Program Evaluation of a Breastfeeding History Questionnaire and Screening for the Risk of In-Hospital Formula Supplementation at an Academic Medical Center

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Abstract

BACKGROUND: Early formula supplementation disrupts the natural course of breastmilk production making it difficult for mothers who supplement to return to an exclusively breastfeeding state. In-hospital formula use leads to increased risk of early breastfeeding cessation when compared to infants who are exclusively breastfed in-hospital.

PURPOSE: This project evaluated the use and impact of a breastfeeding history questionnaire and screening tool (BAP Breastfeeding History Questionnaire and Screening tool) that prenatally predicts the risk of formula use in-hospital for each couplet.

METHODS: A retrospective review of 490 mother-infant couplet charts were assessed to evaluate use of the BAP Questionnaire and Screening tool and the effect of lactation support provided to couplets based on their calculated risk of non-medically indicated in-hospital formula use.

RESULTS: For this project, 282 couplets met inclusion criteria. Of those, 230 couplets were identified as high risk for in-hospital formula supplementation. Six percent of high-risk couplets did not receive lactation support. Of the couplets identified as high risk and who did not receive lactation support, 36% used formula in-hospital. Twenty-three total couplets were not provided any lactation support regardless of their risk level and 30% of those patients used formula.

CONCLUSION: Utilizing the BAP Breastfeeding History Questionnaire and Screening Tool prenatally can assist with identifying couplets at risk for in-hospital formula supplementation. Recognizing this risk allows lactation resources to be focused on high-risk couplets to decrease non-medically indicated formula use and promote long term breastfeeding success.

KEYWORDS: BAP questionnaire, in-hospital formula use, formula supplementation, exclusive breastfeeding, program evaluation

Introduction & Background

The American Academy of Pediatrics (AAP) recommends exclusive breastfeeding for six months followed by breastfeeding with the addition of solids for one year or longer as desired by the mother and infant couplet (American Academy of Pediatrics, 2012). According to the AAP, pediatricians are critical in their communities for advocating in support of breastfeeding as there are very few medical contraindications to breastfeeding (AAP, 2012). Nurses and providers should be enlightened on the health risks of not breastfeeding, societal and economic benefits of breastfeeding and techniques to support breastfeeding mothers and infants without introducing formula to the infant (AAP, 2012). Hospitals should also support maternal and infant breastfeeding initiation and sustainment throughout a dyad's hospital stay. However, this policy statement is not adhered to by all pediatric providers globally as formula supplementation is offered at various stages for a number of reasons to include: maternal fatigue, instrumental or operative deliveries, and perceived insufficient milk supply (Tarrant et al., 2015).

It is necessary to address this topic and support breastfeeding dyads as the benefits of breastfeeding are important to infant health. Providing any breastmilk to an infant reduces the incidence of otitis media by 23% and in infants exclusively breastfed for at least three months, the incidence of otitis media was decreased by 50% (AAP, 2012). Breastmilk can lower the risk of hospitalization for respiratory tract infections, reduce the incidence of gastrointestinal tract infections, and decrease the risk of necrotizing enterocolitis (NEC) in infants born premature. Breastfeeding can also decrease the risk of sudden infant death syndrome (SIDS) and reduce infant mortality rates (AAP, 2012). Breastfeeding results in many changes in infant outcomes and risks when compared to formula-fed infants to include: decreased risk of celiac disease,

inflammatory bowel disease, obesity, type 1 and type 2 diabetes, and cancers like leukemia and lymphoma (AAP, 2012).

Breastfeeding is not only beneficial for infants, but also for mothers. Breastfeeding mothers can have decreased blood loss and shortened time to complete involution of the uterus in the postpartum stage due to the hormone, oxytocin, that is secreted during breastfeeding (AAP, 2012). Breastfeeding is also associated with decreased rates of type 2 diabetes mellitus, in the absence of gestational diabetes. These benefits are amplified with increased cumulative durations of breastfeeding. This is calculated by total months of breastfeeding of all children versus the amount from breastfeeding just one child (AAP, 2012). Breast cancer, ovarian cancer, rheumatoid arthritis, cardiovascular disease, hyperlipidemia, and hypertension risks are all decreased by a cumulative breastfeeding duration of greater than 12 months. Even lower rates are seen with cumulative breastfeeding durations greater than 24 months (AAP, 2012). For women who carry the breast cancer gene 1 (BRCA1) mutation, the decrease in risk is even greater. BRCA1 women who breastfeed for 12 months or longer experience a 37% lower risk of breast cancer (Schwarz & Nothnagle, 2015). Mothers who have never breastfed have a 32% higher risk of developing ovarian cancer (Schwarz & Nothnagle, 2015). It is imperative to encourage breastfeeding for increased durations for enhanced maternal and infant health outcomes.

Providers should support mothers through pregnancy and postpartum with lactation education to increase chances of success with breastfeeding goals (Keister et al., 2008). Guiding parents through their decision to exclusively breastfeed if medical complications arise, can increase long-term breastfeeding success. Prenatal providers are crucial in influencing mothers to selection of feeding methods and supporting those plans (Burns et al, 2018). Utilizing a

breastfeeding screening questionnaire prenatally can identify mother-infant dyads at increased risk of formula use and dyads who may need increased lactation support postpartum. Infant medical concerns such as hyperbilirubinemia, weight loss, or signs of failure to thrive must be managed delicately to continue to promote breastfeeding. Postpartum maternal and infant providers should support mothers through exclusive breastfeeding as much as possible and use careful decision making when prescribing formula supplementation (Keister et al., 2008). Lactation consultants or specialists should be utilized when concerns with latch, hyperbilirubinemia, weight loss, or signs of failure to thrive are first discovered. This will further promote exclusive breastmilk intake before formula supplementation becomes medically necessary (Keister et al., 2008).

Most United States (U.S.) hospitals offer free formula for infant use in the hospital. Some hospitals even give out formula for families to take home to continue using. In the 2015, 17% of U.S. breastfed infants received supplementation with formula in the first 48 hours of life (Jenco, 2020). Generally, the first 48 hours are spent in the hospital, prior to discharge home. Exclusive breastfeeding rates and duration of breastfeeding would increase if formula was not so accessible in the hospital (Tarrant et al., 2015). Tarrant et al. (2015), in a study conducted in Hong Kong, chose to no longer accept free formula samples from suppliers to give out to patients in public hospitals. If families were to choose to use formula, they would need to pay for it in the hospital or provide their own from home. When formula was offered for free in the hospital, 23% to 82% of healthy newborn infants used formula supplementation prior to leaving the hospital (Tarrant et al., 2015). After they implemented the change of not providing free formula in the hospital, exclusive breastfeeding while inpatient increased from 17.7% to 41.3%. The median duration of breastfeeding also increased from eight to 12.5 weeks (Tarrant et al., 2015). This confirms that

when dyads are not offered formula supplementation in the newborn setting, exclusive breastfeeding success rates increase.

Globally, only 37% of infants are exclusively breastfed for six months (Zakarija-Grković et al., 2017). However, according to the World Health Organization (WHO) (2018) of those infants exclusively breastfed at six months of life, 71% of them are still breastfed at one year of life. According to the Centers for Disease Control and Prevention (CDC) of United States dyads, 57.6% of infants are receiving some amount of breastmilk at six months and of those, 35.9% of infants receives some amount of breastmilk at 12 months (CDC, 2018). U.S. infants who are exclusively breastfed at six months remains much lower at 24.9% (CDC, 2018). Dyads who choose to or are advised by pediatric providers to supplement in the first few days of life have decreased success reaching six and 12-month goals (Dabritz et al., 2010). According to the CDC, Virginia is slightly higher than national averages for some amount of breastmilk at six months of life at 62.5% and 12 months of life at 39.3% (CDC, 2018). Of Virginia infants, 26.6% were exclusively breastfed at six months of life (CDC, 2018).

While exploring the culture surrounding formula supplementation among nurses, providers, and patients at a large academic health center, a research team can evaluate the impact of early formula supplementation on breastfeeding success rates. This hospital, located in the Eastern U.S., is a WHO Baby-Friendly Health Initiative institution dedicated to pregnancy, labor, delivery, and postpartum care for mothers and infants while promoting breastfeeding throughout. Because this hospital follows mothers through pregnancy, inpatient, and postpartum phases, nurses and providers can assess those mothers for increased risk of formula supplementation or total use easily and provide those mothers with increased breastfeeding resources. Infants with medical contraindications to breastfeeding are rare but can be seen in

infants with galactosemia, phenylketonuria, and infants born to mothers with human T-cell lymphotropic virus type I or II, untreated brucellosis, untreated active tuberculosis, or active herpes simplex virus (HSV) lesions on the breast (AAP, 2012). Women with active tuberculosis or HSV lesions on the breast can give expressed breastmilk to their infants safely. Contraindications also include some women with human immunodeficiency viruses (HIV), and some maternal substance abuse users. Maternal tobacco smoking and alcohol use are not recommended with breastfeeding, but are not medically contraindicated AAP, 2012). Mothers and infants with medical contraindications to breastfeeding should not breastfeed and will not be assessed for breastfeeding outcomes in this program evaluation. For those patients, formula would be necessary.

Nurses play an important role in supporting pregnant women and new mothers in their breastfeeding endeavors. According to a study by Siggia and Rosenberg (2014), when nurses are trained in lactation support, exclusive breastfeeding percentages rise. They studied the Baby-Friendly Health Initiative (BFHI) newly instated at a large academic medical center (AMC) and lactation education among nurses. Prior to lactation education provided to nursing staff at the facility, exclusive breastfeeding rates were averaged at 38.55% over a four-month period (Siggia & Rosenberg, 2014). Facility nurses were trained in a lactation course as outlined by the WHO BFHI, totaling 20 hours of lactation and breastfeeding support education. Some of these hours were didactic education and at least five of these hours were hands-on skills training. After training all nursing staff, exclusive breastfeeding rates averaged 53.5% measured over a four-month period (Siggia & Rosenberg, 2014). This data further guides the belief that nurses and providers can impact the outcome of exclusive breastfeeding rates in mother and infant dyads.

Search Methods

A systematic literature review was conducted to investigate the effects of early formula supplementation on breastfeeding outcomes in mothers who intended to breastfeed exclusively. To identify the literature, a search was performed using PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), OVID Medline, the Joanna Briggs Institute EBP Database (JBI), and Cochrane Library. All of the searches were restricted to results published in English language only. OVID Medline and PubMed searches were further restricted to human species results.

In the PubMed database, the sort option "Best Match" was selected for the search resulting in *formula supplementation* (2,942), *early limited formula* (599), *breastfeeding* (55,796), *breast milk* (44,810), *duration* (594,416) and *length of time* (179,309). Results were then combined in the same manner as the previous database searches with OR and AND (216). English language, human species and 10-year (2010-2020) timeframe limiters were then placed (91).

In the CINAHL database, an "Any Word" search was performed using *formula supplementation* (805), *early limited formula* (79), *breastfeeding* (20,156), *breast milk* (8,374), *duration* (120,348) and *length of time* (34,405) were searched with "Find all my search terms" and "Apply equivalent subjects" applied and without the "Suggested Subject Terms" applied in the "Advanced Search" method. The results of formula supplementation and early limited formula were combined using OR (879). The results of breastfeeding and breast milk were combined using OR (24,395). The results of duration and length of time were combined using OR (149,941). These combined search result groupings were further merged using AND (66). These CINAHL results were further restricted to results published within 10 years (2010 through

2020), peer-reviewed, and English language only (34).

In the OVID Medline database, only keyword searches were performed. *Formula supplementation* (191), *early limited formula* (6), *breastfeeding* (25,346), *breast milk* (13,058), *duration* (570,953) and *length of time* (11,776) were combined in the same way as in the other databases (42). English language, human species and 10-year (2010-2020) timeframe limiters were then placed (20).

In the JBI database, only keyword searches were performed. *Formula supplementation* (3), *early limited formula* (0), *breastfeeding* (261), *breast milk* (112), *duration* (1834) and *length of time* (194) were combined in the same manner as CINAHL using OR and AND (1).

In the Cochrane library, keyword searches were performed for *formula supplementation* (2 reviews, 118 trials), *early limited formula* (1 trial), *breastfeeding* (16 trials), *breast milk* (12 reviews, 1,521 trials), *duration* (34,617 trials) and *length of time* (40 reviews, 2,229 trials). Those without review numbers posted resulted in 0 Cochrane reviews. These keywords were combined in the same manner as CINAHL using OR and AND (1 trial). No Cochrane reviews were obtained from this search; however, the sole trial result was secured for further literature review as it pertained to the PICOT.

The total number of articles retrieved from the five databases was 147. After removing all duplicates, there were 97 articles remaining. After the title and abstract reviews, 73 articles were removed. Reasons for removal of articles included: infants admitted to the Neonatal Intensive Care Unit (NICU) or unwell newborns, prolonged breastfeeding implications on childhood diseases, diabetes mellitus, maternal health outcomes, maternal refusal to breastfeed, no evaluation of early formula use, exclusive breast pumping outcomes, or complete irrelevance to the PICOT question. After full text review of the remaining articles, 16 were excluded for an

outcome of childhood obesity, irrelevance to PICOT, maternal desire to use formula supplementation, NICU admission or complicated birth breastfeeding success, and Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) participation effects on breastfeeding outcomes. A total of eight articles were retained for analysis. Figure 1 shows the search development, using a Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram.

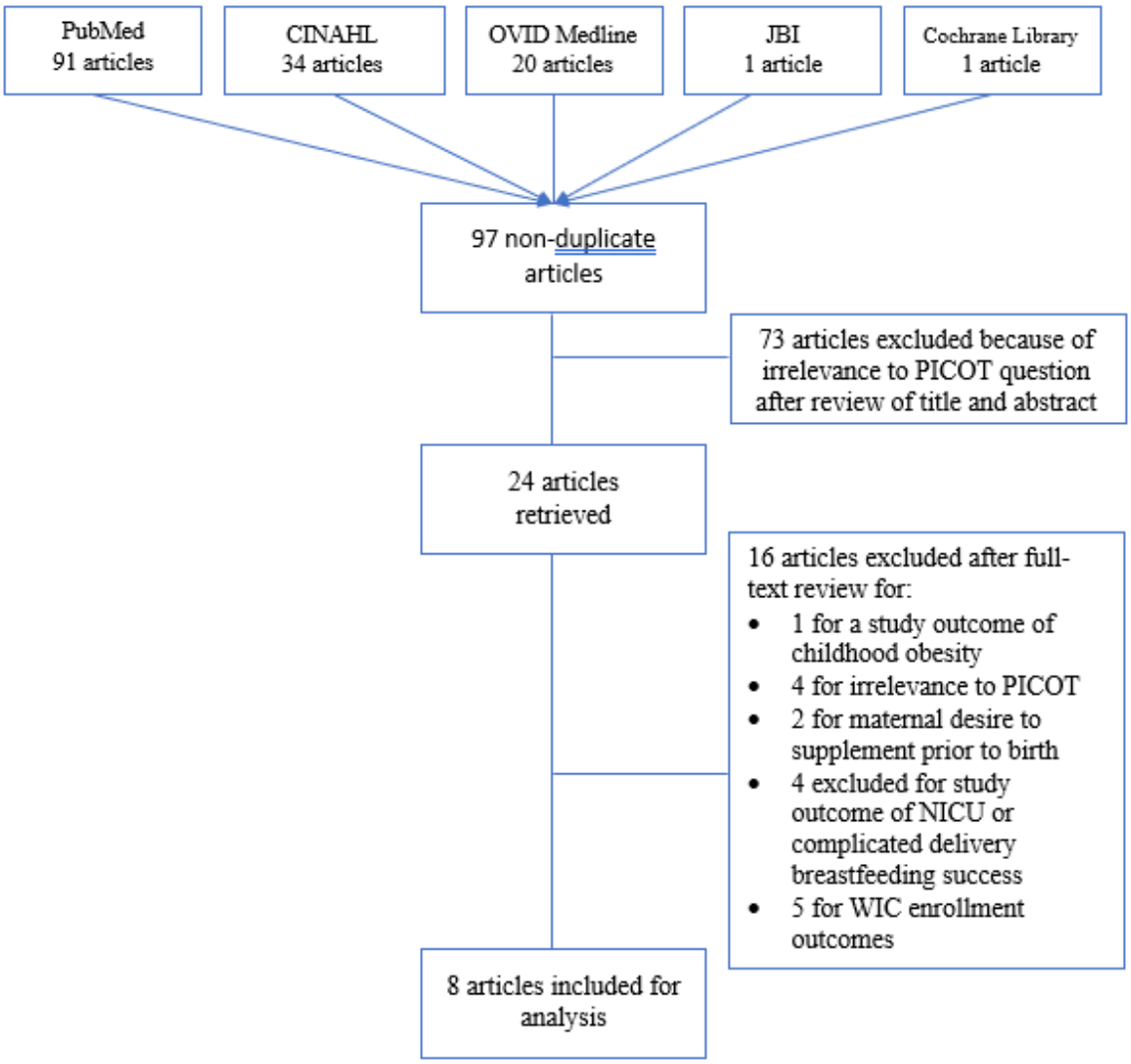

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram for the systematic literature search process. CINAHL = Cumulative Index to Nursing and Allied Health Literature; JBI = Joanna Briggs Institute EBP Database.

Summary of Data and Analysis

A total of eight articles were retained for analysis after a systematic search of the database. Two experts in the field were contacted that resulted in three breastfeeding screening tool articles being added in that originally were not retained in the literature review (E. Drake, personal communication, June 1, 2020; A. Kellams, personal communication, April 4, 2020). Two of those articles were greater than 10 years old, thus excluded from original searches. However, this also demonstrates the need for increased development, study of and use of breastfeeding screening tools to predict breastfeeding outcomes or risk of formula use. A compiled list of the 11 retained articles can be found in Table 1. These articles range in levels of evidence and quality from Level I to Level III-A using the Johns Hopkins Nursing Evidence-based Practice rating scale. A thematic analysis was conducted on the articles retained. Three themes were consistently found among the articles. The first theme related to the topic was the effect of in-hospital formula supplementation on the duration or outcome of exclusive breastfeeding success. The second related theme was analyzing the reasons for early formula supplementation in healthy newborns of mothers who prenatally intended to exclusively breastfeed. The third theme related to the effects of use and validation of breastfeeding screening tools. The articles remaining for full analysis were in agreement that any amount of early limited formula or formula supplementation could lead to poor breastfeeding duration outcomes.

Thematic Analysis and Synthesis of Evidence

In-Hospital Formula Supplementation

The first theme related to the topic was the effect of in-hospital formula supplementation on the duration or outcome of exclusive breastfeeding success. This theme was evidenced by Flaherman et al. (2019), Chantry et al. (2014), Parry et al. (2013), Tarrant et al. (2015), and Vehling et al. (2018). All of these studies showed infants who received any formula supplementation in-hospital were at higher risk of any or exclusive breastfeeding cessation compared to infants who were exclusively breastfed in-hospital. Flaherman et al. (2019), in the sole randomized control study (RCT) of 161 mothers, showed no difference in any breastfeeding rates between mothers who were in the intervention group with early limited formula use or control group without early limited formula use at the six-month mark. This was a novel finding for this study. However, after continuing to follow the control and intervention groups for 12 months, the control group had higher rates of breastfeeding at 12 months than those who used formula supplementation in-hospital (Flaherman et al., 2019).

Chantry et al. (2014) followed mother-infant dyads at the University of California Davis Medical Center (UCDMC) which has an abundance of breastfeeding resources for staff and patients. Prenatally, 393 mothers were interviewed and graded using the validated Infant Feeding Intention (IFI) Scale which grades mothers' intentions to breastfeed from 0 to 16 (Chantry et al., 2014). They were then grouped by the strength of their breastfeeding intentions using weak, moderate, strong, and very strong based on the grades of the IFI Scale. Once delivered, mothers were interviewed and information was received from the electronic health record (EHR) to verify if formula supplementation had been used within 24 hours of birth, at 72 hours of life, and at the 7th day of life (Chantry et al., 2014). Telephone interviews were conducted at 14, 30, and 60-days to document feeding types. Chantry et al. (2014) found that infants receiving any in-hospital formula supplementation were not likely to not be exclusively breastfed at the 30- and 60-day

marks (67.8%) in comparison to in-hospital exclusively breastfed infants (36.7%). Infants receiving in-hospital formula supplementation were also found to be more likely to have stopped breastfeeding entirely (32.8%) by day 60 postpartum than the exclusively breastfed group (10.5%) (Chantry et al., 2014).

Parry et al. (2013) researchers utilized four public hospitals in Hong Kong to recruit 1246 mother-infant dyads for the study completed in 2006 and 2007. The study applied a longitudinal prospective cohort design and researchers followed the mother-infant dyads for 12 months postpartum or until breastfeeding cessation occurred. Results showed that within 48 hours of birth, 82.5% of healthy newborns had received in-hospital formula supplementation (Parry et al., 2013). Within five hours of birth, 50% of newborns had received formula supplementation (Parry et al., 2013). Only 28% of newborns were put to the breast to nurse within the first hour of life and 50% were put to the breast by three hours of life (Parry et al., 2013). Early formula supplementation disrupts the natural course of breastmilk production making it difficult for mothers who supplement to return to an exclusively breastfeeding state. Of infants who received formula within the first 48 hours of life, 12.5% showed a duration of any breastfeeding at 12 months of life. Of infants who were exclusively breastfed within the first 48 hours of life, 25% showed a duration of any breastfeeding at 12 months of life (Parry et al., 2013).

Tarrant et al. (2015) utilized a prospective cohort study design with cohort 1 being a group of 1320 Hong Kong mother-infant dyads. Cohort 1 was recruited in 2006-2007 while the hospital still offered free infant formula for in-hospital supplementation use. Cohort 2 followed 1240 mother-infant dyads after the policy of not offering free infant formula was implemented in 2011-2012. Both cohorts (n=2560) were followed for 12 months postpartum or until they reached breastfeeding cessation. Mothers who desired to exclusively use formula or supplement

with formula were charged at the market rate for the formula used in the hospital. The results showed that infants in cohort 1 received more formula supplementation and were at higher risk of breastfeeding cessation than infants in cohort 2. In cohort 1, 64.4% of infant feeds were breastmilk in the first 24 hours of life, 72% of infant feeds were breastmilk in the second 24 hours of life, and only 69.2% of total in-hospital infant feeds were breastmilk (Tarrant et al., 2015). In cohort 2, 83.3% of infant feeds were breastmilk in the first 24 hours of life, 86.2% of infant feeds were breastmilk in the second 24 hours of life, and 84.2% of total in-hospital infant feeds were breastmilk (Tarrant et al., 2015). All of these comparisons between cohort 1 to cohort 2 were statistically significant at the level of $P<0.001$ (Tarrant et al., 2015). The mean amount of formula supplementation feeds given in the first 24 hours of life dropped from 2.7 in cohort 1 to 1.17 in cohort 2 (Tarrant et al., 2015). The duration of breastfeeding also increased between cohort 1 and cohort 2 with a median breastfeeding duration increasing from 8 to 12.5 weeks (Tarrant et al., 2015).

The final study pertaining to the first theme examines the association of maternal education, newborn feeding type in hospital, and outcomes of breastfeeding duration (Vehling et al., 2018). Mothers (n=3195) were interviewed through 24 months postpartum to assess feeding types. Results showed that 97.5% of all maternal-infant dyads-initiated breastfeeding in the hospital (Vehling et al., 2018). Of those who initiated breastfeeding, 74.1% were exclusively breastfed throughout the duration of the hospital stay; 25.9% received some type of in-hospital formula supplementation (Vehling et al., 2018). Exclusive breastfeeding rates at three months were 61.1% of infants and at six months were 18.5% of infants, while 75.1% of infants received some amount of breastmilk at six months and 43.9% of infants received some amount of breastmilk at 12 months (Vehling et al., 2018). Ten months was the median breastfeeding

duration for any amount of breastmilk (Vehling et al., 2018). These findings suggest that any formula supplementation led to shortened duration of any breastfeeding, while exclusive breastfeeding in-hospital led to increased duration of breastfeeding (Vehling et al., 2018).

Reasons for Early Formula Supplementation

The second related theme was analyzing the reasons for early formula supplementation in healthy newborns of mothers who prenatally intended to exclusively breastfeed. This theme was evidenced by Biro et al. (2011), Chantry et al. (2014), Grassley et al. (2014), Parry et al. (2013), and Temple et al. (2017).

Biro et al. (2011) performed a descriptive population-based survey in Australia in September through October 2007 to explore the reasons for use of in-hospital formula supplementation among 4,085 mother-infant dyads. Results of this study showed that 94.9% of mothers initiated breastfeeding in the hospital; however, 23% of these women utilized some amount of in-hospital formula supplementation (Biro et al., 2011). Only 5.1% of mother-infant dyads were exclusively formula fed. The Baby-Friendly Health Initiative sets the standard recommendation for exclusive breastfeeding while in-hospital at 75% of newborns; this was not met in this study at 59.3% of newborns being exclusively breastfed (Biro et al., 2011). Some reasons for increased use of in-hospital formula supplementation include: maternal lack of confidence in ability to satisfy the newborns dietary needs, increased maternal BMI, maternal tobacco use, non-English speaking background, infants born via cesarean section, babies admitted to the NICU, and clinician recommendation (Biro et al., 2011). While most of the infants were born at Baby-Friendly hospitals, researchers found that lack of clinician breastfeeding support increased the rate of formula supplementation in infants who were sleepy or fussy and had breastfeeding difficulties. Increased rates of supplementation were also cause by

a deficit of provider breastfeeding knowledge to help influence maternal decision to use formula or not. First-time mothers were also twice as likely to give their infants in-hospital formula (Biro et al., 2011).

Chantry et al. (2014) researchers discovered trends in reasoning for in-hospital supplementation. Perception of low milk supply (18%), signs of insufficient intake (16%), and poor infant breastfeeding behavior/latch (14%) were the top three trends (Chantry et al., 2014). Even with ample breastfeeding support and resources, almost half of mothers used formula supplementation while in-hospital (Chantry et al., 2014). Those who chose to supplement with formula, had decreased chances of achieving desired breastfeeding duration goals.

Grassley et al. (2014) studied the common reasons for initiation of formula supplementation in healthy newborns in a retrospective cross-sectional review of 302 maternal-infant electronic health records. Records were reviewed at two hospitals within the same health system using two different time periods of September 2007 through December 2007 and September 2009 through December 2009. The second time period was after the hospital had implemented a stricter infant blood sugar policy which appeared to have led to increased rates of in-hospital formula supplementation (Grassley et al., 2014). Both hospitals had three Internationally Board-Certified Lactation Consultants (IBCLC) who worked on dayshift only. They found that time of birth affected newborn supplementation rates. Forty-nine percent of infants born between 10:00 P.M. and 9:00 A.M. received formula supplementation compared with 31% of infants born between the hours of 10:00 A.M. and 9:00 P.M. (Grassley et al., 2014). This can easily be related to the fact that IBCLC support is not available during nightshift hours and nurse census was lower on nightshift than dayshift (Grassley et al., 2014). Other trends in the use of formula supplementation included: maternal desire to supplement, infant hypoglycemia,

sleepy or fussy infant, or health provider recommended. Study findings support the need to encourage early (initiating breastfeeding no later than the first hour of life) and frequent breastfeeding, immediate skin-to-skin contact, staff breastfeeding education and awareness, and assisting mothers to meet these goals regardless of method of delivery. Encouraging these behaviors can decrease the chance of in-hospital formula supplementation (Grassley et al., 2014).

Researchers discovered that 95% of cesarean section infants received in-hospital formula by 48 hours of life (Parry et al., 2013). Trends that researchers discovered leading to increased risk of in-hospital formula use included: spousal desire to use formula, lower maternal education level, induction of labor, large birth weight infants, forceps or vacuum-assisted vaginal deliveries, or cesarean section deliveries. While trends protective of exclusive breastfeeding included: higher maternal education, unassisted vaginal birth, previous breastfeeding experience, desires to breastfeed exclusively, and initiating breastfeeding within one hour of birth (Parry et al., 2013).

Temple et al. (2017) explored the reasoning behind in-hospital formula supplementation of healthy newborns whose mothers intended to exclusively breastfeed. They utilized a non-experimental cross-sectional study design of 496 mothers who prenatally intended to breastfeed exclusively for six months. The study took place in Newfoundland and Labrador, Canada where exclusive breastfeeding rates at 6 months of life are the lowest in Canada at 17.1% (Temple et al., 2017). Nearly 100% of all births in this region take place within 10 hospitals, none of which are Baby-Friendly designated hospitals (Temple et al., 2017). Results showed that 22.5% of infants born to mothers who planned to exclusively breastfeed received in-hospital formula supplementation within the first few hours to days of life (Temple et al., 2017). Of those receiving supplementation, 75% received formula supplementation for non-medically indicated

reasons (Temple et al., 2017). Reasons for non-medically indicated supplementation include: no previous breastfeeding experience, negative impressions of the first breastfeeding encounter, and receiving advice from a hospital physician. In this study specifically, when breastfeeding advice was received from a medical physician, a 3-fold increase of non-medically indicated in-hospital formula supplementation occurred (Temple et al., 2017). This may indicate the need for further breastfeeding education for providers and staff members to support breastfeeding dyads.

Breastfeeding Screening Tool

The third theme related to the topic was the effects of use and validation of breastfeeding screening tools. This theme was evidenced by Bender et al (2019), Dennis (2003), and Evans et al. (2004). All three of these articles assessed the use of a breastfeeding screening tool or validated a specific screening tool.

Researchers in Bender et al. (2019) validated the BAP Breastfeeding History Questionnaire and Screening tool at the University of Virginia. In a prospective observational study of 433 women, they examined efficacy of the BAP screening tool (Bender et al., 2019). The aim for the screening tool is to be performed prenatally to identify the risk and occurrence of non-medically indicated formula use during the postpartum inpatient stay. Results scoring <1 indicated first time mothers or multiparous mothers with breastfeeding problems in previous children and increased risk of formula use (Bender et al., 2019). On the contrary, scores ≥2 indicates prior breastfeeding success and decreased risk of formula use (Bender et al., 2019. Results from the Bender et al. (2019) study validated the BAP Breastfeeding History Questionnaire and Screening tool and confirmed that the antenatal screening tool successfully identified women who are likely to use formula during the inpatient stay. Not only were those

women more likely to use formula supplementation during their stay, but they were at increased risk of using formula for the majority of feeds in-hospital.

Evans et al. (2004) examines the use of a Modified Breastfeeding Attrition Prediction Tool (BAPT) prenatally (BAPT1) as well as postnatally (BAPT2) administered to 117 women who anticipated to breastfeed for at least eight weeks. The BAPT was originally developed by Janke in 1992 to predict women at risk for early breastfeeding attrition. The BAPT utilizes the Theory of Planned Behavior with four subscales assessing positive breastfeeding sentiment attitudinal scale, negative breastfeeding sentiment attitudinal scale, social and professional support scale, and breastfeeding control scale (Evans et al., 2004). Women received follow-up calls eight weeks postpartum to assess feeding types. This study was not able to accurately predict early attrition; however, two prior studies in 1994 and 2002 did find a correlation in BAPT results and early breastfeeding attrition risks (Evans et al., 2004).

Dennis (2003) sought to reduce the number of items on the Breastfeeding Self-Efficacy Scale (BSES) and perform an assessment on the new shortened version, BSES-SF. The original BSES has 33 items and is self-reported through Likert scales with a possible score ranging from 33 to 165. The higher the scoring, the higher levels of breastfeeding self-efficacy (Dennis, 2003). In the BSES-SF, only 14 questions remained with similar Likert scale scoring and higher scores indicating higher levels of breastfeeding self-efficacy. The BSES-SF was validated after this successful study use in 491 postpartum women (Dennis, 2003). The BSES-SF is an excellent tool for breastfeeding self-efficacy and can: identify mothers at high risk, assess breastfeeding behaviors, and evaluate the effect of interventions. When the BSES-SF was administered at one week postpartum, the results were a reliable predictor of future breastfeeding practices at four and eight weeks (Dennis, 2003).

Evaluation and Recommendation

A search of the gray literature was conducted to address the possibility of publication bias by searching: "effects of formula supplementation in breastfed infants and duration of breastfeeding" in Google Scholar and looking at the first 20 results. There was no evidence of publication bias based on the similarity of the results found in the gray literature. The findings were all consistent with our systematic review. Several themes in the gray literature included: analyzing the reasons for early formula supplementation in healthy newborns of mothers who prenatally intended to exclusively breastfeed, the effect of in-hospital formula supplementation on the duration or outcome of exclusive breastfeeding success, the effects of use and validation of breastfeeding screening tools, and reasons for supplementation in specifically low-income families. Within the initial database search all four themes were also found. However, for the analysis of the literature the fourth theme was removed as those articles were WIC-initiated and focused on low-income access to formula. Several articles found in the gray literature search were the same articles found in the initial database search and some were duplicates of the articles retained for final analysis.

The overall quality of the literature was very compelling and sought to answer the nursing practice question. The levels of evidence varied from Level I to Level III-A using the Johns Hopkins Nursing Evidence-based Practice rating scale. Quality ratings were consistently at Quality Rating A. Strengths of the evidence include: consistency in themes among the database articles retained for analysis, no publication bias shown in the gray literature search, longevity of studies, use of electronic health records to collect data, and documentation of socioeconomic status and participant demographics to verify (or refute) generalizability of specific studies. Limitations of the evidence include: maternal self-report and the possibility of participant bias,

length of time between birth event and evaluation of supplementation and the possibility of recall bias, and lack of generalizability of specific results based on participant demographics.

Specific recommendations derived from the Temple et al. (2017) study include: advocating for an increase in the number of Baby-Friendly hospitals to support breastfeeding outcomes, increased breastfeeding education among staff members and providers, increased public education to help normalize and support breastfeeding, and pursuing a collaborative approach to perinatal care that empowers women to feel confidence in their abilities to breastfeed their newborns. It would be beneficial for our clinical practice to change based on these findings.

Based on the review of the literature, recommendations would include prenatal discussion of maternal desire to breastfeed along with education of the benefits for mother and baby and use of breastfeeding questionnaires to predict breastfeeding outcomes. It also recommends increased support of in-hospital breastfeeding (24 hours per day) with a focus on expanded resources for infants born on nightshift as supported by Grassley et al. (2014). Finally, provider education on the importance of avoiding recommending formula supplementation in the first two weeks of life unless an absolute medical indication is present is recommended. Specifically, it would be beneficial to educate all providers and nurses on the common reasons for formula supplementation or breastfeeding cessation and give them feasible tools to help prepare for and combat this to support exclusive breastfeeding. Utilizing the BAP Breastfeeding History Questionnaire and Screening tool can help predict mothers with increased risk of formula use in the inpatient setting and alert providers to the need of increased breastfeeding support (Burns et al., 2018). When formula supplementation is non-medically indicated, the benefits of supporting maternal-infant dyads through exclusive breastfeeding outweigh the risk of contributing to early breastfeeding cessation by supporting early formula supplementation (Temple et al., 2017).

Purpose of the Scholarly Project

The purpose of this DNP project is to perform a formal program evaluation of a breastfeeding history questionnaire and screening program for the risk of in-hospital formula supplementation at an academic medical center. The BAP Breastfeeding History Questionnaire and Screening tool has been tested and formally validated previously. However, the program has not yet been evaluated at this organization. The goal of the BAP Breastfeeding History Questionnaire and Screening tool is to use a simple prenatal screening questionnaire to predict in-hospital formula supplementation (Burns et al., 2018).

Methods

Conceptual Framework

In 1997, the director for the Centers for Disease Control and Prevention recognized the need for a program evaluation framework and began to gather professionals and subject matter experts to create the CDC Framework for Program Evaluation in Public Health (CDC, 1999). It was formally published in 1999 to serve as a systematic approach and guideline to program evaluation specifically in public health matters. Because breastfeeding can improve the overall health and well-being of children and adults, and community resources and support are important to consider, we can apply the CDC Framework for Program Evaluation to this scholarly project for the evaluation of the BAP Breastfeeding History Questionnaire and Screening tool.

The CDC (1999) Framework for Program Evaluation consists of six sequential steps to guide this scholarly project: 1. Engage the stakeholders, 2. Describe the program, 3. Focus the evaluation design, 4. Gather credible evidence, 5. Justify conclusions, and 6. Ensure use and share lessons learned. This framework also employs four standards of effective evaluation: Utility, Feasibility, Propriety, and Accuracy (Figure 2).

Figure 2. The conceptual framework for this scholarly project by the CDC (1999), Framework for program evaluation in public health (No.RR-11).

Definition of Terms

Formula use/supplementation: Any use of nonmedically indicated formula given to the infant during the immediate inpatient postpartum stay (Burns et al., 2018).

Exclusive breastfeeding: Absolutely no use of formula or formula supplementation; sole infant intake is breastmilk (AAP, 2012).

Exclusive formula feeding: Complete use of formula without use of breastmilk or breastfeeding.

Formula use rates: Healthy People 2020 recommends a goal for reduction in formula use in the first 48 hours of life from 24.2% to 14.2% of infants (US Department of Health and Human Services, 2016). The CDC Breastfeeding Report Card revealed that 17% of mothers who breastfed also gave formula to their newborn in the first 48 hours of life (CDC, 2018).

Approval of setting

Approval of this program evaluation was granted by the labor and delivery nurse manager and medical director of the breastfeeding medicine program. The documented approval is located in Appendix A.

Setting

This scholarly project took place in the labor and delivery and postpartum units at a 608-bed AMC with a Level 1 Trauma Center. The units consist of four antenatal rooms, four triage rooms, eight labor rooms, and 15 private postpartum suites each designed to house one couplet. There are 34 Registered Nurses on staff and five nurses per shift, including the charge nurse. There are 8 Internationally Board-Certified Lactation Consultants (IBCLCs) on staff. This hospital documented 1,929 live births in 2019. The DNP student investigator examined charts retroactively between September and November 2019 to ensure that holidays and staff furlough/alterations due to the present-day effects of Covid-19 did not skew the results.

Participant inclusion criteria consisted of: women aged 18 years or older with singleton pregnancies who presented to prenatal care prior to 20 weeks gestation with a resulting term delivery (≥37 weeks gestation). Exclusion criteria consisted of: multiple gestation pregnancies, pre-term delivery (<37 weeks gestation), NICU admission, medical contraindication to breastfeeding, or pregnancy loss. Multiple gestation pregnancies, pre-term delivery, and NICU admission dyads were excluded due to the assumed increase of medically indicated formula supplementation. Those with medical contraindications to breastfeeding were excluded out of the necessity to utilize formula as sole infant nutrition.

Participant Demographics

Between the months of September and November 2019, 490 pregnant mothers were admitted to labor and delivery. After reviewing each chart for exclusion criteria, 334 mother-infant couplets remained. Of those, 52 couplets were excluded for their intent to formula feed. A total of 282 couplets with intent to breastfeed remained to be assessed for this project. Figure 3 portrays a visual for this process. Three percent of women were 18 to 19 years old, 47% of

women were 20 to 29 years old, 48% of women were 30 to 39 years old and 2% of women were 40 years or older. The majority of women were White or Caucasian at 65%, while Black or African American (14%), Asian (4%), and Other (17%) made up the minority. Most women (84%) did not identify as Hispanic or Latino. For marital status, 60% of women were married, 37% were single, and 3% were divorced, legally separated, or engaged. The largest insurance group was Medicaid at 39% ahead of various other insurance agencies. Finally, 62% of women were multiparous, leaving 38% as primiparous. The DNP student investigator attempted to collect education levels on participants but this demographic characteristic was grossly missing in the record and only 14 of the 282 women meeting inclusion criteria had a documented education level. Table 2 depicts the demographic characteristics.

Birth Characteristics

Birth characteristics of the couplets meeting inclusion criteria were also examined as shown in Table 3. Spontaneous Vaginal Deliveries (SVD) accounted for 70% of all births. Assisted vaginal delivery, utilizing a vacuum or forceps to assist with delivery, were limited in only 2% of births. Five percent of mothers had a successful vaginal birth after cesarean section (VBAC) and cesarean sections accounted for 23% of births. Only 51 women did not use any method of anesthesia, while others utilized multiple modalities such as spinal/epidural anesthesia, nitrous oxide, general anesthesia, or local anesthesia. Interestingly, 54% of births took place on nightshift as measured by delivery between 7:00 P.M. and 7:00 A.M. All other birth events took place on day shift.

Table 3. Delivery Characteristics of Study Participants (*N* = 282)

Characteristic	**n (%)**
Delivery Characteristics	
SVD	199 (70%)
Assisted Vaginal Delivery	5 (2%)
VBAC	13 (5%)
C-Section	65 (23%)
Anesthesia[a]	
None	51
Spinal/Epidural	204
Nitrous Oxide	25
General Anesthesia	3
Local Anesthesia	4
Time of Delivery	
Day Shift (0700-1900)	130 (46%)
Night Shift (1900-0700)	152 (54%)

[a]Some patients used multiple anesthesia modalities

Procedures

Step 1: Engage stakeholders. Stakeholders were identified. This included employees who were involved with conducting the BAP Breastfeeding History Questionnaire and Screening tool, those who identified the women with increased risk of formula supplementation (prenatal providers, labor and delivery nurses, newborn providers), and those who supported mothers with increased needs identified (nurses and lactation consultants). The key stakeholders were the labor and delivery nurse manager, medical director of the breastfeeding medicine program, and the lactation department nurse manager. Staff nurses were also included as stakeholders in this project as they are the front line for assisting mothers with breastfeeding support and identifying needs. A staff nurse was interviewed with a series of questions about the BAP Breastfeeding History Questionnaire and Screening tool, breastfeeding support, and questions to gauge breastfeeding knowledge among registered nurses working on the unit. The majority of

stakeholders were involved in the inpatient setting, but few had outpatient crossover or involvement as well. Stakeholders were contacted to determine the best methods for communication throughout the evaluation, desired level of involvement, and their plan for dissemination of results of this evaluation. The dissemination products were reviewed and authorized by the compliance officer prior to release. The DNP student developed a written plan for stakeholder involvement and dispersed this information to stakeholders. A detailed checklist for actions completed during this step and the written plan for stakeholder involvement are located in Appendix B.

Step 2: Describe the program. Following the CDC framework, the BAP Breastfeeding History Questionnaire and Screening tool and overall program was described using a logic model. The logic model depicts a visual representation of the program to describe the relationship between the BAP Breastfeeding History Questionnaire and Screening tool and the intended effects or outcomes. Barriers to successful implementation of the program were identified in the logic model. The logic model and a detailed checklist for actions completed during this step are located in Appendix C.

Initial Description of the BAP Breastfeeding History Questionnaire and Screening tool.

Approach. Breastfeeding success is impacted by prior experiences with breastfeeding (Burns et al., 2018). The approach used was to perform a simple screening questionnaire to all mothers prenatally or upon inpatient admission directed to elicit answers identifying how many babies the mother has previously breastfed (B), how many infants she felt she was able to breastfeed successfully (A), and how many infants the mother had problems breastfeeding (P) (Burns et al., 2018). The BAP score is calculated by adding B and A, then subtracting P ((B+A)-P). The lower the score or a score of zero, indicates a higher risk of in-hospital formula use while

a score greater than or equal to two indicates lower risk of in-hospital formula supplementation. Table 4 below illustrates the BAP Breastfeeding History Questionnaire and Screening tool.

Table 4. BAP Breastfeeding History Questionnaire and Screening Tool

B	Number of babies mother has previously breastfed
A	Number of infants mother felt she was able to breastfeed successfully
P	Number of infants mother had problems breastfeeding
BAP Score	(B+A)-P

Prenatal Provider Responsibilities. The intent of the BAP Breastfeeding History Questionnaire and Screening tool is to be conducted prenatally or, if missed prenatally, upon hospital admission to labor and delivery or the newborn nursery. Providers following women through pregnancy can perform this early on in pregnancy to help identify women who may need increased breastfeeding support in the immediate postpartum period. Currently at this AMC, the BAP Questionnaire is almost always performed prenatally (97% of patients in this study had the questions completed prenatally) and always upon newborn admission to the hospital by the pediatric provider. A numerical score is not listed in the EHR, but can be deciphered from written answers documented in the questionnaire.

Labor and Delivery, Postpartum requirements. As a Baby-Friendly designated hospital, staff should continue to promote exclusive breastfeeding and limit nonmedically indicated formula use. Pediatric staff on these units are expected to perform the questionnaire upon newborn hospital admission if it has not been previously completed. Pediatric staff should to take note of the BAP responses and direct mothers to increased breastfeeding support via lactation consultants or breastfeeding specialists on staff if indicated. However, this burden should not fall

solely on the pediatric providers, but should be shared among floor nurses and obstetric providers as well.

Lactation requirements. Lactation consultants make rounds on each couplet during their inpatient hospital stay whether they have chosen to breastfeed or use formula. Lactation consultants should verify the patient's BAP Breastfeeding History Questionnaire answers and offer increased support to mothers desiring to breastfeed who have BAP scores <2 or answers indicating problems breastfeeding. Free lactation classes are also readily available monthly to mothers prenatally.

BAP timeline. The implementation the BAP Breastfeeding History Questionnaire and Screening tool at this AMC is described below.

Timeline highlights

2012-2013: Stakeholders recognize need for breastfeeding screening tool and devise pilot study

06/2013: BAP pilot program completed in Philadelphia, PA

6-10/2013: Testing of Breastfeeding History Questionnaire and Screening tool retroactive chart review conducted

2/2018: Testing of Breastfeeding Questionnaire to Identify Mothers at Risk for Postpartum Formula Supplementation published

7/2019: BAP Breastfeeding History Questionnaire and Screening tool formally validated and incorporated into UVA EPIC charting

Goals. The goal of the BAP tool is to acknowledge the importance of assessing a woman's breastfeeding history for future breastfeeding success and identifying couplets that may

be at higher risk for nonmedically indicated formula use during the postpartum hospital stay (Burns et al., 2018).

Step 3: Focus the evaluation. Continuing to follow the CDC framework, the DNP student and stakeholders streamlined the focus of the evaluation in Step 3 to four foci: Foci A-D. Each focus, contains relevant questions the DNP student investigator aimed to answer. The final evaluation plan was listed in a table consisting of four columns: evaluation questions, indicators, data source(s), and data collection methods. The evaluation table and a detailed checklist for actions completed during this step are located in Appendix D.

Focus A: Analyze and evaluate existing data.

1. Which setting is the BAP Breastfeeding History Questionnaire and Screening tool being completed in routinely?
2. Is a score being given for the questionnaire or can a score be produced retroactively based on answers? If not scored in the EHR, the DNP student will assign a calculated score to each patient based on written answers determined by the BAP formula. A number will be added for each reported breastfeeding success, followed by a subtraction (if any) of each reported breastfeeding problem. These will formulate the final score.

Focus B: Evaluate the response to BAP answers/scores.

1. What are floor staff doing once risk of formula supplementation is recognized?
2. Who initially recognizes the risk and what do they do with that knowledge?

Focus C: Evaluate the impact of breastfeeding support (IBCLC or Breastfeeding Specialist).

1. How did breastfeeding support impact non-medically indicated formula use while in-hospital in mothers with a questionnaire response indicating increased risk for formula supplementation?
2. Did early identification of an increased risk of formula supplementation contribute to increased support and decreased formula use?
3. If mothers received breastfeeding support via nurses or lactation consultants, were they less likely to supplement with formula than those who did not receive the same support?
4. Did mothers with BAP scores >2 receive lactation support?

Focus D: Evaluate the effect of the BAP Breastfeeding History Questionnaire and Screening tool on high priority outcomes such as exclusive breastfeeding while in-hospital.

1. By performing the BAP Breastfeeding History Questionnaire and Screening tool, is in-hospital exclusive breastfeeding more likely as risks for formula use are being identified for each mother-infant dyad?
2. What is the total percentage of infants receiving formula within the first 48 hours of life and how does that compare to the Healthy People 2020 objectives and CDC Breastfeeding Report Card rates?

Step 4: Gather credible evidence. Data was gathered for evaluation through retrospective auditing of charts in the UVA EPIC electronic health record system and personal interviews with staff. Descriptive and quantitative data were both extracted. The quality of the data pulled from these sources was monitored and all data remained deidentified throughout the project. Data was collected in Microsoft Excel and was analyzed using statistical software from the same program

and Statistical Package for Social Sciences, Version 26 (SPSS). A statistician was consulted throughout the data collection and analyzation process. A detailed checklist for actions completed during this step are located in Appendix E.

Results are as follows:

Focus A: The BAP Breastfeeding History Questionnaire questions are currently being assessed prenatally and upon newborn admission to the hospital. Lactation consultants will also address the questionnaire if it has not been covered yet during consultations within the hospital stay. In this project, 97% women had the BAP questionnaire documented prenatally and 100% of women had the BAP questionnaire documented upon admission to the unit for delivery. While there was near perfect completion of the BAP questionnaire prenatally, it is not being completed entirely. A final score or risk level is not being calculated or documented in the chart based on the patients' answers. However, this score was able to be retrospectively calculated by the DNP student based on the answers completed in the EHR for this project. The questionnaire does collect appropriate data to predict the risk of in-hospital formula supplementation. All of the couplets assessed had completed answers to every question in the BAP questionnaire, they simply lacked a final risk score.

Focus B: Throughout personal interviews with staff members, we discovered more about the implementation of the questionnaire and the recognition of the risk factor score. The BAP questions were almost always asked prenatally by a women's health provider during a prenatal appointment and then again by a pediatric provider during the newborn admission assessment. During their consultations, lactation consultants would fill in the blanks if there was a need. Interviewing floor nurses, it was brought to the attention of the DNP student that the RNs working on the floor may not even be aware of this screening tool or understand the importance

of the questionnaire results. Because there is not a calculated score in the chart, a couplet with an increased risk of in-hospital formula supplementation can easily be missed by an RN taking care of the couplet. On the other hand, lactation consultants are able to identify this risk and understand the importance of continued breastfeeding support for mothers with BAP scores revealing increased risk.

Focus C: In this study, 230 of 282 total couplets were identified as high risk for formula supplementation. Of those high-risk couplets, 216 received lactation support from lactation consultant, leaving 14 high risk couplets, or 6%, without any lactation support throughout their hospital stay. Five patients who were considered to have a high risk of in-hospital formula supplementation and did not receive lactation support, used formula. Fifty-two couplets were scored as low risk based on their BAP score and 9 of those couplets, or 17%, went without a lactation consult.

Looking at all of the participants, the lactation department consulted 92% of the 282 couplets regardless of risk level. Overall, 24 of the 282 couplets went without a lactation consult and 29% of those couplets supplemented with formula. This is higher than the formula rate for those who received support from a lactation consultant. Of mothers who saw a lactation consultant during their hospital stay, 24% supplemented with formula to some extent while in-hospital. While there is a clinical significance in these numbers, there was no statistical significance found when a Chi-Square test was performed comparing formula supplementation rates of those who received lactation consultant support and those who did not receive lactation consultant support. The Chi-Square test showed the minimum expected count was less than 10 for Lactation Support with Formula, so the Yates' continuity correction was used. The results indicate no significant relationship, $\chi 2\ (1) = .126$, $p=.722$.

Overall, 76% of couplets were able to exclusively breastfeed throughout the duration of their hospital stay and 24% of all mothers supplemented with formula in-hospital regardless of their risk or a lactation consult. Formula is currently offered at no charge to the patient while in-hospital. This provides easy access to formula when requested or offered.

Focus D: When assessing the couplets who met inclusion criteria for this project, it was discovered that of the 334 meeting inclusion criteria, 52 women were automatically excluded for their intent to use formula. The remaining 84% of mothers desired to breastfeed and were included in the study. Of the 282 mothers included in the study due to their intent to breastfeed, all of the mothers utilized breastfeeding as the infants first feeding method and met criteria for "ever breastfed". National averages for U.S. Births in 2018 show that 82.3% of births ever breastfed and Virginia births in 2018 show that 81.7% ever breastfed (CDC, 2018). These rates are comparable to our 84% found in this project. The 2018 CDC Breastfeeding Report Card reports that 17.2% of all U.S. breastfed infants received formula in the first two days of life and 20.9% of Virginia breastfed infants received formula in the first two days of life. In this study, 24% of couplets meeting our inclusion criteria used formula supplementation in the first 2 days of life in-hospital.

Additional Data: Additionally, the DNP student looked further into the data to assess breastfeeding status at the 2-week and 2-month postpartum visits. Available data decreased with each well visit. As stated previously, out of 282 couplets, 76% of couplets exclusively breastfed and 24% of couplets utilized some form of formula supplementation during their hospital stay. At the 2-week well child check, data was available for 182 couplets. Of those 182 couplets, 64% exclusively breastfed, 23% utilized a combination of breastmilk and formula, and 13% of couplets exclusively formula fed. At the 2-month well child check, data was available for 166

couplets. Of those 166 couplets, 47% exclusively breastfed, 20% utilized a combination of breastmilk and formula, and 33% of couplets exclusively formula fed. As time continued on, percentages for exclusive breastfeeding rates decreased while formula use increased. Refer to Figure 4 for visual depiction of breastfeeding status.

Step 5: Justify conclusions. Conclusions were linked to the evidence collected and consistent with the agreed upon values and standards of the stakeholders. Alternative justification for results were explored and refuted as necessary. Recommendations made are consistent with the results of the data and conclusions. A detailed checklist for actions completed during this step are located in Appendix F.

Recommendations: After data extraction and analyzation, the DNP student investigator has multiple recommendations and conclusions from the results of the data. The BAP Breastfeeding History Questionnaire should be completed at the first prenatal appointment and a calculated score should be given at that time. By providing the patient's BAP score early on in pregnancy, the prenatal provider can tailor education resources about breastfeeding as needed. Of course, we recommend breastfeeding education at the first prenatal appointment with increased emphasis to first time mothers or those with high-risk BAP scores (score of <2). The DNP student recommends having a template or flow sheet inserted into the EHR for ease of usability. It is recommended that this tool would calculate the BAP score automatically and assign a color based on the patient's risk level. Colors such a green (>2), yellow (1-2), and red (0) can highlight the BAP score to help increase attention to this number. Green would represent no risk, yellow would represent mild to moderate risk, and red would indicate high risk of formula use. By highlighting the score in assigned colors, the provider or nurse assessing the patient, conducting the appointment, or completing the admission assessment would automatically trigger the

medical providers attention to the in-hospital formula use risk level. It is also recommended that nurses working the floor and interacting with couplets must understand this tool and the importance of recognizing the BAP score for a couplet's breastfeeding success. Breastfeeding education is provided at various prenatal appointments and should continue as is for all mothers. However, increased prenatal breastfeeding resources and education for those first-time mothers or high-risk mothers are recommended.

Another major recommendation is increased access to lactation consultants on each shift. While this AMC currently has a robust lactation department and many floor nurses trained on providing breastfeeding support, not every nurse is trained or comfortable in doing so. Nurses also have multiple patients and a list of tasks for each couplet to accomplish throughout their shift. Floor nurses have also mentioned how beneficial it would be to have a lactation consultant at each delivery to facilitate the first latch while the RN is taking care of various postpartum assessments or postpartum emergencies in that critical first hour after birth. By assigning at least a single lactation consultant to nightshift or to every shift with skeleton crews (holidays, weekends, etc.), we can ensure that a couplet struggling to breastfeed is not provided with formula due to lack of available breastfeeding support. Lactation consultants should continue to prioritize couplets identified as high risk for in-hospital formula supplementation or those couplets with known difficulties when making their rounds.

In order to meet the Healthy People 2020 goals for reducing the use of formula in the first 48 hours of life from 24% to 14% (US Department of Health and Human Services, 2016), we also recommend removal of access to free formula. Currently, at this AMC, there are no extra charges to the patient for formula use in-hospital. The recommendation is to charge the patient for non-medically indicated formula use in-hospital based on the success in increasing exclusive

breastfeeding during the hospital stay in Hong Kong (Tarrant et al., 2015). After the Hong Kong hospital implemented the change of not providing free formula in the hospital, exclusive breastfeeding in-hospital increased from 17.7% to 41.3%. The median duration of breastfeeding also increased from 8 to 12.5 weeks (Tarrant et al., 2015). While exclusive breastfeeding rates in-hospital were much higher in this project's participants compared to that of Hong Kong, charging for formula could still provide an increase of exclusive breastfeeding rates in-hospital. Because early formula supplementation can lead to early cessation of breastfeeding, the DNP student is hopeful that long-term breastfeeding rates would also increase if this recommendation were to be put in place. If formula use is medically indicated, and thus unavoidable, alternatives to bottle feeding techniques are recommended. Use of a spoon, cup, syringe, or finger feeding are all acceptable feeding techniques.

The final minor recommendation is in regard to patient demographics. This study was unable to use any education level data compared to other studies because education was simply not documented. Of 282 participants, 268 women did not have an education level documented. This data could be beneficial in comparison to other like studies in the future and is recommended for collection prenatally or during the maternal admission assessment.

Step 6: Ensure use and lesson learned. Interim and final findings and conclusions were shared with stakeholders for their review and future use moving forward with the BAP Breastfeeding History Questionnaire and Screening tool program. Strengths and limitations of the program were addressed, along with recommendations for future action of the program. Findings aim to be unbiased and accurate. A detailed checklist for actions completed during this step and the executive summary distributed to stakeholders are located in Appendix G.

Data Analysis

The data obtained in this DNP project was compiled in Microsoft Excel and analyzed within Microsoft Excel and using Statistical Package for Social Sciences, Version 26 (SPSS). Both qualitative and quantitative data were collected. Demographic data and numerical trends were collected and compared to those in the literature analysis and national averages. A statistician was consulted throughout the data collection and analyzation process.

Ethical Considerations

The program evaluation provided minimal risk to participants as data was compiled retroactively without any change or effect on patient care. Furthermore, there was minimal risk to stakeholders and they were able to decline to participate at any time. The data collected during this evaluation remained deidentified and confidential throughout the DNP project. Deidentified data was stored in a secure online storage for the university. Access to the deidentified data collected was available to the DNP student, DNP advisor, and any stakeholders requesting access. Finalized, summarized results were shared with the prenatal/OBGYN staff, labor and delivery/postpartum unit staff, and lactation consultants. The proposal for this project was also submitted to the UVA IRB for a letter of determination. This project was determined to not meet the criteria of Research with Human Subjects and is not subject to the IRB-HSR review. The letter of determination is found in Appendix H.

Sustainability Plan

Sustainability of the BAP Breastfeeding History Questionnaire and Screening tool is important for identifying mothers who are at increased risk of in-hospital formula supplementation. An effective program evaluation was necessary to ensure that strengths could be amplified and limitations could be addressed. Throughout the BAP program evaluation, the

DNP advisor, stakeholders, and staff utilizing the program were informed of the decided upon processes that helped guide the evaluation to ensure quality information was collected. The program evaluation results were disseminated to stakeholders and staff in Step 6. Included in Step 6 were recommendations for future use, improvements, and sustainability of the program at this AMC.

Strengths and Weaknesses of the Design

A strength of the CDC (1999) framework is that it provided a systematic method for this program evaluation. Using the CDC framework, a practical and specific step-by-step plan was created to evaluate the BAP Breastfeeding History Questionnaire and Screening tool program. Each chart was meticulously reviewed during data extraction to ensure the most accurate data was documented and retrieved. Another strength is the history of the BAP Breastfeeding History Questionnaire and Screening tool as it has previously successfully passed a pilot test, actual test of implementation, and validation—all published with data readily accessible. A final strength is the simplicity of the BAP Questionnaire. It provides three easy-to-answer questions for the provider to ask the expecting mother and acknowledges past successes and problems encountered with breastfeeding (Burns et al., 2018).

A limitation to this design relates to accounting for the broad range of staff who interact with and administer the BAP Questionnaire to patients. Another limitation may be encountered in the timing of completion of the BAP Questionnaire. Those assessed only upon admission to the labor and delivery unit/newborn nursery may miss out on resources and education they could have benefited from prenatally to limit use of in-hospital formula. The DNP student investigator compared the program evaluation results to those of state and national averages. However, different inclusion or exclusion criteria exists for the CDC Breastfeeding Report Card compared

to the criteria of this project. Because of this, data may not seem as equal or like when compared to the state and national averages reported in the CDC Breastfeeding Report Card. There is also the chance of human error as a single DNP student extracted data from 490 charts individually.

Nursing Practice Implications

Early formula supplementation or use is linked to decreased breastfeeding success and duration (Chantry et al., 2014). However, encouraging breastfeeding and providing increased support can decrease the chance of in-hospital formula supplementation (Grassley et al., 2014). Thus, the success of the BAP Breastfeeding History Questionnaire and Screening tool program can impact the use of in-hospital formula supplementation by recognizing the need for increased breastfeeding support in those with scores <2. This program is important in determining risk factors for mothers and providing early intervention to support breastfeeding in this Baby-Friendly institution. This program has now been formally evaluated and all outcomes can be utilized to guide future use or recommendations of the BAP Breastfeeding History Questionnaire and Screening tool.

Products of the Scholarly Practice Project

This scholarly project produced a completed program evaluation with results and recommendations for future use of the BAP Breastfeeding History Questionnaire and Screening tool. The DNP student distributed all findings and recommendations to the stakeholders via an executive format summary. A manuscript will be submitted for publication to UVA's scholarly repository, Libra, and the peer reviewed journal, Clinical Lactation. Guidelines for submission to Clinical Lactation are in Appendix I.

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Table 1

Summary of Literature Review

Study Reference (Author, Year)	Design	Subjects & Setting	Intervention, Control/Comparison	Outcomes	Level of Evidence & Quality Grade (Johns Hopkins)	Theme 1	Theme 2	Theme 3
Bender et al. (2018)	Prospective observational study	433 Virginian dyads assessed prenatally with BAP questionnaire in a Baby-Friendly hospital	BAP Breastfeeding History Questionnaire and Formula to predict risk of in-hospital formula use	Formula supplementation rates in mothers with scores ≤1 were 67% vs. 37% in mothers with higher scores. Prior negative breastfeeding experiences were likely to lead to formula supplementation in-hospital.	Level III/A			X
Biro et al. (2011)	Non-experimental population-based survey	4,085 Australian dyads surveyed during the postpartum period to recall supplementation events in the hospital and	In-hospital formula supplementation vs. EBF in hospital	94.9% initiated breastfeeding, but 23% used formula at some point in-hospital. Reasons for use included: maternal lack of confidence, increased maternal	Level III/A		X	X

		current EBF practices.		BMI, tobacco use, c-section delivery, lack of clinician support and clinician recommendation to supplement. First-time mothers were twice as likely to supplement.				
Chantry et al. (2014)	Prospective cohort	393 dyads at the University of California Davis Medical Center who anticipated to breastfeed >1 week prenatally. Dyads were followed for 60 days postpartum.	In-hospital formula supplementation vs. EBF in-hospital	67.8% of infants who received formula supplementation were not EBF at 30 or 60 days of life compared to 36.7% of in-hospital EBF infants. Low milk supply, signs of insufficient intake, and poor latch caused formula supplementation.	Level II/A	X	X	
Dennis (2003)	Non-experimental longitudinal survey	491 breastfeeding mothers in British Columbia who participated in mailed questionnaires at 1, 4, and 8	Administration of a shortened BSES (BSES-SF) to decrease redundancy and shorten	When given at 1 week postpartum, the BSES-SF was a reliable predictor of breastfeeding behaviors at the 4 and 8-week postpartum marks. The BSES-SF can	Level III/A			X

		weeks postpartum		identify mothers at high risk for needing increased support, assess breastfeeding behaviors, and evaluate interventions.				
Evans et al. (2004)	Prospective Observational Study	117 women who anticipated to breastfeed for at least 8 weeks at a specialty women's hospital in the southeastern U.S.	Administration of BAPT prenatally (BAPT1) and postnatally (BAPT2) to predict early breastfeeding attrition.		Level III/A			X
Flaherman et al. (2019)	RCT	161 EBF mothers who were not yet producing copious milk and infants who were 24 to 72 hours old at two U.S. academic medical centers with newborn weight loss at or above the 75th percentile for age. Dyads	Early Limited Formula (ELF), a structured formula supplementation protocol (10mL formula fed after each breastfeeding until mothers produced copious milk), compared with control dyads, who continued exclusive breastfeeding and received a safety	No difference in breastfeeding rates between groups at 6 months of life (a novel finding). However, at the 12-month mark, the EBF group had higher rates of breastfeeding than the ELF group.	Level I/A	X		

		were followed for 1 year.	teaching intervention					
Grassley et al. (2014)	Retrospective cross-sectional review of EHR	302 dyads' EHR were reviewed for this study from two hospitals within the same health system, over two different time periods	In-hospital formula supplementation vs. EBF in-hospital over two different time periods after implementation of a stricter infant blood sugar policy	Reasons for formula supplementation included: born on nightshift without lactation support, maternal desire to supplement, infant hypoglycemia, fussy infant and lack of clinician support. Lack of provider breastfeeding knowledge also contributed to supplementation.	Level III/A		X	X
Parry et al. (2013)	Prospective cohort	1246 dyads from four public Hong Kong hospitals during hospital stay and through mailed surveys 12 months postpartum.	In-hospital formula supplementation vs. EBF in-hospital	82.5% of healthy newborn received supplementation in the first 48 hours of life. 95% of c-section births resulted in formula supplementation. Other reasons include: spousal desire to use formula, lower education levels, and assisted	Level II/A		X	X

				operative deliveries.				
Tarrant et al. (2015)	Prospective cohort	2560 postpartum dyads during stay in Hong Kong public hospitals followed for 12 months postpartum via mailed surveys.	Dyads with access to free formula while in-hospital (cohort 1) vs. dyads without access to free formula in-hospital (cohort 2), though they could pay for formula if they desired to use it.	In cohort 1, 69.2% of total in-hospital feeds were breastmilk, while cohort 2 saw a rise at 84.2%. The duration of total breastfeeding increased from 8 to 12.5 weeks from cohort 1 to 2. By removing access to free formula (a Baby-Friendly measure), EBF rates increase.	Level II/A	X		X
Temple et al. (2017)	Cross-sectional non-experimental	496 dyads who prenatally intended to EBF for 6 months in Newfoundland, Canada during stay in a non-baby-friendly, public hospital.	In-hospital formula supplementation vs. EBF in-hospital	22.5% of infants who planned to EBF prenatally received supplementation in-hospital and 85% for non-medically indicated reasons. Reasons include: no prior experience breastfeeding, negative experience of first latch, and receiving advice	Level III/A		X	

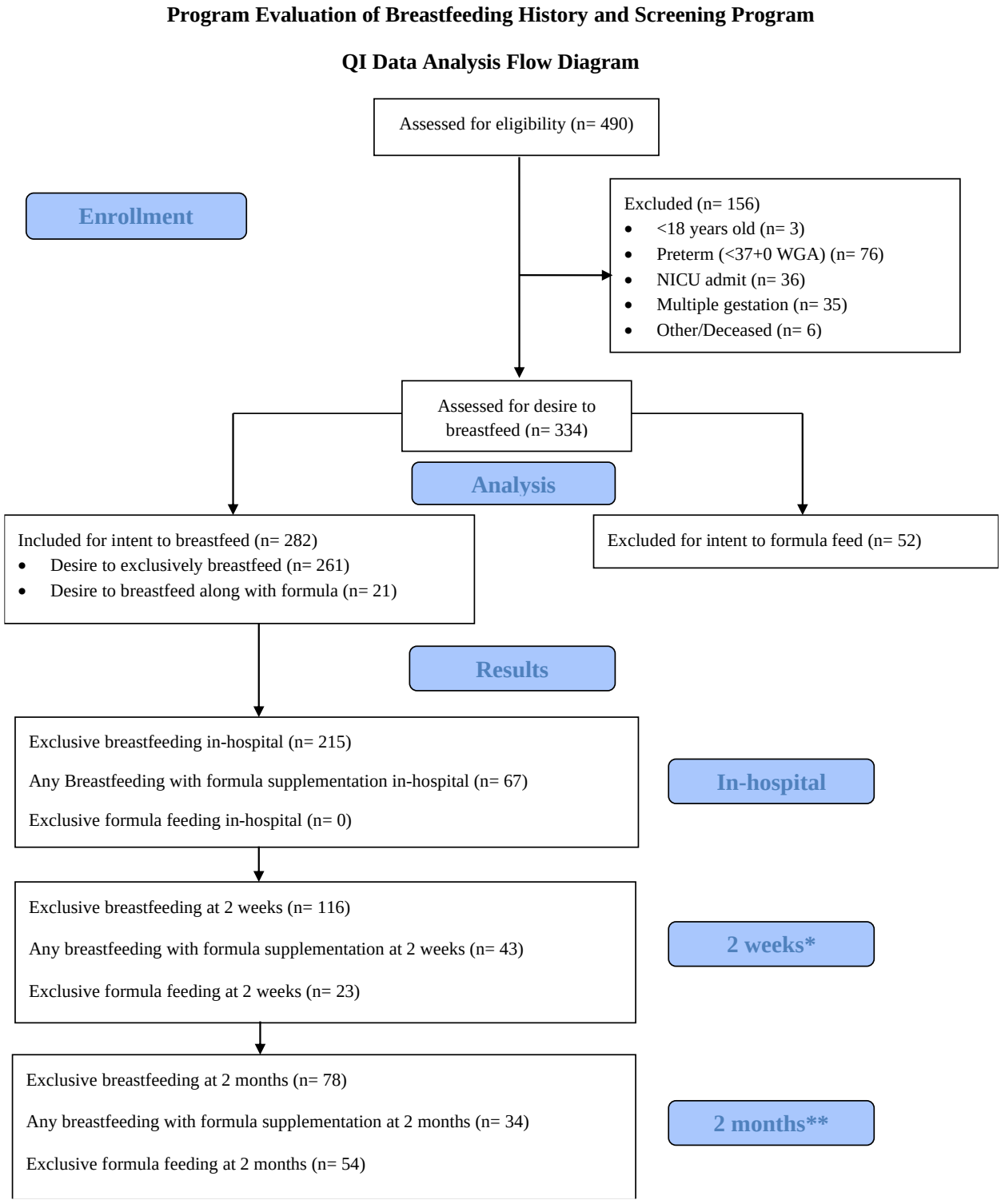
				from hospital physician.				
Vehling et al. (2018)	Non-experimental longitudinal survey	3195 Canadian dyads in the CHILD pregnancy cohort, with mailed surveys for up to 24 months.	In-hospital formula supplementation vs. EBF in-hospital	97.5% of dyads initiated breastfeeding in-hospital but 25.9% of those received supplementation. EBF rates at 6 months were 18.5% of infants, while 75.1% of infants were receiving some breastmilk. EBF in-hospital led to increased duration of EBF.	Level III/A	X		

Note: EBF = exclusive breastfeeding/exclusively breastfed; RCT = randomized control trial; EHR = electronic health record

Table 2. *Demographic Characteristics of Study Participants* (*N* = 282)

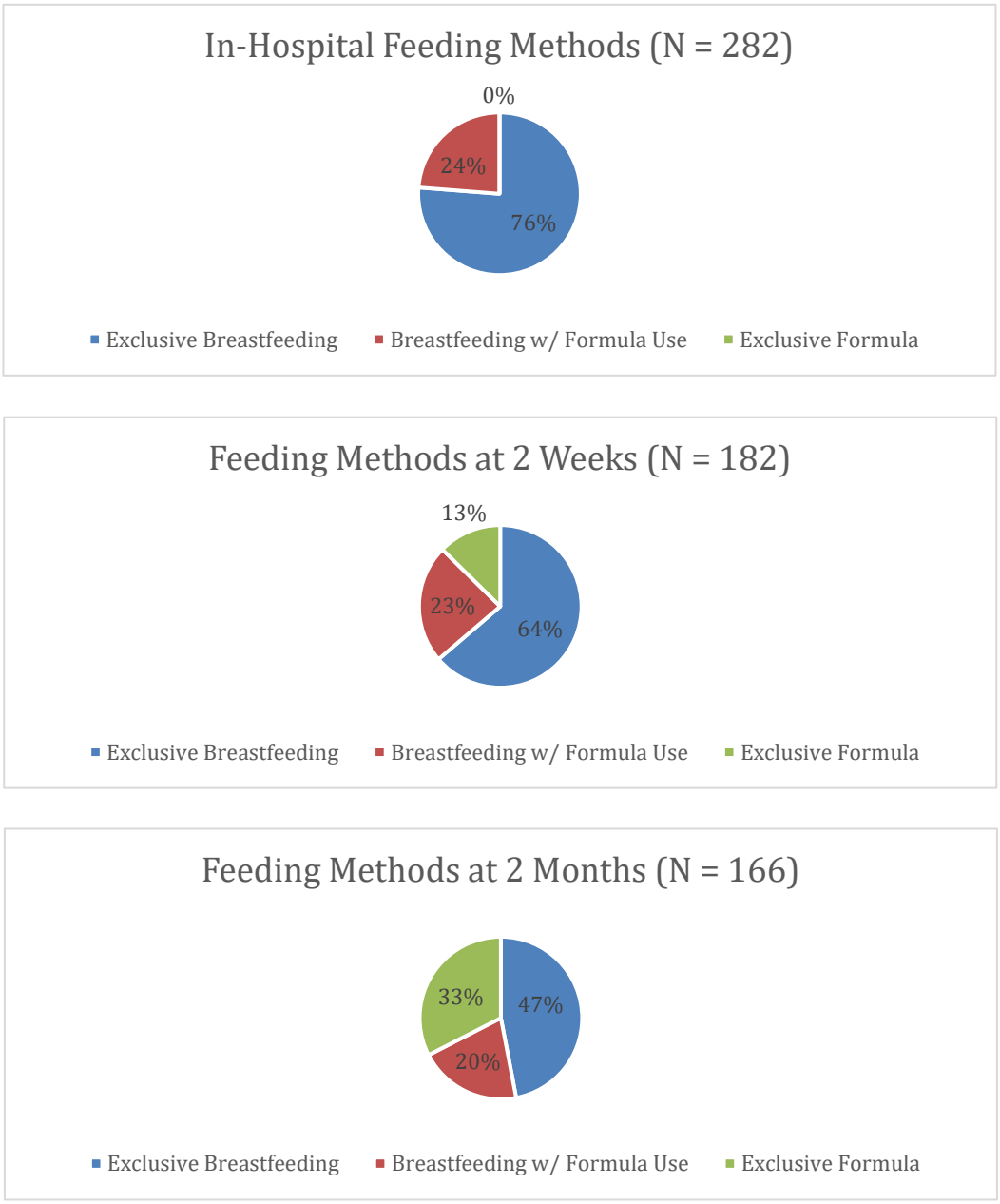
Characteristic	**n (%)**
Age	
18-19	8 (3%)
20-29	131 (47%)
30-39	136 (48%)
40 or Older	7 (2%)
Race	
White	184 (65%)
Black or African American	41 (14%)
Asian	10 (4%)
Other (including multiracial)	47 (17%)
Hispanic, Latino or Spanish Origin	
Yes	52 (18 %)
No	230 (82%)
Marital Status	
Single	105 (37%)
Married	168 (60%)
Separated	6 (2%)
Divorced	1 (<1%)
Engaged	1 (<1%)
N/A	1 (<1%)
Insurance	
Medicaid	109 (39%)
Aetna	73 (26%)
Anthem	44 (16%)
United Healthcare	26 (9%)
Tricare	15 (5%)
Cigna	6 (2%)
Piedmont Community Health	3 (1%)
Optima	2 (1%)
None listed	2 (1%)
VHN Medcost Virginia	1 (<1%)
Parity	
Primiparous	107 (38%)
Multiparous	175 (62%)

Figure 3. *Consort-like flow diagram depicting couplets included for analysis*



*Data available on 182 couplets only
**Data available on 166 couplets only

Figure 4. *Pie Chart depiction of breastfeeding status in-hospital, at 2 weeks and 2 months of life*



Appendix A

Project Site Approval

From: "Longo, Robin *HS" <RJL4H@hscmail.mcc.virginia.edu>
Date: July 1, 2020 at 10:52:51 AM EDT
To: chelsea Wood <csrayman@me.com>
Subject: RE: Meeting

You do have my permission to view records and also to solicit any support needed in furthering your project.

Happy to provide any additional information or access to documentation you may need.

Robin Longo

Appendix B

Step 1

CDC Program Evaluation Framework Checklist for Step 1

Engage Stakeholders

The first step in the CDC Framework approach to program evaluation is to engage the stakeholders. Stakeholders are people or organizations that are invested in the program, are interested in the results of the evaluation, and/or have a stake in what will be done with the results of the evaluation. Representing their needs and interests throughout the process is fundamental to good program evaluation. A program may have just a few or many stakeholders, and each of those stakeholders may seek to be involved in some steps or all six steps. This checklist helps identify stakeholders and understand their involvement in the evaluation.

Although "Engaging Stakeholders" is the first of the 6 steps, the first three steps of the CDC Framework are iterative and can happen in any sequence. For instance, identifying the right stakeholders may make more sense to do for your evaluation after drafting the purpose, user, and use of the evaluation that happens in Step 3. That said, this checklist will help you think through the key points in identifying and engaging stakeholders throughout your evaluation.

☐ Brainstorm potential stakeholders. These may include, among others:
- ☐ People affected by your program
- ☐ People involved in implementing the program or conducting the evaluation
- ☐ People who will use the results of the evaluation. These may include internal staff, partners, program participants, community members, and other organizations, among others

In brainstorming the list be sure to think broadly, including in your list:
- ☐ People in the above categories who share your priorities, and people who don't
- ☐ People in the above categories who are critics as well as supporters

☐ Especially if the list is very long, try to extract the subset of most important stakeholders. Some helpful criteria for identifying whether a person or organization is a key stakeholder include that they:
- ☐ Increase the credibility of your program or your evaluation
- ☐ Are responsible for day-to-day implementation of the program activities that are being evaluated and will need to implement any changes
- ☐ Can advocate for the changes to the program that the evaluation may recommend, OR actively oppose the recommended changes
- ☐ Fund or authorize the continuation or expansion of the program

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- ☐ Discuss with key stakeholders individually the best way to engage them—in person, phone, email etc. Regardless of chosen medium, in the engagement discussions get clarity on the following questions: [NOTE: If a preliminary logic model for the program has been completed, then use it to help frame and target the questions.]
  - ☐ What do you see as the main outcomes of the program?
  - ☐ What do you see as the main activities of the program?
  - ☐ Which of the activities and outcomes are most important to you? That is, to retain your involvement and support, which activities must be effectively implemented and/or which outcomes achieved?
  - ☐ What do you see as the most important evaluation questions at this time?
  - ☐ [If outcomes are included] How rigorous must the design be?
  - ☐ Do you have preferences regarding the types of data that are collected (e.g., quantitative, qualitative)?
  - ☐ What resources (e.g., time, funds, evaluation expertise, access to respondents, and access to policymakers) might you contribute to this evaluation effort?
  - ☐ In what parts or steps of this evaluation would you want to be involved? All or just some specific ones?
  - ☐ How would you like to be kept apprised of this evaluation? How best to engage you in the steps in which you want to be involved?
  - ☐ (How) will **you** use the results of this evaluation?

- ☐ Examine the results of the stakeholder discussion for insights related to development/refinement of the program description and logic model. Also examine for a starter set of important evaluation questions, which will be elaborated during Step 3.

- ☐ Especially if there are many stakeholders, summarize the results of the engagement discussions with a [simple or detailed as you prefer] plan for stakeholder involvement, including which stakeholders will participate/provide input during the major stages of the project and what their roles and responsibilities will be for each step.

Step 1

Written Plan for Stakeholder Involvement

Stakeholders will be contacted through email minimally and only if all other resources have been exhausted. Stakeholders will be available to answer questions and assist with networking or answering questions, if need. Email is the preferred and decided upon method of communication. Stakeholders will receive an executive format summary of the project via email once complete with access to the entire manuscript if requested.

Appendix C

Step 2

CDC Program Evaluation Framework Checklist for Step 2

Describe the Program

A **logic model** is a graphic depiction (road map) that presents the shared relationships among the resources, activities, outputs, and outcomes/impacts for your program. It depicts the relationship between your program's activities and its intended effects, in an implicit 'if-then' relationship among the program elements — if I do this activity, then I expect this outcome. Among other things, a logic model helps clarify the boundary between 'what' the program is doing and 'so what'—the changes that are intended to result from strong implementation of the "what."

A logic model can focus on any level of an enterprise or program: the entire organization, one of its component departments or programs, or just specific parts of that department or a program. Of course, the boundary between "what" and "so what" will vary accordingly.

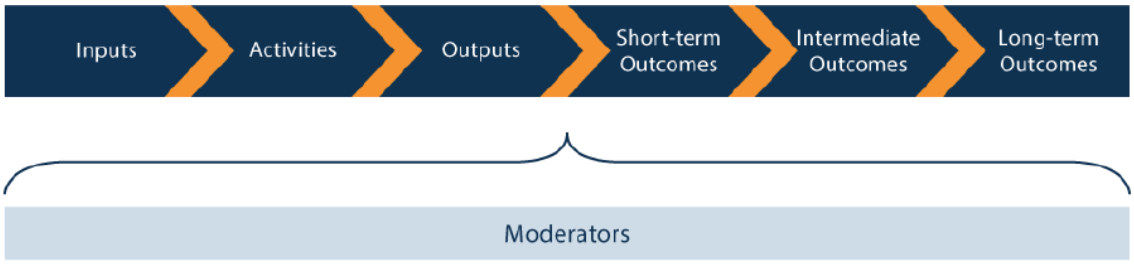
Related Terms

Logic models are the most common, but not the only, name applied to a visual depiction of a program. Here are some names of others approaches that either replicate or closely resemble logic models in their format and intent. There are occasions where one approach/format is a better fit than another, but often any of these will work equally well:

- Program Roadmaps
- Theory of Change
- Theory of Cause
- Theory of Action
- Concept(ual) Maps
- Outcome Maps
- Logical Frameworks (LogFrames)

Logic models differ widely in format and level of detail. Here are some key terms used in logic models, although not all are employed in any given model:

- Inputs: The resources needed to implement the activities
- Activities: What the program and its staff do with those resources
- Outputs: Tangible products, capacities, or deliverables that result from the activities
- Outcomes: Changes that occur in other people or conditions because of the activities and outputs
- Impacts: [Sometimes] The most distal/long-term outcomes
- Moderators: Contextual factors that are out of control of the program but may help or hinder achievement of the outcomes



Let's get started. Here are the key steps to developing a useful logic model:

- ☐ Gather information available on the program, including but not limited to:
  - ☐ Mission and vision
  - ☐ Goals and objectives
  - ☐ Current program descriptions such as websites, program descriptions, fact sheets
  - ☐ Strategic plans
  - ☐ Business, communication, and marketing plans
  - ☐ Existing/previous logic models
  - ☐ Existing performance measures and/or program reviews

- ☐ Review the information and extract from it to create a two-column table including:
  - ☐ Column 1: Activities: What the program and its staff do.
  - ☐ Column 2: Outcomes: Who or what beyond the program and its staff needs to change and how. In generating outcomes, it helps to Identify the target audiences for program activities and the action they must take in order for the activities to be successful.
  - ☐ Within the list in column 2, identify the most distal outcome: What is the big public health problem you aim to address with your program?

- ☐ Clarify the activities and outcomes with stakeholders* to ensure:
  - ☐ Appropriate classification; no activities are actually outcomes and no outcomes listed are actually activities
  - ☐ No major redundancy in list of activities or list of outcomes
  - ☐ No major missing activities or outcomes

☐ Decide whether the activities should be ordered sequentially. If so:
- ☐ Think about the "logical" relationship among the activities—which may or may not be the same as how they unfold over time— and determine if some activities need to occur before others can be implemented
- ☐ Order the activities within the columns into earlier or later activities to reflect the sequential relationships

☐ Decide whether the outcomes should be ordered sequentially
- ☐ Think about the "logical" relationship among the outcomes-- will some outcomes logically need to occur before others can be achieved?
- ☐ Move the outcomes into columns to reflect the sequence in which the outcomes should occur. Label the columns as needed (i.e., short-, mid, long-term; or [proximal, intermediate, distal)

☐ Check in with your stakeholders
- ☐ To ensure the activities and outcomes reflect their understanding of the program to ensure:
  - There are no major missing activities or outcomes
  - The logical progression of activities
  - The logical progression of the outcomes
- ☐ To (re)affirm the intended uses of the logic model (i.e., assess implementation, assess effectiveness, performance measurement, strategic planning)

The intended uses of the logic model, will determine which, if any, of the elaborations below would make the logic model more useful.

☐ If **depicting the program logic** in a roadmap format is desirable, then:
- ☐ Write each of the existing activities and outcomes on a sticky note, or equivalent
- ☐ Move the notes around to allow for drawing of lines to depict logical relationships
- ☐ Draw in lines remembering that lines may go from:
  - One or more activities to a subsequent activity
  - One or more activities to an outcome
  - One or more proximal outcomes to a more distal outcome

☐ If **outputs** are desired because stakeholders would like clarification of the direct result of the activities, then using the logic model table or (better) the roadmap:
- ☐ Identify the activities for which outputs are desired
- ☐ Identify the link between those activities and their successor activities or outcomes
- ☐ Thinking about that logical link, what are the key attributes of the activity that must be present for it to produce its successor activity or outcome
- ☐ Place the outputs in the appropriate place in the logic model table or roadmap

☐ If **inputs** are desired because stakeholders would like clarification of necessary resources to implement the program, then:
- ☐ Identify the key inputs without which the program cannot be implemented. Think about broad categories such as staff, equipment, data, funds, and partnerships.
- ☐ Place the inputs into a column to the left of the activities in the logic model.
- ☐ If it is important to see the link between each input and the activity it affects, then draw arrows from each input to the related activity

☐ If **moderators** are desired because—in the view of stakeholders and users—clarification of potential facilitators or barriers in the larger environment is necessary:
- ☐ Identify the key moderators, thinking of broad categories such as political, economic, social, and technological
- ☐ Identify what links in the program logic will be facilitated or impeded by the presence or absence of sufficient levels of the moderator. Remember moderators can facilitate or impede the ability of one activity/output to generate a successor activity/output, one activity/output to generate an outcome, a proximal outcome to generate a more distal outcome
- ☐ Be especially conscious of key moderators without which the program cannot be implemented
- ☐ Place the moderators into the appropriate place in the logic model table or roadmap.
- ☐ If using a roadmap, decide whether to leave the moderators in one block at the bottom of the logic model or draw lines from each moderator to the logical link it will facilitate or hinder
- ☐ Review and affirm or further refine with stakeholders, especially those who will use the logic model

☐ Review and affirm the elaborations of the logic model with stakeholders to ensure it accurately represents the program and the relationships among the components

☐ Create a narrative to go with the logic model. A one-page logic model will not be able to capture all the nuances of the program. The narrative will help explain the components of the logic model and how they work together to accomplish the outcomes. The narrative should include the following:
- ☐ An expanded description of the activities, outcomes, and other components of the logic model
- ☐ Any key linkages between activities, between activities and outcomes, and between different outcomes
- ☐ Attribution v. contribution to outcomes, etc.
- ☐ Stakeholder expectations for what will be accomplished, etc.

*Stakeholders are people or organizations that are invested in the program, are interested in the results of the evaluation, and/or have a stake in what will be done with the results of the evaluation. This definition is found in *Checklist for Step 1: Engage Stakeholders*.

Step 2

Logic Model

BAP Questionnaire	Calculating BAP Scores	Calculated BAP Scores	Calculated BAP score on every pregnancy Awareness/Alert of BAP scores upon hospital admission	Flowsheet w/ built-in BAP Questionnaire calculator
LDRP Flowsheets/ Pediatric Flowsheets	Extracting data from normal charting activity	In-hospital formula supplementation activity		Lactation assistance access on every shift Lactation assistance at each delivery Avoid use of non-medically indicated formula supplementation Non-bottle formula feeding techniques when use is medically indicated Reduced access to formula
Epic Charting System	Retrospective audit of existing flowsheets	Assessment of breastfeeding patterns/support; long term breastfeeding success		
Provider/Staff Expertise	Interviews to guide desired information	Valuable frontline worker insight	Realization of importance of BAP score	

Appendix D

Step 3

CDC Program Evaluation Framework Checklist for Step 3

Focus the Evaluation

In Step 2 you described the entire program, but usually the entire program is not the focus of a given evaluation. Step 3 is a systematic approach to determining where to focus this evaluation, this time. Where the focus lies in the logic model is determined, in conjunction with stakeholders, through application of some of the evaluation standards. While there are more than 30 standards, the most important ones fall into the following four clusters:

- **Utility:** Who needs the information from this evaluation and how will they use it?
- **Feasibility:** How much money, time, skill, and effort can be devoted to this evaluation?
- **Propriety:** Who needs to be involved in the evaluation to be ethical?
- **Accuracy:** What design will lead to accurate information?

☐ The standards help you assess and choose among options at every step of the framework, but some standards are more influential for some steps than others. The two standards most important in setting the focus are "utility" and "feasibility." Ensure that all stakeholders have common understandings of the phases (formative/summative) and types of evaluations (needs assessment/process/outcome/impact).

☐ Using the logic model, think through where you want to focus your evaluation, using the principles in the "utility" standard:

- ☐ Purpose(s) of the evaluation: implementation assessment, accountability, continuous program improvement, generate new knowledge, or some other purpose
- ☐ User(s): the individuals or organizations that will employ the evaluation findings
- ☐ Use(s): how will users employ the results of the evaluation, e.g., make modifications as needed, monitor progress toward program goals, make decisions about continuing/refunding
- ☐ Review and refine the purpose, user, and use with stakeholders, especially those who will use the evaluation findings

☐ Identify the program components that should be part of the focus of the evaluation, based on the utility discussion:

- ☐ Specific activities that should be examined
- ☐ Specific outcomes that should be examined
- ☐ Specific pathways from activities to specific outcomes or outcomes to more distal outcomes
- ☐ Specific inputs or moderating factors that may or may not have played a role in success or failure of the program

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☐ Refine/expand the focus to include additional areas of interest, if any, identified in Steps 1 and 2
- ☐ Does the focus address key issues of interest to important stakeholders?
- ☐ Did the program description discussion identify issues in the program logic that may influence the program logic?
- ☐ Are issues of cost, efficiency, and/or cost-effectiveness important to some or all stakeholders?

☐ Refine/expand the focus to include additional areas of interest based on the propriety and accuracy evaluation standards
- ☐ Are there components of the program—activities, outcomes, pathways, or inputs/moderators that must be included for reasons of "ethics" or propriety?
- ☐ Are there components of the program—activities, outcomes, pathways, or inputs/moderators that must be included to ensure that the resulting focus is "accurate"?

☐ "Reality check" the expanded focus using the principles embedded in the "feasibility" evaluation standard
- ☐ The program's stage of development: Is the focus appropriate given how long the program has been in existence?
- ☐ Program intensity: Is the focus appropriate given the size and scope of the program, even at maturity?
- ☐ Resources: Has a realistic assessment of necessary resources been done? If so, are there sufficient resources devoted to the evaluation to address the most desired items in the evaluation focus?

☐ At this point the focus may still be expressed in very general terms—this activity, this outcome, this pathway. Now, convert those into more specific evaluation questions. Some examples of evaluation questions are:
- ☐ Was [specific] activity implemented as planned?
- ☐ Did [specific] outcomes occur and at an acceptable level?
- ☐ Were the changes in [specific] outcomes due to activities as opposed to something else?
- ☐ What factors prevented the activities in the focus from being implemented as planned? Were [specific inputs and moderating factors] responsible?
- ☐ What factors prevented (more) progress on the outcomes in the focus? Were [specific moderating factors] responsible?
- ☐ What was the cost for implementing the activities?
- ☐ What was the cost-benefit or cost-effectiveness of the outcomes that were achieved?

☐ Consider the most appropriate evaluation design, using the four evaluation standards—especially utility and feasibility—to decide on the most appropriate design. The three most common designs are:

- ☐ Experimental: Participants are randomly assigned to either the experimental or control group. Only the experimental group gets the intervention. Measures of the outcomes of interest are (usually) taken before and after the intervention in both groups.
- ☐ Quasi-experimental: Same specifications as an experimental design, except the participants are not randomly assigned to a "comparison" group.
- ☐ Non-experimental: Because the assignment of subjects cannot be manipulated by the experimenter, there is no comparison or control group. Hence, other routes must be used to draw conclusions, such as correlation, survey or case study.

Some factors to consider in selecting the most appropriate design include:

- ☐ With what level of rigor must decisions about "causal attribution" be made?
- ☐ How important is ability to translate the program to other settings?
- ☐ How much money and skill are available to devote to implementing the evaluation?
- ☐ Are there naturally occurring control or comparison groups? If not, will selection of these be very costly and/or disruptive to the programs being studied?

☐ Start the draft of the evaluation plan. You will complete the plan in Step 4. But at this point begin to populate the measurement table (see example below) with:

- ☐ Program component from logic model (activity, outcome, pathway)
- ☐ Evaluation question(s) for each component

Evaluation Questions	Indicators	Data Source(s)	Data Collection Methods

Figure 1: Evaluation Plan Measurement Table

☐ Review and refine the evaluation focus and the starter elements of the evaluation plan with stakeholders, especially those who will use the evaluation results.

Step 3

Focused Evaluation Design Table

Evaluation Questions	Indicators	Data Source(s)	Data Collection Methods
How is the program currently being used?	• Desired Goals • Collected data	• Personal Interviews • Epic chart audit	• Virtual interview • Remote access
What is the response once a risk is identified?	Provided lactation support	• Personal Interviews • Epic chart audit	• Virtual interview • Remote access
How did breastfeeding support impact formula supplementation?	• Formula use rates • Methods of formula supplementation • Reasons for formula use	Epic chart audit	Remote access
By performing the BAP Breastfeeding History Questionnaire and Screening tool, is in-hospital exclusive breastfeeding more likely as risks for formula use are being identified for each mother-infant dyad?	• Exclusive breastfeeding rates • Formula supplementation rates	Epic chart audit	Remote access

Appendix E

Step 4

Gathering credible evidence

Definition	Compiling information that stakeholders perceive as trustworthy and relevant for answering their questions. Such evidence can be experimental or observational, qualitative or quantitative, or it can include a mixture of methods. Adequate data might be available and easily accessed, or it might need to be defined and new data collected. Whether a body of evidence is credible to stakeholders might depend on such factors as how the questions were posed, sources of information, conditions of data collection, reliability of measurement, validity of interpretations, and quality control procedures.
Role	Enhances the evaluation's utility and accuracy; guides the scope and selection of information and gives priority to the most defensible information sources; promotes the collection of valid, reliable, and systematic information that is the foundation of any effective evaluation.
Activities	• Choosing indicators that meaningfully address evaluation questions; • Describing fully the attributes of information sources and the rationale for their selection; • Establishing clear procedures and training staff to collect high-quality information; • Monitoring periodically the quality of information obtained and taking practical steps to improve quality; • Estimating in advance the amount of information required or establishing criteria for deciding when to stop collecting data in situations where an iterative or evolving process is used; and • Safeguarding the confidentiality of information and information sources.

Adapted from Joint Committee on Standards for Educational Evaluation. Program evaluation standards: how to assess evaluations of educational programs. 2nd ed. Thousand Oaks, CA: Sage Publications, 1994.

Appendix F

Step 5

Justifying conclusions

Definition	Making claims regarding the program that are warranted on the basis of data that have been compared against pertinent and defensible ideas of merit, value, or significance (i.e., against standards of values); conclusions are justified when they are linked to the evidence gathered and consistent with the agreed on values or standards of stakeholders.
Role	Reinforces conclusions central to the evaluation's utility and accuracy; involves values clarification, qualitative and quantitative data analysis and synthesis, systematic interpretation, and appropriate comparison against relevant standards for judgment.
Activities	• Using appropriate methods of analysis and synthesis to summarize findings; • Interpreting the significance of results for deciding what the findings mean; • Making judgments according to clearly stated values that classify a result (e.g., as positive or negative and high or low); • Considering alternative ways to compare results (e.g., compared with program objectives, a comparison group, national norms, past performance, or needs); • Generating alternative explanations for findings and indicating why these explanations should be discounted; • Recommending actions or decisions that are consistent with the conclusions; and • Limiting conclusions to situations, time periods, persons, contexts, and purposes for which the findings are applicable.

Adapted from Joint Committee on Standards for Educational Evaluation. Program evaluation standards: how to assess evaluations of educational programs. 2nd ed. Thousand Oaks, CA: Sage Publications, 1994.

Appendix G

Step 6

Ensuring use and sharing lessons learned

Definition	Ensuring that a) stakeholders are aware of the evaluation procedures and findings; b) the findings are considered in decisions or actions that affect the program (i.e., findings use); and c) those who participated in the evaluation process have had a beneficial experience (i.e., process use).
Role	Ensures that evaluation achieves its primary purpose — being useful; however, several factors might influence the degree of use, including evaluator credibility, report clarity, report timeliness and dissemination, disclosure of findings, impartial reporting, and changes in the program or organizational context.
Activities	• Designing the evaluation to achieve intended use by intended users; • Preparing stakeholders for eventual use by rehearsing throughout the project how different kinds of conclusions would affect program operations; • Providing continuous feedback to stakeholders regarding interim findings, provisional interpretations, and decisions to be made that might affect likelihood of use; • Scheduling follow-up meetings with intended users to facilitate the transfer of evaluation conclusions into appropriate actions or decisions; and • Disseminating both the procedures used and the lessons learned from the evaluation to stakeholders, using tailored communications strategies that meet their particular needs.

Adapted from a) Joint Committee on Standards for Educational Evaluation. Program evaluation standards: how to assess evaluations of educational programs. 2nd ed. Thousand Oaks, CA: Sage Publications, 1994; and b) Patton MQ. Utilization-focused evaluation. 3rd ed. Thousand Oaks, CA: Sage Publications, 1997.

Checklist for ensuring effective evaluation reports

- Provide interim and final reports to intended users in time for use.
- Tailor the report content, format, and style for the audience(s) by involving audience members.
- Include an executive summary.
- Summarize the description of the stakeholders and how they were engaged.
- Describe essential features of the program (e.g., in appendices).
- Explain the focus of the evaluation and its limitations.
- Include an adequate summary of the evaluation plan and procedures.
- Provide all necessary technical information (e.g., in appendices).
- Specify the standards and criteria for evaluative judgments.
- Explain the evaluative judgments and how they are supported by the evidence.
- List both strengths and weaknesses of the evaluation.
- Discuss recommendations for action with their advantages, disadvantages, and resource implications.
- Ensure protections for program clients and other stakeholders.
- Anticipate how people or organizations might be affected by the findings.
- Present minority opinions or rejoinders where necessary.
- Verify that the report is accurate and unbiased.
- Organize the report logically and include appropriate details.
- Remove technical jargon.
- Use examples, illustrations, graphics, and stories.

Adapted from Worthen BR, Sanders JR, Fitzpatrick JL. Program evaluation: alternative approaches and practical guidelines. 2nd ed. New York, NY: Addison, Wesley Logman, Inc. 1997.

Step 6

Program Evaluation Executive Summary

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A program evaluation of the BAP Breastfeeding History Questionnaire and Screening Tool was conducted to evaluate the response when the risk of in-hospital formula supplementation is identified. The CDC Framework for Program Evaluation was utilized. Early formula use disrupts the natural course of breastmilk production (Parry et al., 2013). Any in-hospital formula supplementation leads to decreased breastfeeding success and duration (Chantry et al., 2014). The benefit of recognizing the risk for in-hospital formula supplementation in each patient can help guide lactation support and streamline lactation resources where they are most needed from prenatal care through hospital discharge to foster long-term breastfeeding success.

BAP Breastfeeding History Questionnaire	
B	Number of babies mother has previously breastfed
A	Number of infants mother felt she was able to breastfeed successfully
P	Number of infants mother had problems breastfeeding
BAP Score*	(B+A)-P

*A BAP score less than 2 indicates risk for in-hospital formula supplementation.

Of 490 couplets admitted to labor and delivery between September 2019 and November 2019, 282 met inclusion criteria for this project. The evaluation was focused on the patients' BAP scores (which were each hand-calculated based on the BPAL answers provided in their charts), the lactation support provided to them, and their in-hospital feeding methods. Also collected were patient demographics, birth characteristic data, and feeding types at the 2-week and 2-month intervals when available. See Flow Diagram at end of summary.

BAP Questionnaire	Calculating BAP Scores	Calculated BAP Scores	Calculated BAP score on every pregnancy Awareness/Alert of BAP scores upon hospital admission	Flowsheet w/ built-in BAP Questionnaire calculator Lactation assistance access on every shift Lactation assistance at each delivery Avoid use of non-medically indicated formula supplementation Non-bottle formula feeding techniques when use is medically indicated Reduced access to formula
LDRP Flowsheets/ Pediatric Flowsheets	Extracting data from normal charting activity	In-hospital formula supplementation activity		
Epic Charting System	Retrospective audit of existing flowsheets	Assessment of breastfeeding patterns/support; long term breastfeeding success		
Provider/Staff Expertise	Interviews to guide desired information	Valuable frontline worker insight	Realization of importance of BAP score	

This logic model was created and utilized to help illustrate the BAP Breastfeeding History Questionnaire and Screening Tool program.
This model helped analyze how the tool is currently being used, evaluate the response once a risk is identified, evaluate how breastfeeding or lactation support impacted formula supplementation in-hospital, and understanding if this tool helped with high priority outcomes such as exclusive breastfeeding rates while in-hospital. We compared these rates to state and national averages to evaluate how well UVA was performing.
Also, included here are the short-term to long-term desired outcomes.

Overall Statistics:

- 97% of patients had a breastfeeding history completed prenatally; 100% of patients upon admission to L&D
- 100% of patients in our sample who intended to breastfeed initiated breastfeeding
- 24% of breastfeeding couplets used formula supplementation in-hospital
- 24 couplets (8%) were not seen by the lactation team
- 29% of patients without lactation support used formula supplementation
- 24% of patients with lactation support used formula supplementation

High Risk Statistics:

- 230/282 couplets were identified as high risk (BAP score <2)
- 94% of those identified as high risk received lactation support during the hospital stay
- 6% of those identified as high risk did not receive lactation support during the hospital stay
- 36% of those labeled high risk AND who did not receive lactation support used formula in-hospital

Comparisons to State/National Averages:

- 84% of mother-baby couplets meeting inclusion criteria in this sample breastfed
    - 81.7% of VA births in 2018 ever breastfed*
    - 82.3% of U.S. births in 2018 ever breastfed*
- 24% of breastfeeding couplets used in-hospital formula supplementation in the first two days of life in this project
    - 20.9% of VA breastfed infants received formula in the first 2 days of life*
    - 17.2% of U.S. breastfed infants received formula in the first 2 days of life*

*****State/National averages from 2018 CDC Breastfeeding Report Card

Recommendations:

- Placement of the calculated BAP score into an automatically calculated flowsheet built into EPIC, with color coding, green, yellow, red to visually identify those patients with increased risk of formula use
- Staff education on the importance of the BAP score and how to identify a risk for early formula use
- Increased prenatal breastfeeding education for high-risk mothers
- Lactation consultants on each shift and, ideally, at delivery to assist with the first latch during "The Golden Hour"
- Avoid non-medically indicated formula supplementation in-hospital
- Alternatives to bottle-feeding techniques should be utilized when formula use is medically necessary
- Reduce access to non-medically indicated formula in-hospital

References

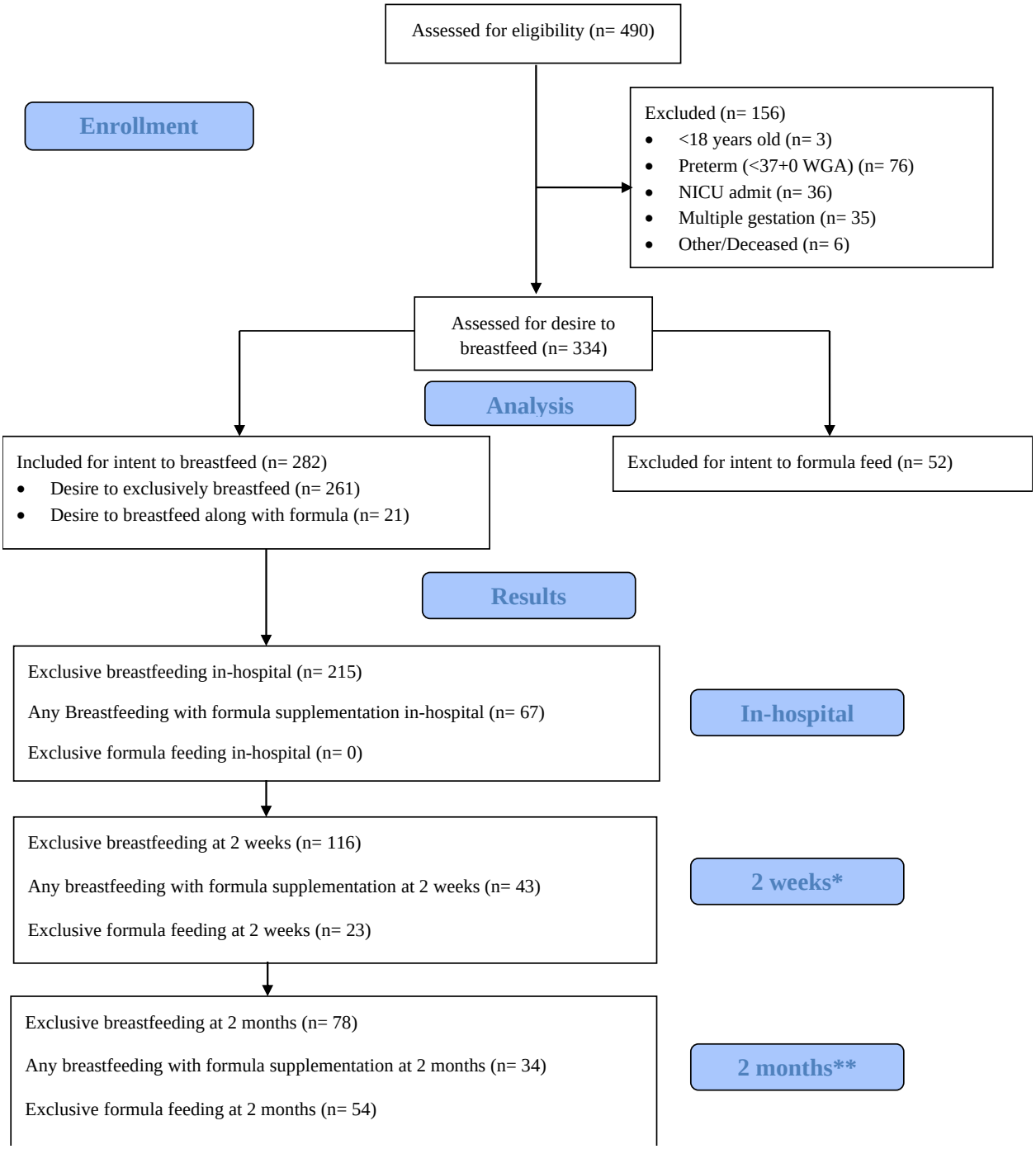
CDC. (2018, August 20). *2018 Breastfeeding Report Card*. Centers for Disease Control and Prevention. https://www.cdc.gov/breastfeeding/data/reportcard.htm

Chantry, C. J., Dewey, K. G., Peerson, J. M., Wagner, E. A., & Nommsen-Rivers, L. A. (2014). In-hospital formula use increases early breastfeeding cessation among first-time mothers intending to exclusively breastfeed. *Journal of Pediatrics, 164*(6), 1339-1345.e5. https://doi.org/10.1016/j.jpeds.2013.12.035

Parry, J. E., Ip, D. K. M., Chau, P. Y. K., Wu, K. M., & Tarrant, M. (2013). Predictors and consequences of in-hospital formula supplementation for healthy breastfeeding newborns. *Journal of Human Lactation, 29*(4), 527–536. doi: 10.1177/0890334412474719

Program Evaluation of Breastfeeding History and Screening Program

QI Data Analysis Flow Diagram



*Data available on 182 couplets only
**Data available on 166 couplets only

Appendix H

FOR IRB-HSR OFFICE USE ONLY

UVA IRB-HSR Study Tracking # 22563_

☒ **Project is determined to NOT meet the criteria of Research with Human Subjects or a Clinical Investigation and therefore is not subject to IRB-HSR Review.**

All project team personnel are required to follow all requirements described in this form and follow:

- *Procurement requirements if participants will be compensated for their time*
- *UVA Information Security policies to protect the data: See Appendix B: Privacy Plan.*

Pick One

☐ No health information/specimens are to be collected or used for this project

☒ Health information/specimens to be collected or used for this project meet the criteria of Deidentified under HIPAA (No identifiers as noted in Appendix A may be collected/ used.)

☐ Health information collected meets the criteria of identifiable

☐ Health Information meets the criteria of Limited Dataset.
HIPAA Data Use Agreement is required to share data outside of UVA.

☐ Data/Specimens used in this project are coded:

Check if applicable

☐ Your project was determined to be QI-Improvement Project. If you decide to publish results of this project you must describe the project in the publication as QI and NOT as research.

IF SENDING OR RECEIVING DATA/SPECIMENS

☐ Provide this signed form to School of Medicine Office of Grants and Contracts and/or Medical Center Procurement if your project has external funding or plans to share data/specimens outside of UVA.

Contact the IRB if anything concerning this project changes that might affect the non-human subject determination.

☐ **Project is determined to be Human Subjects Research or a Clinical Investigation** and must be submitted to the IRB-HSR for review and approval prior to implementation. Please go the Protocol Builder to create your submission. https://www.irb.virginia.edu/

Name of IRB Staff: Karen Mills	***Date:*** 08-10-20_

Appendix I

SPRINGER PUBLISHING COMPANY

Author Guidelines for *Clinical Lactation*

Clinical Lactation is a peer–reviewed journal summarizing recent advances in clinical care in the field of human lactation, and is the official journal of the United States Lactation Consultant Association. The aim of the journal is to advance clinical practice for lactation specialists who work in a variety of settings: hospital, private practice, WIC, and mother–to–mother–support organizations. The articles being solicited for Clinical Lactation are concise, readable reports that summarize issues related to clinical care, treatment innovations and applications. All articles should contain specific implications and suggestions for clinical practice. Suitable topics for submission include, but are not restricted to:

Treatment innovation
Treatment dilemmas
Case presentations
Implementation of specific programs
Outcomes of policies or programs

Papers should be consistent with the current evidence base (if applicable), and should constitute a substantive contribution to the professional literature on clinical lactation. All articles can be hyperlinked to videos, websites, PowerPoint slides, or other ancillary sources of information.

Types of Contributions

Articles on Clinical Practice. These articles include process and program descriptions, clinical audit and outcome studies, and the presentation and description of original clinical practice ideas. These articles should generally not exceed 2,000 words (approximately 8 pages of double–spaced text), not including references, and should be written in a readable, user–friendly style.

Brief Reports of Research Findings. Brief reports of research findings are concise reports of new research. These articles are limited to 2,000 words, not including references and must have direct clinical relevance. These reports can be hyperlinked to other documents or websites with additional information.

Brief Literature Reviews. Brief literature reviews are concise articles on a highly specific topic related to clinical practice, ending with applications for practice. These manuscripts are also limited to 2,000 words (8 pages of double–spaced text).

Case Reports. Case reports offer clinicians a forum to share an interesting case, with the implications for broader clinical practice. These reports will typically range from 3–5 manuscript pages (750–1250 words).

Letters to the Editor. Letters and responses pertaining to articles published in *Clinical Lactation* or on issues relevant to the field, brief and to the point, should be prepared in the same style as other manuscripts (250–300 words).

Manuscripts and Other Requirements

1. Authors should submit their manuscript and supporting files (tables, figures) using Editorial Manager at www.editorialmanager.com/clinlact.
2. Place authors' names, positions, titles, place of employment, mailing addresses, and email addresses on the cover page so that the manuscripts may be reviewed anonymously, and ensure that the manuscript uploaded to the Editorial Manager site is blind.
3. Manuscripts should be professionally prepared in accordance with the *Publication Manual of the American Psychological Association*, 6th edition.
4. An abstract of approximately 125 words should be included.
5. Authors should also supply a list of four to six keywords, not appearing in the title, which will be used for indexing. Terms from the medical subject headings (MeSH) list of Index Medicus should be used, if at all possible.
6. Double-space everything, including references, quotations, tables, and figures.
7. Leave generous margins (at least one inch all around) on each page.
8. Type should not exceed 18 characters per inch.
9. Avoid footnotes whenever possible.
10. Quotations of 300 words or more from one source require written permission from the copyright holder for reproduction. Adaptation of tables and figures also requires reproduction approval from the copyrighted source. It is the author's responsibility to secure such permission, and a copy of the publisher's written permission must be provided to the publisher immediately upon acceptance of the manuscript for publication.
11. All figures must be submitted in camera-ready form. TIFF should be 300 ppi, EPS at 800 ppi.

Note: Authors bear full responsibility for the accuracy of references, quotations, tables, and figures. Upon acceptance of the article, authors are expected to fill out the copyright agreement form and mail it to the publisher at mhughes@springerpub.com.