Feeding practices among vulnerable newborns in Vietnam: a pre- and post-evaluation of integrating a human milk bank into newborn care services

Andrew Kwist

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Stephen Hawes

Kiersten Israel-Ballard

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Abstract

Feeding practices among vulnerable newborns in Vietnam: a pre- and post-evaluation of integrating a human milk bank into newborn care services

Andrew Kwist

Chair of the Supervisory Committee:

Stephen Hawes

Department of Epidemiology

Introduction: Infant feeding practices and lactation support when mother's own milk is unavailable, especially among vulnerable infants in neonate intensive care unit situations (i.e. pre-term, low birthweight) are not well understood globally. Integration of human milk banking services and provision of donor human milk as early essential newborn care may offer the support and resources necessary to achieve optimal infant feeding practices. Previous studies suggest improved breastfeeding rates at discharge with the introduction of an integrated human milk banking program, however this finding has not been well characterized. An impact evaluation is underway to investigate changes in infant feeding practices to increase safe use of human milk from before and after integration of a human milk bank at the Da Nang Hospital for Women and Children in Da Nang, Vietnam.

Methods: A pretest and posttest evaluation was conducted surrounding the opening of the human milk bank at the Da Nang Hospital for Women and Children in Da Nang, Vietnam, a WHO-designated Center of Excellence for early essential newborn care. All infants admitted to the neonatal ward on day one of life were included and 14 days of data collection took place on volumes, routes, and types of feed for each infant until discharge or death. Outcomes of interest were exclusive quality-controlled human milk feeding, any exposure to formula, and any exposure to another mother’s milk. Chi-squared tests and the Mantel-Haenszel method were used to investigate the associations between exposure to the milk bank and each outcome of interest.

Results: The proportion of infants fed exclusive quality-controlled human milk was significantly higher in the posttest group relative to the pretest group on all 14 days of the study; posttest exclusive quality-controlled human milk feeding was 100% at day 1 and reduced steadily through follow-up to 65% by day 14, while pretest was 4% at day 1 and reached 0% by day 9 (all χ2 $p<0.001$). The proportion of infants exposed to formula was significantly lower in the posttest group than the pretest group during the first seven days of data collection (all χ2 $p<0.05$) and was similar thereafter; posttest exposure to formula was between 0% and 4% throughout follow-up while pretest exposure to formula was 36% at day 1 and reduced to 4% by day 8. The proportion of infants exposed to another mother’s milk was significantly lower in the posttest group compared to the pretest group through day 10 (all χ2 $p<0.001$); posttest exposure to another mother's milk was between 0 and 3% throughout follow-up, while pretest exposure to another mother's milk was 73% at day 1 and reduced throughout follow-up to 4% by day 14.

Conclusion: Results of this study suggest a positive impact of the integration of a human milk bank into newborn care services in Vietnam, specifically for an increase in the uptake of quality-controlled human milk and decreases in exposure to formula and another mother's milk. This study informs future models for integrating human milk banking into health systems in Vietnam. Further research to determine the best practices for the provision of donor human milk, as well as improved data collection and better alignment of global nutrition policies are all necessary to achieve equitable access to human milk for vulnerable infants.

Introduction

Despite considerable progress in neonatal health in recent years, 4.6 million babies die in the first year of life globally, and nearly 3 million of these die in the first 28 days of life (1). Neonates with certain adverse health outcomes such as low-birth weight, preterm birth, neonatal sepsis, and necrotizing enterocolitis are faced with significant risk of death and morbidity. While a global effort is underway to address these conditions through various other interventions, breastfeeding has the potential to have a significant positive impact if adequately scaled. It is estimated that exclusive breastfeeding could prevent 823,000 deaths each year in children under five (2). While breastfeeding offers significant health benefits to mother and infant alike, anecdotally approximately 15-40% of vulnerable infants globally do not have access to their own mother's milk and are therefore may be unable to benefit from these health-promoting effects (3). Reasons for this lack of access are varied, but include maternal death or morbidity, inability of mother to express milk, separation of mother and infant, or avoidance of breastfeeding because of the risk of transfer of disease such as HIV.

For these vulnerable infants that do not have access to mother's own milk, the World Health Organization (WHO) recommends donor human milk as the optimal alternative and cites lower incidence of necrotizing enterocolitis and other gut disorders related to formula as justification for this recommendation (4). Despite this recommendation, the WHO provides minimal guidance on the provision of donor human milk, thus further research is needed to guide best practices and models for the use of donor human milk.

Several studies have shown the impact of the use of donor human milk, with demonstrated reductions in risk of a number of infant health outcomes, including necrotizing enterocolitis and neonatal sepsis, in addition to improvements in feeding tolerance and reductions in length of stay in the neonatal intensive care units (5-11). Additionally, several studies have investigated changes in infant feeding practices as a result of introduction of donor human milk into a hospital or NICU setting. Many studies suggest positive impact, with several studies finding that the use of donor human milk increased intake of human milk, as well as reduced exposure to formula and non-pasteurized shared milk from another mother (9, 12-15). However, these results have not been well characterized and warrant further research (12, 16). Mixed results have been seen regarding how the use of donor human milk affects intake of mother's own milk (16-19).

To our knowledge, no study has been conducted investigating the impact of the introduction of donor human milk on neonatal feeding practices specifically in Vietnam. Further, several varying models exist for the use of donor human milk due to lack of standardization – therefore, research is needed to investigate the impact of integration of a human milk bank (HMB) into neonatal care services under the Mother-Baby Friendly Initiative Plus model designed by PATH. Using this model, PATH and its partners have provided technical assistance to the Da Nang Hospital for Women and Children in Da Nang, Vietnam throughout its integration of a HMB into a larger breastfeeding promotion and Kangaroo Mother Care intervention to facilitate a supportive, empowering environment for mothers and infants. Throughout integration, PATH has led ongoing research on the impact of the HMB but this study focuses specifically on the changes in feeding on the neonatal ward component. Specifically, this study aims to investigate changes in intake of quality-controlled human milk, as well as exposure to formula, and exposure to another mother's milk. We hypothesize that the group of infants exposed to the HMB will have improved feeding practices relative to the group unexposed to the HMB.

Methods

To investigate the impact of integrating the HMB into newborn care services on vulnerable infant feeding practices, a pretest and posttest evaluation was conducted surrounding the opening of the HMB in February 2017. The study site was the neonatal ward of the Da Nang Hospital for Women and Children in Da Nang, Vietnam, a WHO-designated Center of Excellence for early essential newborn care which has excelled in regard to increasing maternal intent to exclusively breastfeed and achieving high rates of early breastfeeding (20, 21). The hospital received technical and financial assistance from two international non-profit health organizations to improve infant health through a variety of interventions.

Inclusion criteria was admission of the infant on day one of life and receipt of consent from the mother or caregiver. Nurses at the neonatal ward prospectively collected data for 14 days on the timing, volumes, administration routes, and types of each feed, in addition to various other covariates and descriptive statistics of infants and their mothers, using a form in the medical records of each infant. Loss to follow up occurred throughout data collection, as infants were discharged or died.

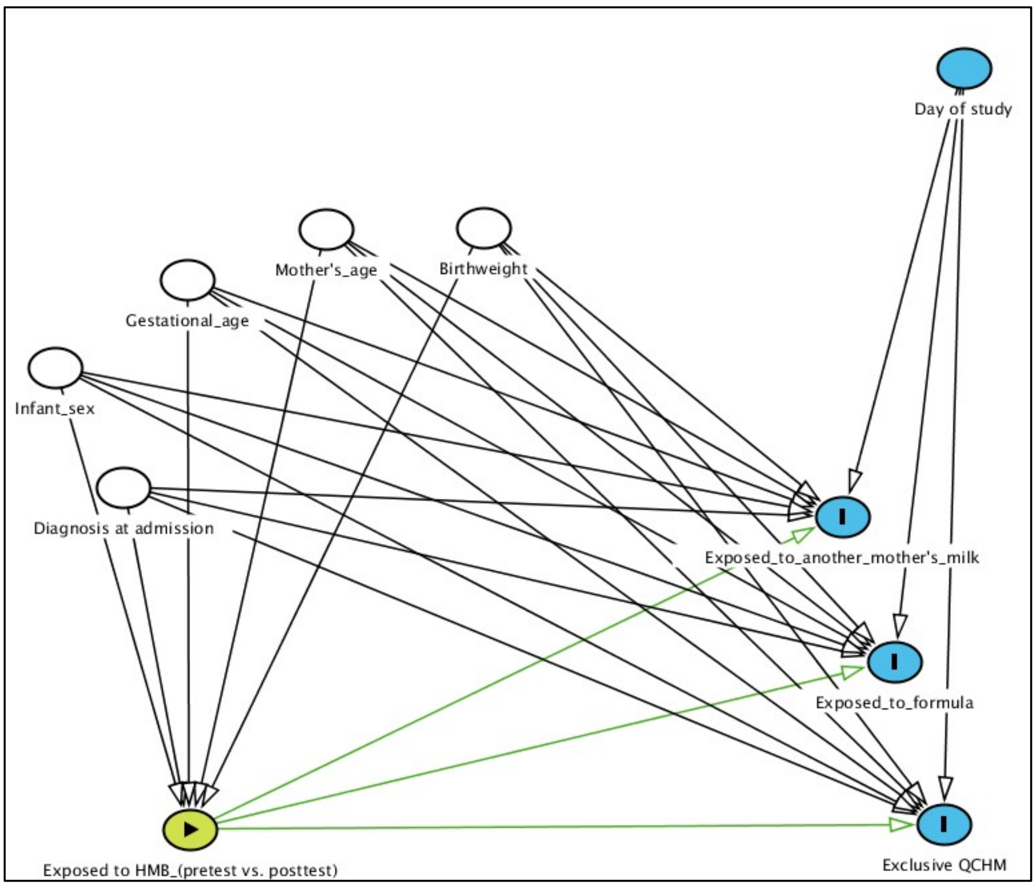
Infants were considered exposed (posttest group) if they were followed throughout October-November 2017, after integration of the HMB. Infants were considered unexposed (pretest group) if they were followed throughout September-December 2016, prior to integration of the HMB. The associations between exposure and three outcomes of interest were investigated:

1) exclusive quality-controlled human milk feeding (EQCHM)
2) any exposure to formula
3) any exposure to another mother's milk (AMM)

For outcome 1 (EQCHM), infants were considered as having experienced this outcome only if they were exclusively fed mother's own milk (MOM) and/or donor milk (DHM) from the milk bank up until the day of analysis. MOM and DHM were combined into one indicator because, as discussed in the Introduction, these feeding methods are prioritized over formula and another mother's milk. To address the concern of overusing donor human milk when mother's own milk should be prioritized, we also conducted a sensitivity analysis within outcome 1, in which we looked specifically at differences between pretest and posttest in proportions of infants that consumed any mother's own milk on each day of the study. For outcomes 2 and 3, an infant was considered as having experienced the outcome if they had any exposure to the respective feeding type on the specific day of analysis.

Five confounders, mother's age (<26, 26-35, >35 years), infant birthweight (<2500, >2500 grams), infant sex, infant gestational age (<28, 28-32, 33-37, >37 weeks), and infant diagnosis at admission (premature, congenital disorder, any infection, or other diagnosis), were identified *a priori.* These confounders were adjusted for in the below analysis methods. One effect modifier, day of study, was also identified *a priori* because it was hypothesized that the strength of association would differ between early and later days of the study. Therefore, subsequent results for each outcome are presented separately within two main strata: days 1-7 and days 8-14. Figure 1 contains a directed acyclic graph (DAG) depicting the assumed relationships between these variables.

Figure 1. Directed acyclic graph (DAG) specifying assumed relationships among exposure, outcomes, and covariates.



For data analysis, chi-squared tests were performed to assess the associations between pretest vs. posttest status and each outcome of interest on each day of the study; results of these tests are presented by study day. To estimate the effect size, the Mantel-Haenszel method was used to calculate crude and adjusted odds ratios for each outcome, comparing posttest to pretest. Infants receiving only parental feeding for an entire day were excluded from analysis on that day only.

Results

There were 108 infants in the pretest group and 136 infants in the posttest group. The average length of stay was similar for pretest and posttest groups (10.4 days and 10.6 days, respectively), with 53% of pretest group and 57% of the posttest group completing all 14 days of follow up. Table 1 provides characteristics of infants and their mothers. Mothers were, on average, somewhat younger in the posttest group, with the proportion of mothers under the age of 26 being 38% in the posttest group, relative to 28% in the pretest group. Infants were somewhat more likely to be low birthweight in the pretest group (69%), compared to the posttest group (61%). Sex distribution was similar, as 66% of infants were male in the pretest group, compared to 60% in the posttest group. Infants in the posttest group were more likely to be full-term (>36 weeks) compared to infants in the pretest group (40% and 32%, respectively). Regarding diagnoses at admission, infants in the posttest group were less likely than pretest infants to be diagnosed as premature (posttest=54%; pretest=65%), more likely to have congenital disorders (posttest=13%; pretest=6%) and infection (posttest=14%; pretest=10%), but equal likelihood of having any other diagnoses (19% in both groups).

Table 1. Characteristics of infant-mother dyads

	Pretest (n=108)			Posttest (n=136)		
	N	%	Mean	N	%	Mean
Mother's Age (years) *						
<26	30	28%		52	38%	
26-35	62	58%	29.3	74	54%	27.4
>35	15	14%		10	7%	
Birthweight (grams)						
<2500	75	69%	2197.4	83	61%	2220.5
>=2500	33	31%		53	39%	
Sex						
Male	71	66%		81	60%	
Female	37	34%		55	40%	
Gestational Age (weeks)						
<28	1	1%		7	5%	
28-32	33	31%	34.5	28	21%	35.1
33-36	39	36%		46	34%	
>36	35	32%		55	40%	
Diagnosis at Admission**						
Premature	70	65%		73	54%	
Congenital Disorder	6	6%		18	13%	
Infection	11	10%		19	14%	
Other	21	19%		25	19%	
Length of follow up (days)						
Days 1-3	15	14%		17	13%	
Days 4-6	9	9%		10	7%	
Days 7-9	16	15%	10.4	20	15%	10.6
Days 10-12	9	8%		13	10%	
Days 13-14	59	55%		76	56%	

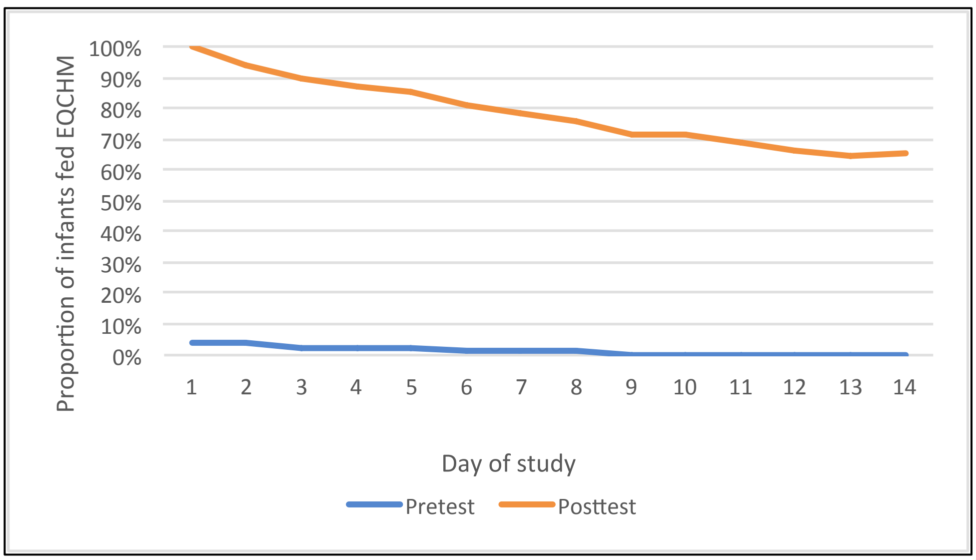
* <1% missing in pretest
** <1% missing in posttest

Table 5 in the appendix provides the specific sample sizes on each day of the study and the results of chi-squared tests for association between pretest vs. posttest status and the three outcomes of interest.

Outcome 1: exclusive quality-controlled human milk feeding (EQCHM)

For the exclusive quality-controlled human milk feeding outcome, statistically significant differences were found on all 14 days of the study, with significantly more infants being exclusively fed either mother's own milk, donor human milk, or both in the posttest group relative to the pretest group. For example, for pretest and posttest respectively, differences in the proportion of infants fed ECQHM were statistically significant on day 1 (4% and 100%, $\chi 2$ $p<0.001$), day 3 (2% and 89%, $\chi 2$ $p<0.001$), day 6 (1% and 81%, $\chi 2$ $p<0.001$), and day 14 (0% and 65%, $\chi 2$ $p<0.001$). Figure 2 shows the proportions in each group fed EQCHM by study day.

Figure 2. Proportion of infants exclusively fed quality-controlled human milk, by study day



In both days 1-7 (adjusted OR: 210, $p<0.001$) and days 8-14 (adjusted OR: 313, $p<0.001$), the odds of infants in the posttest group being exclusively fed EQCHM were significantly higher than infants in the pretest group. Table 2 provides crude and adjusted odds ratios of EQCHM feeding.

Table 2. Crude and adjusted odds ratios of exclusive quality-controlled human milk feeding, comparing posttest to pretest, by days 1-7 and 8-14

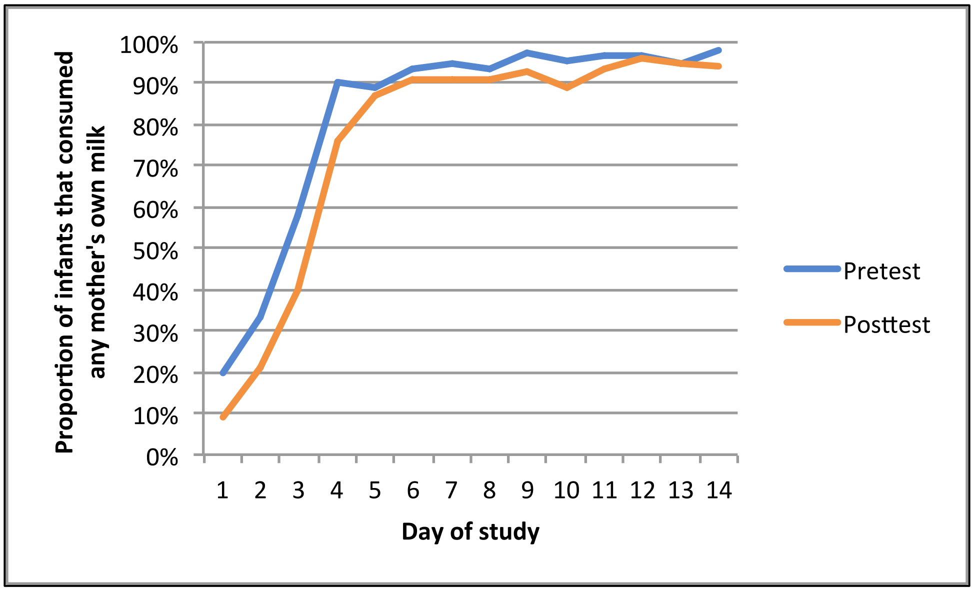
	Crude odds ratio (95% CI)	**Adjusted odds ratio* (95% CI)**
Days 1-7	281 (100 - 790) **	210 (79 - 554) **
Days 8-14	1023 (63 - 16500) **	313 (63 - 1550) **

*Adjusted for mother's age, birthweight, infant sex, diagnosis at admission, and gestational age

** p-value<0.001

For the sensitivity analysis to investigate whether intake of mother's own milk changed from pretest to posttest, we found statistically significant differences on day 1 (pretest=20%; posttest=9%, $\chi 2$ $p<0.05$), day 2 (pretest=34%; posttest=21%, $\chi 2$ $p<0.05$), day 3 (pretest=58%; posttest=40%, $\chi 2$ $p<0.05$), and day 4 (pretest=90%; posttest=76%, $\chi 2$ $p<0.05$). On all other days of the study, significant differences were not found. Specific estimates can be found in Table 5. Figure 3 suggests similar trends between pretest and posttest regarding exposure to mother's own milk throughout the 14 days of the study.

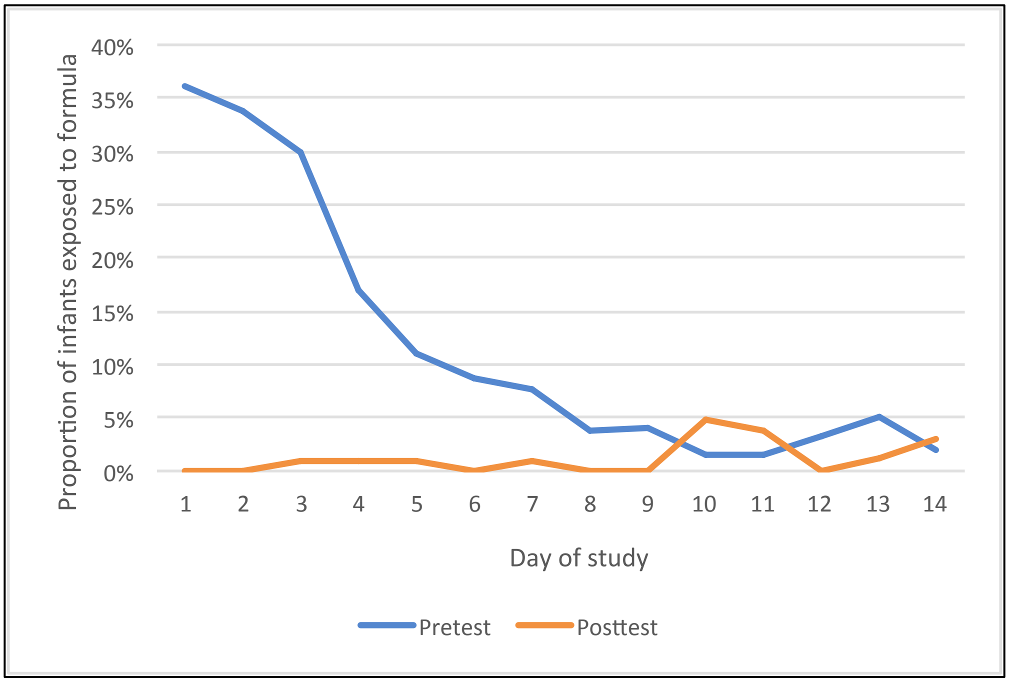
Figure 3. Proportion of infants that consumed any mother's own milk, by study day



Outcome 2: Exposure to formula

Statistically significant differences in the proportion of infants exposed to formula were found in the first seven days of data collection, but not on days 8-14. While the differences were consistently higher in the posttest group throughout the first seven days, with day 1 (pretest=36%; posttest=0%, $\chi 2$ $p<0.001$) and day 6 (pretest=9%; posttest=0%, $\chi 2$ $p<0.005$) showing significant differences, this trend did not continue throughout days 8-14, with the proportion of infants in posttest group actually being higher in day 10 (pretest=2%; posttest=5%, $\chi 2$ $p>0.05$) and day 14 (pretest=2%; posttest=3%, $\chi 2$ $p>0.05$). Figure 4 shows the proportions of infants exposed to formula, by study day, within pretest and posttest groups.

Figure 4. Proportion of infants exposed to formula, by study day



Within days 1-7, the odds of exposure to formula of infants in the posttest group were significantly lower than the pretest group (adjusted OR: 0.01, p<0.001). This effect was attenuated but not significant in days 8-14 (adjusted OR: 0.18, p=0.08). Table 3 provides crude and adjusted odds ratios of exposure to formula.

Table 3. Crude and adjusted odds ratios of exposure to formula, comparing posttest to pretest, by days 1-7 and 8-14

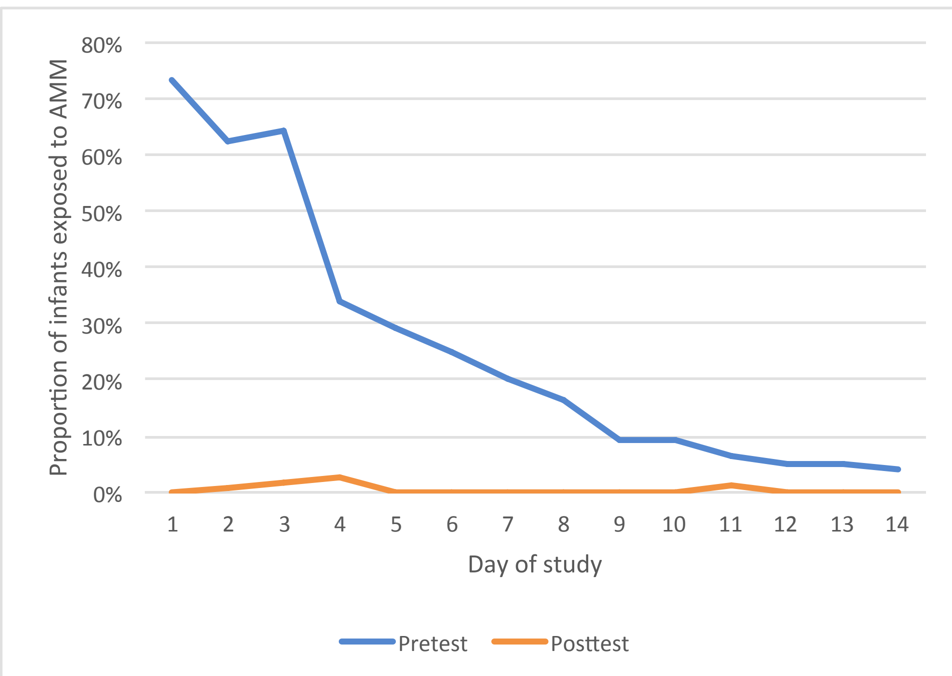
	Crude odds ratio (95% CI)	**Adjusted odds ratio* (95% CI)**
Days 1-7	0.02 (0.01 - 0.05) **	0.01 (0.0 - 0.06) **
Days 8-14	0.57 (0.25 - 1.23)	0.18 (0.02 - 1.56)

*Adjusted for mother's age, birthweight, infant sex, diagnosis at admission, and gestational age
** p-value<0.001

Outcome 3: exposure to another mother's milk

For the exposed to another mother's milk outcome, more infants were exposed to another mother's milk in the pretest group relative to the posttest group on each day of the study, and these differences were statistically significant on all days except days 11 and 14. The proportions of infants exposed to AMM were higher in the pretest group on day 1 (pretest=73%; posttest=0%, χ2 p<0.001), day 3 (pretest=64%; posttest=2%, χ2 p<0.001), day 6 (pretest=25%; posttest=0%, χ2 p<0.001), and day 14 (pretest=4%; posttest=0%, χ2 p>0.05). Figure 5 shows the proportions of infants exposed to formula, by study day, for pretest and posttest groups.

Figure 5. Proportion of infants exposed to another mother's milk, by study day



In both days 1-7 (adjusted OR: 0.02, p<0.001) and 8-14 (adjusted OR: 0.02, p<0.001), the odds of exposure to AMM was lower in the posttest group relative to the pretest group.

Table 4. Crude and adjusted odds ratios of exposure to another mother's milk, comparing posttest to pretest, by days 1-7 and 8-14

	Crude odds ratio (95% CI)	**Adjusted odds ratio* (95% CI)**
Days 1-7	0.01 (0.0 - 0.03) **	0.02 (0.01 - 0.04) **
Days 8-14	0.02 (0.0 - 0.15) **	0.02 (0.0 - 0.30) **

*Adjusted for mother's age, birthweight, infant sex, diagnosis at admission, and gestational age
** p-value<0.001

Discussion

This study demonstrated that infants born into newborn care services after integration of a HMB experienced improved feeding practices relative to infants born before the HMB was integrated. Specifically, data suggest higher odds of being exclusively breastfed safe human milk and lower odds of being exposed to formula and another mother's milk, comparing posttest to pretest. The study indicates that integrating a HMB into newborn care services provides the opportunity for infants to improve EQCHM intake while decreasing exposure to formula and AMM. It also demonstrates that the odds of exposure to formula was attenuated and not statistically significant within days 8-14 compared to days 1-7. We hypothesize that this may be due to a large proportion of mothers of preterm infants experiencing compromised initiation of lactation in the infants' early days of life (22). Unlike the situation for the pretest group, mothers without adequate milk volumes in the early days after birth in the posttest group were likely able to supplement with donor human milk, rather than formula, as an alternative to their own milk. This suggests a particular impact of donor human milk in the early days of the life of a vulnerable neonate. These important findings should be considered when developing models for the use of donor human milk in future research and practice.

These results are consistent with other studies investigating the impact of the introduction of donor human milk for vulnerable infants in neonate intensive care unit situations. In particular, the results are aligned with several studies that found that the introduction of donor human milk increased intake of human milk as well as reduced exposure to formula and non-pasteurized shared milk from another mother (9, 12-15). Interestingly, the insignificant effect size for exposure to formula within days 8-14 is similar to findings from Arslanoglu et al. (12) in which they observed an insignificant difference in exclusive formula rate at discharge among very low birthweight infants in several hospitals in Italy. Again, this highlights the importance of donor human milk in the early days of an infant's life and the need for continued support for mothers to encourage exclusive human milk feeding during this time. All of the aforementioned studies were conducted in high-income settings; this current study fills a research gap that exists for human milk banking in low- and middle-income countries and demonstrates that scale-up of HMBs is possible in low-resource settings.

The sensitivity analysis regarding intake of MOM suggests that donor human milk could be inadvertently overused and replace mother's own milk. This should be carefully monitored and prevented. Further research is warranted to ensure that support for mothers' lactation is prioritized over the use of donor human milk. However, even though significant differences between pretest and posttest were found within days 1-4, the lack of significant differences during the remainder of the days suggests that this may only be a concern in the early days of life when mothers may not be present with their infants. These mixed findings are aligned with the Williams et al. systematic review which found mixed results of the impact of the introduction of

DHM into neonatal units on the provision of MOM, with 9 studies finding either an increase or no effect on MOM provision and 1 study finding a reduction in MOM provision (16). Further, the Da Nang Hospital for Women and Children is aware of these data and consequently has begun to address the overuse of DHM and ensure lactation support is in place to prioritize MOM.

Strengths of this study include the granularity of data collection in the neonatal ward and the longitudinal nature. Many other similar studies have investigated feeding outcomes at cross-sectional time points such as at discharge from the neonatal unit (12, 13, 15). The present study differs, in that infants were followed longitudinally for several days, which provides comprehensive data on the exact volumes and timings of each infant's feeds, apart from feed volume from direct breastfeeding at the breast. Additionally, both pretest and posttest groups had a relatively long length of stay, with the majority of infants in both groups remaining in the neonatal ward throughout the entire 14 days of data collection. Finally, the magnitude of association for each outcome is so great that they are unlikely to be confounded by biases or seen by chance.

The study also has limitations that restrict generalizability and causal inference. First, the quasi-experimental nature may negatively impact the internal validity as confounding factors could have influenced findings. This was mitigated by adjusting for several maternal and infant factors in the Mantel-Haenszel analysis. Second, the analysis does not account for volumes of MOM fed directly at the breast due to lack of measurement feasibility. Therefore, dichotomous outcome variables were used to assess whether the mother did or did not receive any MOM. Additionally, the generalizability of this study is limited due to its high level of financial and technical assistance. Two international health non-profit organizations partnered to provide technical support and funding to this study site which likely offered a significant advantage for this hospital to excel in providing breastfeeding support and encouragement of optimal breastfeeding practices. Coupled with the fact that this hospital was already established as a Center of Excellence for early essential newborn care, this possibly means that the integration of the HMB and positive outcomes were more feasible than elsewhere; we may not have seen the full extent of the impact due to those behaviors already having been influenced through previous interventions. Finally, the study is limited by the period of admission into the neonatal ward being unpredictable based on the severity of the case. As healthy infants were more likely to be discharged than sicker infants, it is likely that the sample remaining at day 14 was sicker than the infants who were discharged. However, we do not consider this to have significantly biased results because the exposure to formula was already attenuated in the later days of the study.

This study is the first to report on the impact of a human milk bank in Vietnam and thus may be seen as a model for further milk banking interventions in Vietnam and the Greater Mekong Region. The positive results of this study should be viewed as motivation for further research on the impact of milk banking in Vietnam that may ultimately justify national scale up of milk banking efforts. Additionally, this study may be an impetus for improved global nutrition policies and programming that can promote and support equitable access to human milk for all infants, especially vulnerable neonates (23, 24).

Conclusion

This study demonstrates a positive impact of the integration of a human milk bank into newborn care services in Vietnam. Specifically, it suggests improved uptake of quality-controlled human milk and decreased exposure to formula and another mother's milk. The impact of the HMB on exposure to formula was attenuated but not statistically significant towards the later days of the study, suggesting a particular impact of donor human milk in the early days of the life and the need for continued support to reduce exposure to formula and AMM during these vulnerable days. This study informs future models for integrating human milk banks into health systems in Vietnam and the Greater Mekong Region. Further research is needed to determine the best practices for the provision of DHM and the impact of human milk banking on health outcomes, particularly in diverse settings with varying levels of resources. Improved data collection and better alignment of global nutrition and newborn policies are also necessary to achieve equitable access to human milk for vulnerable infants.

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APPENDIX

Table 5. Results of chi-squared tests for association between pretest/posttest status and outcomes of interest, by study day

	N		Proportion of infants exclusively fed quality-controlled human milk*			Proportion of infants exposed to mother's own milk			Proportion of infants exposed to formula			Proportion of infants exposed to another mother's milk		
	Pretest	Posttest	Pretest	Posttest	$\chi2$ p-value	Pretest	Posttest	$\chi2$ p-value	Pretest	Posttest	$\chi2$ p-value	Pretest	Posttest	$\chi2$ p-value
Day 1	97	121	4%	100%	0.000	20%	9%	0.025	36%	0%	0.000	73%	0%	0.000
Day 2	98	124	4%	94%	0.000	34%	21%	0.033	34%	0%	0.000	62%	1%	0.000
Day 3	90	113	2%	89%	0.000	58%	40%	0.011	30%	1%	0.000	64%	2%	0.000
Day 4	82	109	2%	87%	0.000	90%	76%	0.012	17%	1%	0.000	34%	3%	0.000
Day 5	82	109	2%	85%	0.000	89%	87%	0.695	11%	1%	0.002	29%	0%	0.000
Day 6	80	107	1%	81%	0.000	94%	91%	0.441	9%	0%	0.002	25%	0%	0.000
Day 7	79	100	1%	78%	0.000	95%	91%	0.314	8%	1%	0.024	20%	0%	0.000
Day 8	80	90	1%	76%	0.000	94%	91%	0.518	4%	0%	0.064	16%	0%	0.000
Day 9	74	85	0%	72%	0.000	97%	93%	0.210	4%	0%	0.061	9%	0%	0.004
Day 10	66	83	0%	71%	0.000	95%	89%	0.161	2%	5%	0.266	9%	0%	0.005
Day 11	64	80	0%	69%	0.000	97%	94%	0.386	2%	4%	0.427	6%	1%	0.103
Day 12	61	80	0%	66%	0.000	97%	96%	0.881	3%	0%	0.103	5%	0%	0.045
Day 13	59	76	0%	64%	0.000	95%	95%	0.963	5%	1%	0.200	5%	0%	0.047
Day 14	51	69	0%	65%	0.000	98%	94%	0.299	2%	3%	0.745	4%	0%	0.970

Note: infants were excluded if they only received parental feeding on that day
* indicator includes mother's own milk and/or donor human milk processed by human milk bank