

Alberta (AB) Collaborative Quality Improvement Strategies to Improve Outcomes of Preterm Infants 32 – 36 Weeks' Gestation: A Stepped-Wedge Cluster Randomized Trial (ABC-QI Trial)

1. Background

Preterm birth is a public health problem: Preterm birth leads to prolonged hospitalization, and results in infant mortality and morbidity. In 2019, there were 30,000 infants born preterm in Canada (8% of live births) and 4,597 infants (8.9% of live births) in Alberta; the highest preterm birth rate among the four largest Canadian Provinces.

Most preterm births are moderate or late preterm: Moderate and late preterm infants (MLPIs) born at 32-36 weeks' gestation represented 85% of all preterm birth in Canada. In Alberta, an annual average of 6,041 patients were admitted to all NICUs, utilizing 80,718 patient-days. **MLPIs represent 41% (2,448) of individual patients and 41% (33,319) of patient days in Alberta NICUs** (Table 1).

Gestational age group	Less than 32 weeks	32-36 weeks	37 weeks or more	Total
No. of patients	561 (9%)	2,448 (41%)	3,032 (50%)	6,041
Patient days	35,045 (44%)	33,319 (41%)	12,354 (15%)	80,718

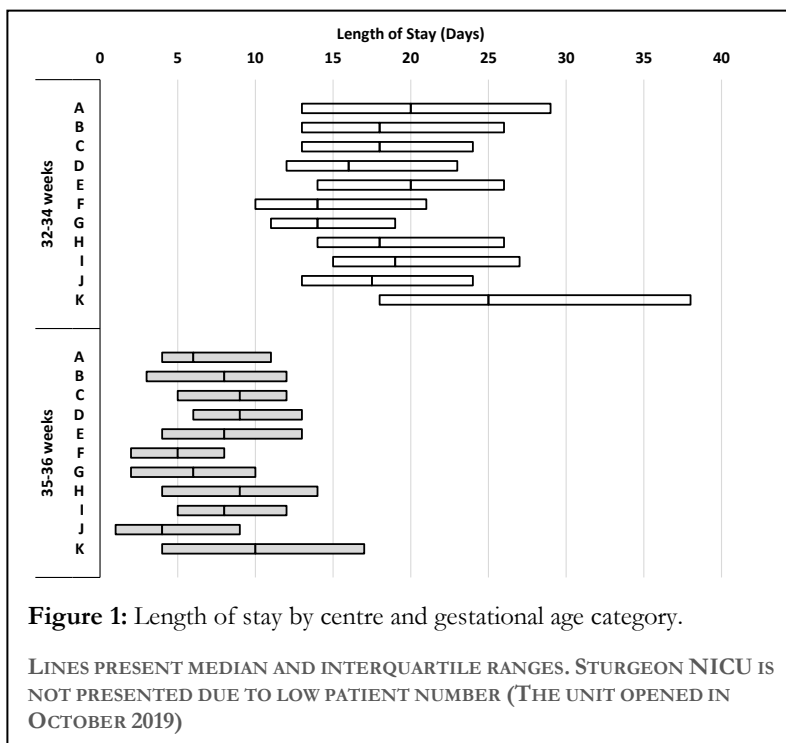
MLPIs have significant morbidities: MLPIs are at increased risk of significant morbidities including hypothermia, respiratory distress syndrome, early onset sepsis, feeding challenges and jaundice. MLPIs have a higher risk of rehospitalization within 30 days after discharge, with increased risk of long-term motor and cognitive impairment and learning difficulties.

Practice variation of MLPIs is associated with inconsistent outcomes and variable length of stay (LOS) between NICUs:

Alberta Family Integrated Care (Alberta FiCare) cluster randomized trial (December 2015 – July 2018) showed a reduction in LOS for patients in NICUs randomized to FiCare arm by a mean (95% CI) of 2.55 (0.66, 4.44) days, without increase in readmissions. However, there was noticeable variation in LOS between regional and urban NICUs. Figure 1 shows the variability of LOS until discharge home in MLPIs admitted to the participating NICUs in 2018 and 2019.

Collaborative quality improvement (QI) is associated with improved patient outcomes:

In a systematic review of 64 studies, collaborative QI was widely adopted to share improvement and learning, and resulted in significant improvements in clinical processes and patient outcomes. **Evidence-based Practice for Improving Quality (EPIQ)** is the collaborative QI methodology adopted by the CNN to decrease mortality and morbidity in very preterm infants.



There is no platform for collaborative QI for MLPIs.

Collaborative QI is superior to individual site QI: After EPIQ-1 trial, the EPIQ team disseminated the NI and BPD care bundles to the NICUs that did not participate in the trial and provided EPIQ training but without collaborative

activities. There was no significant change in outcomes highlighting the importance of the collaborative component of QI implementation.

Collaborative QI is associated with cost saving: In a systematic review of 8 studies, collaborative QI had the potential for cost savings to the healthcare system in both acute and chronic conditions. Collaborative QI in high-risk neonates with birth weight <1500g was associated with cost savings that offset institutional expenditure for QI activities. Isolated QI activities such as early discharge for late preterm infants may not result in the expected benefit and may increase cost due to post-discharge healthcare utilization.

2. Aims

Primary research question: In infants born at 32-36 weeks' gestation, does implementation of collaborative QI strategies compared to current practice lead to reduction in length of stay prior to discharge home in Alberta?

Secondary research questions: In infants born at 32-36 weeks' gestation, does implementation of collaborative QI strategies compared to current practice lead to: 1) reduction in cost to the healthcare system, and 2) improved short term clinical outcomes.

3. Methods:

3.1. Study Design:

We will use stepped-wedge cluster randomized trial design. Each of the 12 participating NICUs (10 Level II and 2 Level III) is considered a cluster and will be randomized to transition to the intervention arm at one of three time points (Figure 2).

3.2. What are the planned trial interventions?

Intervention arm (Collaborative QI Strategies): The study **intervention** is a constellation of collaborative QI strategies: 1) QI Team Building; 2) QI Education; 3) Implementation of 2 standardized practice care bundles (Respiratory Care, and Nutritional Care); 4) QI mentoring; and 5) Collaborative networking. Based on the randomization, 4 NICUs will transition to the intervention arm at the end of each year.

Control arm (current management): All participating NICUs will be in the control arm during the first year prior to randomization to create a baseline of the current practices and between-units variation. NICUs in the control arm can continue conducting QI activities relevant to their practice, but without receiving the interventions outlined above.

4. Questions:

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