The Maternal and Child Survival Program

Asia Gestational Age Estimation Study Concept

PTB/LBW Global Technical Working Group on Implementation Challenges and Solutions
May 1, 2015

www.mcsprogram.org
USAID’s flagship

Maternal and Child Survival Program

Vision Statement
Self-reliant countries equipped with the analytical tools and effective systems enabling them to be on track to end preventable child and maternal deaths
Program Basics

Awarded: Launched June 2014
Length: 5 Years
Funding Ceiling: 500 Million
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When does accurate gestational age matter?
Clinical Utility of GA Estimation

- Effectiveness/safety can depend on GA
  - SP for malaria prophylaxis in pregnancy
  - Antenatal corticosteroids (ACS)
  - Magnesium sulfate (MgSO$_4$) for neuroprotection
- Induction of labor
- Birth planning and complication readiness (BP/CR)
- Facilitates good clinical decision making/preparation
  - Delivery of preterm infant with special care needs
  - Potential transfer and/or transport to a higher level of care
ACT Trial

• For every 1000 women exposed to antenatal corticosteroids (ACS)
  • Excess of 3.5 neonatal deaths occurred
  • Risk of maternal infection likely increased
• Scale-up strategies should explore minimum care needed to attend infants exposed to ACS
• Pragmatic and accurate methods needed to identify women at risk of preterm birth
  • Assessment of gestational age where ultrasound is unavailable

UN Commission on Life Saving Commodities
ACS Working Group

• ACS should only be used @ 24 to 34 weeks
  • Must accurately assess GA and risk of preterm birth
  • Adequate care available for preterm newborns
  • Reliable, timely and appropriate diagnosis and treatment of maternal infection

• Innovation to improve GA assessment is a research gap

• Current methods for GA assessment compromise quality of care and research
## Advantages and Disadvantages of Different Strategies

<table>
<thead>
<tr>
<th>Strategy</th>
<th>Advantages</th>
<th>Disadvantages</th>
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<tbody>
<tr>
<td>Last menstrual period</td>
<td>Inexpensive, Standardized, Limited training, Accepted tools</td>
<td>Subject to patient recall bias, Inaccurate and/or imprecise if recent progestin use, BF, irregular menses, Using Naegele’s Rule alone does not enable providers to estimate GA</td>
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<tr>
<td>Estimated date of conception</td>
<td>Inexpensive, Standardized, Limited training, Accepted tools</td>
<td>Subject to patient recall bias, Imprecise in context of typical patterns for frequency of intercourse</td>
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<tr>
<td>Uterine examination</td>
<td>Inexpensive</td>
<td>Subject to poor interrater reliability among providers, Requires specialized training, Imprecise, particularly if large uterine fibroids, obesity, multiple gestation</td>
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<tr>
<td>Quickening</td>
<td>Inexpensive</td>
<td>Imprecise, subject to patient recall bias, Awareness varies between nulliparous and multiparous women, Not useful for timing certain key interventions, e.g., IPTp-SP</td>
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<tr>
<td>Infant examination</td>
<td>Inexpensive, Standardized</td>
<td>Imprecise, not useful for pre-delivery decision-making, Requires specialized training</td>
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<tr>
<td>Ultrasound examination</td>
<td>Precise if correctly done, Expanding</td>
<td>Costly, sensitive equipment with need for power supply and specialized care, Requires specialized training, may be subject to local standards for cadre scope, Can be a financial burden</td>
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Outstanding Questions

- How are GA data generated, analyzed, documented, and used?
  - Both antepartum and intrapartum settings
- Optimal strategies to improve GA assessment in LMIC?
  - How should we adapt interventions to determine GA?
- To what extent could we optimize usage of time-sensitive perinatal interventions if precision of EGA could be improved?
- Is there room to right-size efforts on GA estimation in settings working toward appropriate use of ACS?
- How do we promote integration of evidence re GA assessment into policy and program decisions?
## Study Objectives

<table>
<thead>
<tr>
<th>Objectives</th>
<th>Outcomes</th>
<th>Proposed Outcome Definitions</th>
<th>Data Sources</th>
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<tbody>
<tr>
<td>To describe estimation of GA data for patient care</td>
<td>Proportions of each documented method for GA estimation</td>
<td>Numerator: for each GA estimation method, the number documented on ANC records</td>
<td>ANC records, Clinical observation</td>
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<td>Denominator: enrolled participants, ANC group</td>
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<td></td>
<td>Proportions of admissions with ANC record available for review by intrapartum care provider (including admissions with EDD recorded in first trimester)</td>
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<td>Denominator: enrolled participants, intrapartum group</td>
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<tr>
<td>To describe utilization of GA data for patient care</td>
<td>Provider strategies for analysis and use of GA data</td>
<td>Qualitative data on decision-making strategies used for GA determination in context of time-sensitive clinical interventions</td>
<td>In-depth interview</td>
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<td>Barriers to appropriate determination, documentation and use of GA data</td>
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<td>To identify strategies to optimize access to GA data in intrapartum settings</td>
<td>Data collection and data transfer systems currently in place</td>
<td>Description of existing mechanisms for GA data collection and communication</td>
<td>Review of GA data collection and communication systems</td>
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Design

• Cross-sectional, observational, mixed-methods
  • Implementation research on clinical practice patterns
  • Analysis, documentation and use of GA data in ANC, IP care
Study Sites and Participants

- Two proposed study site countries
  - Cambodia and India
- ANC and IP clients, as well as care providers in these settings
- Number/type of facilities TBD, likely larger facilities
Expected Challenges and Strengths

• Challenges
  • Missing and self-reported data, social desirability/recall bias
  • Patient tracking, retrospective/cross-sectional data
  • No longitudinal data on individual participants: can’t determine causal relationships between ANC and clinical/service outcomes in IP setting

• Strengths
  • Identify current practice patterns (not previously described)
  • Mixed methods
  • Identify strategies to optimize availability of most precise GA data in IP setting
Anticipated Products

• Summary report on GA estimation in the study region
• Presentation of findings to all stakeholders
• Publication of primary results in peer-reviewed journal
Thank You

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Diagnostic Ultrasound

- Electronic technology that uses high frequency sound
- Variety of uses in pregnancy
  - Routine screening for GA and anatomy
  - Follow-up for suspected complications of pregnancy
- Training, training, training
  - Human factors drive quality and interpretation of images
- Optimal use of ultrasound during ANC
  - Accurate documentation of estimated date of delivery
  - Appropriate communication of GA data for clinical decision-making in intrapartum care setting
  - Fetal anatomic survey and other pertinent obstetrical data