa, MD,** Quality Improvement Rep for Department of OBGYN at UCSD
- **Food and Drug Administration (FDA)**
  - **Audrey Gassman, MD,** Deputy Director of the Division of Bone, Reproductive & Urologic Products (DBRUP)
- **Nurse Practitioners in Women's Health (NPWH)**
  - **Susan Kendig, JD, MSN, WHNP-BC, FAANP,** Director of Policy

Background

Background and Goals

- **Goals for the Systematic Review:**
  - To integrate information on the effectiveness and harms of outpatient cervical ripening, and related patient preferences, and inform American College of Obstetrics & Gynecology (ACOG) clinical practice guidelines on the topic.
  - PCORI is commissioning, via the Agency for Healthcare Research and Quality (AHRQ), a systematic evidence review to understand the options available to monitor fetal wellbeing in the outpatient setting and to understand which CR methods are appropriate for women experiencing fetal demise.

- **Goal for this webinar:** to receive stakeholder input on the Key Questions for this Systematic Review.

Questions for Participants

- We are asking participants to provide their thoughts on the planned systematic review and the research questions (see Key Questions in subsequent slides).
- Please provide any feedback you have OR
- Address one of the following sample questions:
  - How would a current systematic review in this topic area be helpful?
  - Do you have input on the treatments, comparisons, outcomes or populations that should be considered as the review protocol is refined?
  - What are other important patient characteristics not reflected in the key questions?
  - Are there nuances regarding this topic not adequately captured by the key questions?

Proposed Systematic Review Key Questions (KQs)

What is a systematic review?

- A systematic review evaluates and synthesizes all available evidence from a body of research.
  - Transparent methods
  - Employs strategies to minimize bias

- Primary **goals of a systematic review** are to:
  - Provide access to high-quality evidence from research
  - Guide future research
  - Establish core building blocks for clinical and policy guideline development

- See Cochrane Consumer Network "What is a systematic review?"

KQ 1: What are the effectiveness and potential harms of CR in the outpatient compared to the inpatient setting?

Population	Pregnant women ≥ 37 wk undergoing CR
Intervention	CR, inpatient setting
Comparator	CR, outpatient setting
Outcomes	Maternal & infant health outcomes Maternal & infant mortality and morbidity
Timing	Follow-up not limited
Setting	Inpatient & outpatient
Study design	RCTs Consider cohorts for harms

KQ 2: What are the comparative effectiveness and potential harms of different methods of CR evaluated in the outpatient setting (balloon catheter, prostaglandins, etc.)?

Population	Pregnant women ≥ 37 wk undergoing CR
Intervention	Method of CR
Comparator	Expectant management, no treatment or placebo, other CR methods
Outcomes	Maternal & infant health outcomes Maternal & infant mortality and morbidity
Timing	Follow-up not limited
Setting	Outpatient
Study design	RCTs Consider cohorts for harms

KQ 3: What evidence informs preference for or tolerability of different methods of CR in the outpatient setting or outpatient compared to the inpatient setting?

Population	Pregnant women ≥ 37 wk undergoing CR
Intervention	1. Setting (inpatient) 2. Method CR (outpatient)
Comparator	1. Setting (outpatient) 2. Expectant management, no treatment or placebo, other CR methods (outpatient)
Outcomes	Preference & tolerability
Timing	Follow-up not limited
Setting	Inpatient & outpatient
Study design	RCTs Consider cohorts

KQ 4: What are the effectiveness and potential harms of available methods for fetal surveillance in pregnant women undergoing CR with prostaglandins in the inpatient and outpatient setting?

Population	Pregnant women ≥ 37 wk CR with prostaglandins
Intervention	Method of fetal surveillance
Comparator	No fetal monitoring or another method of fetal surveillance
Outcomes	Maternal & infant health outcomes Maternal & infant mortality and morbidity
Timing	Follow-up not limited
Setting	Inpatient & outpatient
Study design	RCTs Consider cohorts

KQ 5: What are the effectiveness and potential harms of CR among women presenting with fetal demise in the late second or third trimester, in the inpatient and outpatient setting?

Population	Fetal demise, 2nd/3rd trimester undergoing CR
Intervention	Method of CR
Comparator	Expectant management, no treatment or placebo, other CR methods
Outcomes	Maternal health outcomes Maternal & mortality and morbidity
Timing	Follow-up not limited
Setting	Inpatient & outpatient
Study design	RCTs

Moderated Discussion

Moderator: Bill Lawrence, MD, MS

Order of Comments

- National Partnership for Women & Families
- Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN)
- University of California San Diego (UCSD)
- Food and Drug Administration (FDA), Division of Bone Reproductive & Urologic Products (DBRUP)
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Key Questions

- **KQ 1:** What are the effectiveness and potential harms of CR in the outpatient compared to the inpatient setting?
- **KQ 2:** What are the comparative effectiveness and potential harms of different methods of CR evaluated in the outpatient setting (balloon catheter, prostaglandins, etc.)?
- **KQ 3:** What evidence informs preference for or tolerability of different methods of CR in the outpatient setting or outpatient compared to the inpatient setting?
- **KQ 4:** What are the effectiveness and potential harms of available methods for fetal surveillance in pregnant women undergoing CR with prostaglandins in the inpatient and outpatient setting?
- **KQ 5:** What are the effectiveness and potential harms of CR among women presenting with fetal demise in the late second or third trimester, in the inpatient and outpatient setting?

Open Comments and Questions Period

Summary and Closing Remarks

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Thank you!