Managing risks in preterm infants in the face of Human Milk Fortifier (HMF) product recall crisis

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Introduction

Exclusive human breastmilk feeding reduces risk of necrotizing enterocolitis (NEC)

Preterm infants are at increased risk of malnutrition

Nutritional fortification of human milk is needed to support optimal growth and development

A recall of HMF product due to possible bacterial contamination resulted in unanticipated disruption of fortification practices in neonatal units globally

Aim: To describe our approach at KKH to mitigate a recent recall of HMF, when no other alternative HMF product was readily available in Singapore.

Methodology

Communicate and Consult

1. Identify & Analyse Risk Exposures

Gathered a multidisciplinary team (doctors, nurses, dietitians and pharmacy procurement staff)	Identified potential health risks from exposure to affected product; risk of malnutrition without fortification; risk on organisation's reputation	Developed & disseminated communication to affected patient families Increased frequency of nutritional screening

2. Consider Alternative Strategies

Short Term	*Medium-Long Term*
• Identified fortification strategies besides HMF • Evaluated existing literature for alternatives	• Sourced for other HMF products

3. Select the Best Risk Management Strategy

Criterion 1:	Criterion 2:	Criterion 3:	Criteria 4:
Nutrient profile of the strategy	Possible impact on NEC risk	Supply of required product	Ease of implementation

4. Implement the Selected Strategy

Developed an interim workflow for the selected strategy	Addressed possible issues during transition in practice	Disseminated risk response plans to stakeholders (doctors, nurses and parents)

5. Monitor Outcomes

Key outcomes include nutritional practices, weight, bone health-related laboratory investigations, electrolyte imbalance, and incidence of NEC

Monitor and Review

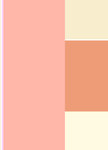
3 Risk Control Measures as part of the interim strategy

1. Delay fortification till larger feed volume of 100 ml/kg/day achieved instead of 80 ml/kg/day previously
2. Start fortification at a lower proportion of formula use
3. Maintain at least 50% feeds as human milk for protective effect against NEC even when high caloric feeds are required

Results

An interim strategy of mixing high caloric preterm formula (SSC30) to expressed breastmilk (EBM) was adopted, acknowledging the risk balance between formula introduction and malnutrition without fortification.

Standard fortification (EBM23) for all preterm infants
- Mixing EBM and SSC30 in a 2:1 ratio



High caloric feeds (EBM25) for malnourished preterm infants
- Mixing EBM and SSC30 in a 1:1 ratio

Comparing nutrient profile of unfortified EBM and EBM23 with fortified EBM+HMF (routine practice prior to HMF recall),

Reduction in nutrient profile of **unfortified EBM**,

To: 85% in Calories,
47% in Protein,
25% in Bone minerals,
1% in Vitamin D,
0% in Vitamin A,
24% in Iron

Improvement in nutrient profile of **EBM23** using SSC30 as an interim fortifier,

To: 98% in Calories,
84% in Protein,
55% in Bone minerals,
43% in Vitamin D,
68% in Vitamin A,
171% in Iron

Comparing outcomes for pre and post cohort,

Pre-Cohort (n=19)		Post-Cohort (n=18)
- Between November to December 2021 *(prior to HMF recall)* - Infants on fortified **EBM+HMF** feeds	**VS.**	- Between March to April 2022 *(after HMF recall)* - Infants on fortified **EBM23** feeds

Both cohorts were **comparable** in birth gestation (25.9 weeks to 31.5 weeks) and birth weight (767g to 1360g).

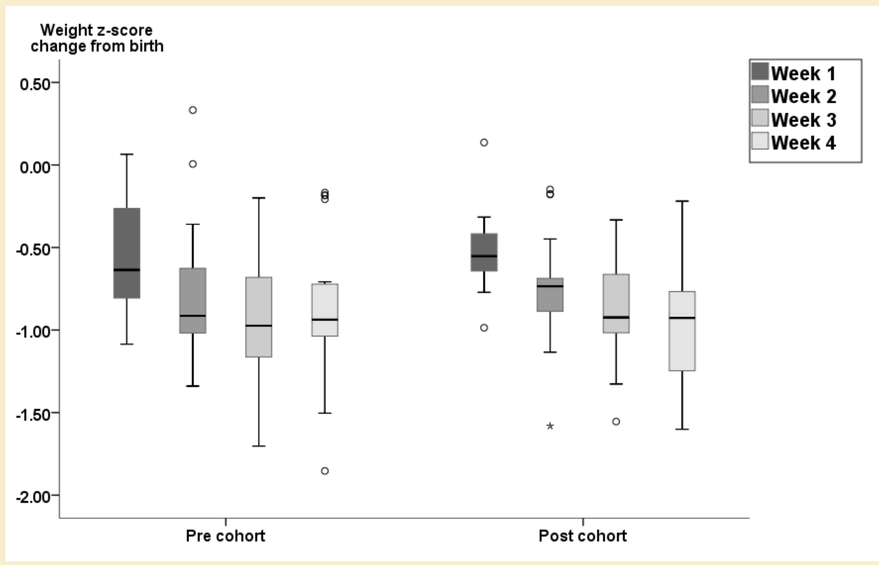
Post cohort had
- Lower proportion of male infants (50% vs. 79%)
- Lower weight z-score at birth (-0.34 vs. +0.01)
- Higher proportion of infants with SGA/IUGR status (28% vs. 16%)

SGA: small for gestational age; IUGR: intra-uterine growth restriction

Feed volume at which the **post cohort** was started on fortification was **significantly delayed** at 125 ml/kg/day compared to 90 ml/kg/day for the pre cohort (p<0.001).

Both cohorts took 11 days to regain birth weight (p=0.893).

Both cohorts had similar pattern for change in weight z-score from birth at Week 1 to Week 4 of life (p=0.635).



Serum levels for alkaline phosphatase and phosphate were **similar** between both cohorts. While serum calcium levels were **significantly higher** in the post cohort at Week 2 (p=0.009) and Week 4 of life (p<0.001), results for both cohorts were all **within normal limits** suggesting no compromise on bone health.

Patients tolerated the feeds well with adequate growth observed. There were NO adverse events including electrolyte imbalance or NEC in affected patients.

Conclusion

- The nutritional product recall caused significant impact on nutritional management of preterm infants.
- Relying on a single company for a highly specialized nutritional product is a major pitfall during product recall.
- A multidisciplinary team was essential in executing a risk management plan that balanced the risks of clinical morbidities while ensuring feasibility and patient safety.

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References
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