Sustainability and Safety of an Early Onset Sepsis (EOS) Guideline for VLBW Infants

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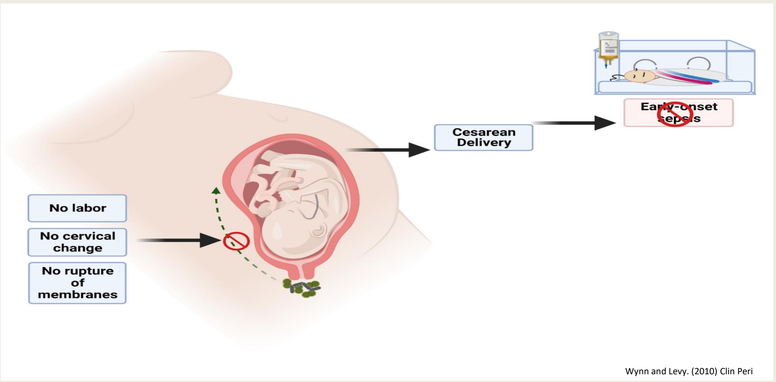
Background

- Approximately 80% of very-low birthweight infants (VLBW; <1500 grams) in the US receive empiric antibiotics at birth due to the risk of EOS
- We previously reported that a guideline based on delivery criteria to determine EOS risk among VLBW infants:
  - *Lowered rates of early antibiotic initiation*
  - *Did not increase short-term adverse outcomes*
- Implemented at our high-risk Level III center through education and written guidance

Defining Low-Risk

- 2018 AAP Clinical Report
- Defined preterm infants at <u>lower risk for EOS</u> when ALL are present:
  - *Obstetric indications for preterm birth (such as preeclampsia)*
  - *Birth by cesarean delivery*
  - *Absence of labor or attempts to induce labor*
  - *Membrane rupture at time of delivery*
- Endorsed management for these infants with ***<u>either</u>***:
  - No laboratory evaluation, no empirical antibiotic therapy
  - Blood culture and no empirical antibiotic therapy



Wynn and Levy. (2010) Clin Peri

Outcomes

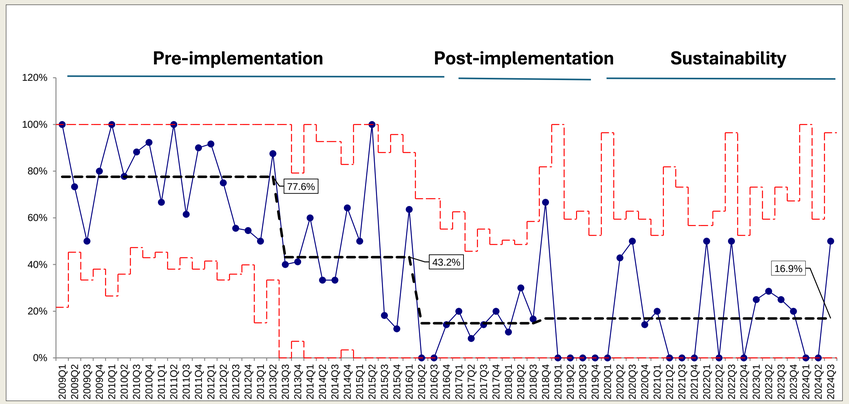
Primary Outcome

- Proportion of all and of low-risk VLBWs administered antibiotics ≤3 days after birth

Balancing Measures

- Proportion of VLBWs with antibiotics initiated on Days 4-7
- Blood or CSF culture-confirmed infection on Days 4-7
- Death or transfer by Day 7

Sustainability



Methods

- <u>Design</u>: Retrospective cohort study
- <u>Population</u>: All VLBWs admitted to the NICU
- <u>Comparison</u>: Antibiotic utilization during different time periods
  - PERIOD 1 (before low-risk EOS implementation): 01/2009 - 03/2017
  - PERIOD 2 (after low-risk EOS implementation): 04/2017 - 01/2020
  - PERIOD 3 (sustainability period): 02/2020 - 09/2024
- <u>Analysis</u>:
  - Statistical Process Control Chart
  - Pre-post analysis using Chi Square, Fischer Exact test and Mann-Whitney-U tests

Results

Sustained Reduction in Antibiotic Initiation: VLBW Infants

N (%) or Median (IQR)z	Period 1 n=298	Period 2 n=83	Period 3 n=102	p-value 1 vs. 2	p-value 2 vs. 3
Day 0-3 after birth					
Blood culture obtained	225 (75.5)	14 (16.9)	19 (19.6)	<0.001	0.63
Antibiotic initiation	185 (62.1)	11 (13.3)	19 (19.6)	<0.001	0.25
Antibiotic initiation: ELBW infants	105/120 (87.5)	8/36 (22.2)	16/45 (35.6)	<0.001	0.19
Blood culture positive for a pathogen	0	0	0	-	-

Take Home Points

- Low-risk criteria should NOT be used to determine obstetric management
- Consider written guideline for use of low-risk EOS criteria
  - Essential in trainee facilities where the specifics can challenge
- Consider carefully application in 22-23 week infants

Conclusion

- Our Level III NICU sustained use of a VLBW EOS risk-stratification guideline over 7 years without safety concerns
  - *Lower proportion of VLBW infants administered empiric antibiotics from birth*
  - *No increase in culture-confirmed infection or transfer or death in the first week after birth*
- Lower rate of antibiotic initiation at 4-7 days in the sustainability period may suggest greater confidence in the guideline over time