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Prenatal Hand Expression of Breast Milk to Reduce Formula Use Postnatally
A Capstone Report

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Chapter I. Introduction

The American Academy of Pediatrics recommends exclusive breastfeeding for six months due to the numerous short- and long-term medical and neurodevelopmental advantages of breastfeeding.[1] The current rate of infants who are exclusively breastfed through six months of age is 24.9%, which is lower than the US goal rate of 25.5%.[2] While the current rate suggests exclusive breastfeeding is nearing the target, the rate may still be low, and the American Academy of Pediatrics policy statement suggests more support is needed to increase exclusive breastfeeding.[2]

In addition to targeting all breastfeeding individuals, it is reasonable to target higher-risk subgroups. High-risk groups include women with diabetes and obesity due to the increased risk of low breastfeeding rates and/or poor breastfeeding outcomes which increases the likelihood of formula supplementation.[3,4,5] Diabetes and obesity may lead to delays in the second stage of lactogenesis (production of transitional milk/when the milk "comes in") after giving birth.[3,6,7] Delayed lactogenesis can increase the risk of excessive neonatal weight loss ($\geq$ 10%) which often results in higher rates of formula supplementation.[8] In addition, infants born to women with diabetes during pregnancy may have hypoglycemia after birth and are supplemented with formula to increase their blood glucose levels.[9] Other complications at the time of delivery can lead to breastfeeding difficulties and formula supplementation such as cesarean delivery, large intrapartum blood loss, a delay in first holding the infant or in the first breastfeeding, and maternal-infant separation.[10]

For women at low risk of pregnancy complications, routine prenatal hand expression of breast milk initiated at 36 weeks gestation could help prevent formula supplementation shortly after birth.[11,12] Prenatally expressed breast milk could be frozen and taken to the hospital to be later used in place of formula supplementation if needed.[11,12] The current national average of infants receiving formula before two days of age is 17.2%. However, in several states in 2015, more than 25% of infants received formula supplementation within the first 48 hours of life.[2] The

practice of prenatal hand expression of breast milk can help the US meet the goal of reducing the number of infants who receive formula supplementation during the first two days of life to 14.2%.[2]

Currently, the early postpartum period is a critical time for establishing and supporting breastfeeding[2], and all Baby Friendly Hospitals teach hand expression after birth.[13] However, during the early postpartum period, new mothers are often tired and experiencing intense emotions after a long labor. The late prenatal period is also a valuable time to be working on breastfeeding support and skill development. In support of this, a study in Western Australia found prenatal expression increased the confidence of new mothers in their ability to nourish their babies without formula supplementation.[14]

Even among mothers intending to breastfeed exclusively, formula supplementation in the hospital is associated with a nearly three-fold risk of breastfeeding cessation by day 60.[10] It is suggested that formula supplementation started in the hospital frequently continues after discharge.[15] One reason for this is that mothers may not be given the support and information they need to remedy problems or situations that led to the supplementation.[15] In addition, women whose newborn infants received in-hospital formula supplementation tend to have lower breastfeeding self-efficacy.[16] While it may seem benign to supplement with formula temporarily, formula use can decrease women's confidence to breastfeed their babies. These findings suggest that efforts to limit formula supplementation whenever possible are warranted.

In this Capstone, I will discuss both the potential benefits of prenatal hand expression of breast milk and present a protocol and an educational handout developed for use at the University of Washington Medical Center. The benefits of prenatal hand expression of breast milk may include women having increased confidence in their breastfeeding abilities and a reduced need for formula supplementation in the first few days of life. Thus, there is potential for a higher likelihood of exclusive breastfeeding to maximize the benefits associated with breastfeeding.

Further, the practice of prenatal hand expression of breast milk can help the US meet and surpass the low *Healthy People 2020* breastfeeding goals.[17]

Chapter II. Position Paper on Prenatal Hand Expression of Breast Milk

The purpose of the position paper provided in this section is to provide context and evidence for the following position: **All pregnant women at low risk of pregnancy complications should be taught hand expression of breast milk around 36 weeks gestation and be encouraged to freeze the expressed breast milk to be used after giving birth should supplementation be needed.**

Evidence supporting this position paper is described in detail below, including discussion on the benefits of breastfeeding; health benefits of colostrum; development of gut microbiome in infants; unique qualities of breast milk; potential complications in infants from maternal diabetes during pregnancy; breastfeeding difficulties and delayed lactogenesis; formula supplementation and its effect on breastfeeding duration and cessation; and research on prenatal hand expression of colostrum. The evidence analysis to support this position was completed by searching PubMed, CINAHL, and Embase databases to locate articles on prenatal hand expression of breast milk using the defined search terms in Appendix A.

Benefits of Breastfeeding

There are numerous benefits of breastfeeding for both infants and the breastfeeding mothers (BMos). For infants, there is a lower incidence and decreased severity of several infectious diseases such as respiratory and gastrointestinal infections and otitis media as well as a reduced risk of sudden infant death syndrome and infant mortality.[18,19] There is also some evidence of protection against chronic diseases during later childhood such as asthma, inflammatory bowel disease, type 2 diabetes and obesity.[18,19,20] For mothers, breastfeeding leads to decreased postpartum bleeding, increased child spacing, and earlier return to prepregnancy weight.[1,18,19,21] Also, BMos have a lower risk of breast and ovarian cancers, type 2 diabetes, and postmenopausal osteoporosis and fractures. [1,18,19,21] Breastfeeding is also related to some

psychosocial benefits including improved mother-infant bonding and less risk of postpartum depression.[19]

Health Benefits of Colostrum

Lactogenesis is the process by which the mammary gland develops the ability to secrete milk and involves alveolar cell maturation.[22] Stage 1 lactogenesis takes place when the alveolar cells in the breast begin to secrete a thick, yellowish-white fluid called colostrum. Stage 1 starts in the 12th to 16th week of pregnancy; however, milk secretion is suppressed during pregnancy due to the high levels of estrogen and progesterone.[23] At approximately 30 to 40 hours postpartum[24], stage 2 lactogenesis (transitional milk) begins which involves the gradual change from colostrum to mature milk (stage 3 lactogenesis).[23] Both stage 1 and stage 2 lactogenesis are hormonally driven so these two stages will occur even if breastfeeding is not initiated.[25] However, stage 3 will only occur when there is regular removal of milk and stimulation of the nipple which triggers both prolactin and oxytocin release.[22]

Human colostrum is the ideal food for newborns since it delivers nutrients in a very concentrated low-volume form.[23] The low volume is needed for the infant's small stomach volume[26], and is ideal as the newborn learns how to suck, swallow and breathe during the feeding process.[23] Compared to mature breast milk, colostrum has more protein, less fat and less carbohydrates. Colostrum also contains high levels of secretory immunoglobin A (IgA) antibodies, which are mainly responsible for the higher protein content of colostrum.[23,27] The IgA helps to protect the newborn from infection; thus, colostrum plays an essential role in providing immunity as well as nutrition to the newborn infant.[23] The infant's immune system is immature at birth and includes incomplete physical and chemical barriers, limited secretory IgA production, and insufficient anti-inflammatory mechanisms of the respiratory and gastrointestinal (GI) tracts.[28] Secretory IgA from colostrum binds pathogens, blocking contact with the intestinal epithelial layer and trapping pathogens within the mucin layers. This process essentially blocks infection without stimulating a significant inflammatory response.[28]

Colostrum is also high in oligosaccharides and lactoferrin.[24] The oligosaccharides in the colostrum are the predominant glycans which function in direct pathogen binding and as prebiotics to facilitate the establishment of a healthy gut microbiome in the infant.[29] Lactoferrin, a glycoprotein found in high amounts in colostrum, has numerous functions in host defense including binding iron and binding to bacterial membranes.[30] Several peptide breakdown products of lactoferrin have antibacterial and antifungal effects.[31] Thus, the unique properties of colostrum help protect infants from a wide range of infectious risks.

Development of Gut Microbiome in Infants

Colostrum is one factor that stimulates gut microbiome development in infants in addition to numerous other exposures. The infant's bowel is considered to be sterile at birth.[23] However, infants derive bacteria from the environment which may include bacteria obtained at birth (mainly vaginal and intestinal microflora if a natural birth), bacteria from the process of breastfeeding (BMo's nipples and surrounding skin and breast milk), and bacteria from the surrounding hospital environment (which includes equipment, air, other infants, and healthcare staff). These exposures during the neonatal period influence the microbial colonization in the newborn's GI tract.[32] The bacteria regulate the development of the intestinal barrier as well as its functions, preventing pathogens, toxins, and antigens from entering the body and causing acute or chronic diseases and conditions.[15] Colostrum-derived oligosaccharides can also pass through the small intestine and enter the colon, where they are fermented by colonizing bacteria. Due to the production of short-chain fatty acids and products of fermentation, and the creation of an acidic environment in the intestinal lumen, protective bacteria such as Bifidobacteria and Lactobacilli can flourish and help stimulate the development of host defense[33] and inhibit the growth of pathogenic bacteria.[15] Overall, promotion of a healthy gut microbiome, including Bifidobacteria and Lactobacilli, is important to promote a healthy immune system.

The microbiota of breast-fed and formula-fed infants tends to vary considerably. Breast-fed infants harbor a fecal microbiota that has two times the number of Bifidobacterium cells when compared to formula-fed infants; additionally, breastfed infants have a more stable and uniform microbiota compared to formula fed infants.[34] A study by Penders et al. (2007)[35] reports that the use of formula increases the number of *Clostridia* in the gut microbiota which is associated with an increased risk of eczema in infants. A recent cohort study with 179 of 579 exclusively breastfed infants having received brief formula supplementation while in the hospital after birth showed that this brief formula supplementation was associated with a significantly lower relative abundance of *Bifidobacteriaceae* and a significantly higher relative abundance of *Enterobacteriaceae* in the infants' microbiota when the infants were three to four months of age compared to the infants who had not received any formula.[36] In contrast, early limited formula supplementation in another study did not lead to a decreased abundance of *Lactobacillus* or *Bifidobacterium* and was not associated with expansion of *Clostridium* (although stool specimens were only collected from 15 infants [8 in the intervention group and 7 in the control group] and analyzed for intestinal microbiota at baseline, at one week, and at one month of age).[37] Since this was such a small group of infants, further research would be needed to confirm any changes in the infant microbiota as a result of limited formula supplementation and to determine if the changes are transient or persistent.

Unique Qualities of Breast Milk

Colostrum and mature breast milk contain a number of components, such as immunoglobins, leukocytes, antioxidants, enzymes and hormones, making them more beneficial and better suited for infants compared to formula.[23] Breast milk is a complex and highly variable biofluid that nourishes infants and helps protect them from disease while their own immune system develops and matures.[38] Breast milk composition varies within a feeding, diurnally, over the duration of lactation, and between mothers and populations.[39] In addition, breast milk uniquely reflects the environment and biological conditions specific to each mother-infant dyad since each BMo produces milk that is suited to her baby's needs.[24] Research from Perrone et al.

(2019)[40] suggests that breast milk is gestational age specific. BMos of premature infants (born at 29-31 weeks gestation) produced breast milk that is higher in lactose and oligosaccharides compared to the breast milk of BMos who gave birth to term infants; differences in breast milk metabolome patterns were still present between the BMos of the preterm infants and BMos of the term infants even 3 weeks after giving birth.[40] Thus, breast milk from mothers who deliver preterm has higher bioactive properties due to the higher amount of oligosaccharides providing evidence of the tailored, individualized nutrition provided by breast milk.[40]

Since the components of colostrum and breast milk actively affect the ongoing development of the infant's immunity and intestinal development, human breast milk has an effect on the infant that cannot be replicated using infant formula[28], which tends to have a standardized composition. Changes continue to be made to infant formula in order to attempt to more accurately mimic the composition of human breast milk.[27] Although formula now contains prebiotics, probiotics, and lactoferrin, and the use of formula has been demonstrated to change newborns' microflora composition to be more similar to that of breast-fed infants and to stimulate an immune response[32], there is simply no substitute for colostrum or breast milk.

Potential Complications in Infants from Maternal Diabetes During Pregnancy

Since there is an increasing number of women of childbearing age who have insulin resistance before conception and due to the lowering of the diagnostic thresholds for diagnosing diabetes (in 1997, the fasting glucose level for diagnosing diabetes was lowered from 140 mg/dL to 126 mg/dL[41]), the proportion of women diagnosed with diabetes during pregnancy is increasing.[42] Some common neonatal risks associated with diabetes in pregnancy are respiratory distress syndrome (RDS) and hypoglycemia; RDS often results in admission to the neonatal intensive care unit (NICU).[43] The hypoglycemia is the result of relatively high production of insulin in the fetus due to exposure to high blood glucose levels.[44] The routine practice of using formula versus colostrum to manage the hypoglycemia has limited evidence for support. Using a retrospective chart review of all term infants born to mothers with either

type 1 or gestational diabetes, Tozier (2013) found that infants who were exclusively fed colostrum (after breastfeeding attempts) had no difference in blood glucose levels when compared to infants who received formula supplementation. The author concluded colostrum stabilizes infant glucose levels as effectively as formula in the first six hours after birth.[45] However, it is important to call attention to the protocols and guidelines at the hospital in the Tozier study. The hospital had a prebirth hand expression guideline available, and women scheduled for a cesarean section, women who were in the early phase of labor induction, or women in labor who were having irregular contractions with a slow progression of labor were taught how to hand express.[45] The other women were taught techniques for hand expression of their colostrum after birth. If the newborn's latch was not effective or the infant was experiencing hypoglycemia, the expressed colostrum was fed to the infant. However, the study did not provide data about how often hand expressed colostrum was used compared to just using breastfeeding to stabilize blood glucose levels.[45] This study suggests that in a hospital with many points of encouragement for hand expression, colostrum may be sufficient to treat hypoglycemia.

The Sugar Babies Study randomized infants with hypoglycemia to either a 40% dextrose gel or a placebo gel and then were encouraged to feed based on the mother's preference, which was the baseline method of feeding (expressed breast milk, breastfeeding, infant formula, or a combination).[46] This study showed that treatment of infants with hypoglycemia with dextrose gel or formula is associated with a significant increase in blood glucose levels while neither breastfeeding nor expressed breast milk was associated with a significant increase in blood glucose levels, although the change in blood glucose levels after breastfeeding trended towards a significant increase (P= 0.09). However, breastfeeding was associated with a reduced need for a second treatment with the dextrose gel.[46] Fifty of the 227 infants with hypoglycemia were not treated with any feed after the gel treatment (usually because the BMos wanted to exclusively breastfeed and these BMos were "unable to express any milk") and 27 of these 50 infants received the placebo gel.[46] Expressed breast milk was available from 103 BMos and of these BMos, 44 of them had prenatally expressed and frozen their milk; 28 of the 44 gave their

infants expressed breast milk during episodes of hypoglycemia.[46] BMos who had expressed breast milk prenatally and the BMos who expressed milk after giving birth had similar volumes of breast milk available.[46] In contrast to the Tozier study, data from the Sugar Babies Study suggest that the use of prenatal expression and feeding of expressed breast milk is not effective for the treatment of neonatal hypoglycemia, although the number of infants receiving expressed breast milk is fairly small. The findings also suggest that breastfeeding may have a slower but more sustained effect on blood glucose concentrations compared to infant formula or dextrose gel.[46] However, blood glucose level data after combination feeding (both breastfeeding and giving the infant expressed breast milk) was not included in the research article.

Breastfeeding Difficulties and Delayed Lactogenesis

Women with gestational diabetes mellitus (GDM) tend to experience more breastfeeding difficulties which often leads to their infants not being exclusively breastfed.[5] Additionally, women with type 1 diabetes mellitus (T1DM) are more likely to breastfeed for a shorter duration.[47] Since infants born to women with GDM, T1DM and type 2 diabetes mellitus (T2DM) are more likely to be separated from their BMo as a result of increased cesarean births[47,48,49] and have a higher risk of RDS and hypoglycemia[43], the successful establishment of breastfeeding can be disrupted.[50] In addition, a systematic review of studies primarily involving women with GDM found that women with GDM may have a 24-hour delay in the onset of lactogenesis compared with other women[6] which can lead to a higher likelihood of supplementation with formula. Obese mothers may also experience a delay in stage 2 lactogenesis based on maternal perception (breast fullness, swelling and leakage) and on physiological markers (> 60 hours or > 72 hours after birth for stage 2 lactogenesis) and tend to breastfeed for a shorter duration than normal weight mothers according to a systematic review.[3] A more recent prospective cohort study showed that there is an association between pre-pregnancy obesity and an increased risk of delayed stage 2 lactogenesis.[7] Additional risk factors for breastfeeding difficulties among women in general include cesarean delivery, large

intrapartum blood loss, a delay in first holding the infant or first breastfeeding, and maternal-infant separation.[10] These situations can also lead to a higher likelihood of supplementation with formula even for the infants of mothers who had no prenatal risk factors.

Breastfeeding within one hour after birth and continuing to breastfeed frequently and/or expressing milk is especially important for women with GDM (and for new mothers in general); these strategies may reduce the risk of perceived delayed stage 2 lactogenesis and increase self-efficacy.[51] A woman with diabetes may have difficulty establishing breastfeeding if her infant requires supplementation with formula to maintain blood sugars.[52] When a breastfed infant is fed formula shortly after birth, this could lead to less interest in breastfeeding due to a full stomach[45] leading to fewer breastfeeds, low maternal milk supply and an earlier termination of breastfeeding.[53] Additionally, when a baby is still unsettled after supplementation with small amounts of hand-expressed colostrum (e.g. 4 mL), the infant may be given a large amount of formula (e.g. 40 mL) and then proceed to sleep for several hours.[54] At the next breastfeed, the baby may not be satisfied with the small amount of colostrum, since the baby's stomach is expecting a larger volume, leading to a decrease in the mother's confidence since her baby does not appear to be satisfied with breastfeeding.[54] Since a newborn baby's stomach will expand as the milk supply increases over the first couple days of life, giving an unnaturally large volume of formula will confuse the infant's stomach and cause the baby to not be satisfied with the normal small volume feeds from breastfeeding.[55] A newborn baby's stomach is about the size of a cherry on day 1 (holds about 5-7 mL) and progresses to the size of an apricot by day 7 (holds about 45-60 mL).[26] New BMos need to be counseled that colostrum is sufficient to meet the newborn's nutritional needs to help counteract the mother's perception that she 'doesn't have enough milk'.[24] Another practice to increase breastfeeding success is increasing skin-to-skin contact within the first hour after birth for mother-baby bonding but also to allow the baby to use his/her olfactory sense to properly latch onto the mom's breast.[24]

The 2018 Breastfeeding Report Card compiled by the Centers for Disease Control and Prevention shows that the national average of infants receiving formula before two days of age is 17.2%; however, in several states more than 25% of infants receive formula supplementation within the first 48 hours of life.[2] One of the *Healthy People 2020* health objectives for the US is to reduce the number of infants receiving formula supplementation during the first two days of life to 14.2%.[17] Formula supplementation that is started in the hospital frequently continues after discharge, especially when mothers are not given the support and information they need to remedy problems or situations that caused the supplementation.[15] BMos may supplement with formula for numerous reasons including real or perceived insufficient milk, to ensure that an infant is satisfied and getting enough milk, to get more sleep, improper latching on during breastfeeding, or because their health care providers are urging them to (e.g. due to conservative hospital hypoglycemia policies or to ensure infant weight gain).[15] Often times, the BMo could benefit from talking with an International Board-Certified Lactation Consultant who could help with any latching on issues, provide reassurance that the infant is getting enough milk through observing the baby during a feeding and weighing the infant before and after a feeding, or explain how to increase milk production through frequent breastfeeding even if the infant is receiving some formula due to a medical reason such as hypoglycemia. These actions could make the difference between exclusive breastfeeding for a long duration and early breastfeeding cessation.

Formula Supplementation and Its Effect on Breastfeeding Duration and Cessation

A recent study on early lactation and infant feeding practices showed that women with GDM were more likely to feed their infants formula within the first two days of life compared to women without GDM (78.8% vs. 52.8%, $P < 0.01$).[56] A high quality large-scale longitudinal cohort study by Chantry et al. (2014)[10] reported that when new mothers begin formula supplementation in the hospital, even when intending to exclusively breastfeed, this was associated with a nearly two-fold greater risk of not fully breastfeeding 30-60 days later and a nearly three-fold risk of breastfeeding cessation by day 60. The most common reason reported

for in-hospital formula supplementation was perceived low milk supply (18% of overall sample), followed by signs of inadequate intake (16%), poor infant breastfeeding behavior (14%), and maternal-infant separation (10%).[10] In addition, the odds of not fully breastfeeding between days 30 and 60 was significantly greater when in-hospital formula supplementation was provided by bottle compared with alternative feeding methods such as cup, finger and supplemental nursing system.[10] Breastfed infants who are supplemented using a bottle may have subsequent difficulty latching onto the breast properly and may cause nipple damage and reduced milk transfer, leading to a possible reduction in the maternal milk supply.[15] Chantry et al. (2014)[10] recommends devising strategies to avoid unnecessary in-hospital formula supplementation and to utilize methods to support breastfeeding when in-hospital formula supplementation is unavoidable. Mothers may not understand that formula introduction after birth is often unnecessary, and/or they may not know that formula use can be temporary.[56] In addition, they may not realize that they can continue to breastfeed even if their infant is receiving some medically necessary formula supplementation and resume exclusive breastfeeding once the medical issue is resolved.[57]

A small high quality RCT explored the use of limited formula supplementation (10 mL after each breastfeeding) beginning when term infants who had lost $\geq$ 5% of their birth weights were 24-48 hours old; formula supplementation was discontinued when mature milk production began.[57] The results suggest that early limited formula supplementation may reduce longer-term formula use at one week and increase exclusive breastfeeding at three months for some infants through reducing the mothers' concern about their milk supply and their newborns' early weight loss and ultimately help support long-term breastfeeding.[57] Several key techniques were incorporated into the intervention that reduced any negative impact of formula supplementation on breastfeeding. First, small amounts of formula (10 mL) were used so that the infant would not be satiated after the supplementation and would still be interested in breastfeeding; second, formula was given with a syringe; and third, there was a clear time frame for discontinuing the formula supplementation.[57] A larger high quality RCT showed no differences in partial breastfeeding rates at one month or in breastfeeding without formula

rates at one month for the group who received early limited formula supplementation (using the same methods as Flaherman et al. 2013[57]) compared to the control group.[37] The newborns in this study had a weight loss that was ≥75th percentile for age based on The Newborn Weight Tool. Flaherman et al. (2018)[37] also concluded that early limited formula supplementation may help to reduce hospital readmission rates due to hyperbilirubinemia or dehydration.

In contrast to the Flaherman et al. studies, Nguyen et al. (2016)[58] performed a high quality large-scale cross-sectional survey in Vietnam where 10,681 mothers with children aged 0-23 months were interviewed about their feeding practices during the first three days after birth and on the day before the interview. In order to minimize the limitation of the cross-sectional design, the researchers used stratified analysis, multiple logistic regression, propensity score-matching analysis, and structural equation modeling. Infant formula feeding during the first three days after birth occurred in 50% of the subjects and was associated with a higher prevalence of subsequent infant formula feeding. This practice was also associated with a higher prevalence of early breastfeeding cessation.[58] In addition, structural equation modeling showed that infant formula feeding during the first three days after birth was associated with a higher prevalence of subsequent infant formula feeding, which in turn was linked to early breastfeeding cessation.[58] Only about half of the women received professional breastfeeding advice during pregnancy and only about one-third received breastfeeding support during the first three days after birth. The researchers also found that breastfeeding misconceptions were associated with infant formula feeding during the first three days after birth and subsequent infant formula feeding.[58] These results emphasize the need to make early, exclusive breastfeeding the norm and to ensure that new mothers receive needed education and support. Additionally, this research suggests that minimizing the early introduction of formula is also important in low- and middle-income countries.

Another area to consider is the breastfeeding self-efficacy of women whose newborn infants receive in-hospital formula supplementation. Hinic (2016)[16] surveyed 107 women within the first four days postpartum using the Breastfeeding Self-Efficacy Scale-Short Form and reported

that women whose infants received in-hospital supplementation with formula tended to have lower breastfeeding self-efficacy. The two Flaherman studies, however, did not show a difference in breastfeeding self-efficacy using the Breastfeeding Self-Efficacy Scale-Short Form within the first week after giving birth for women whose infants were in the limited formula supplementation group compared to the women whose infants were in the exclusive breastfeeding group.[37,57] Glassman et al. (2014)[59] interviewed 209 women within a week of giving birth which included use of the Breastfeeding Self-Efficacy Scale-Short Form. The majority of the mothers were doing mixed feeding (both breastfeeding and providing formula). Higher levels of education, breastfeeding a previous child for ≥ six months, woman being foreign born and higher breastfeeding self-efficacy scores were associated with more breastfeeding. In addition, higher breastfeeding self-efficacy scores were associated with exclusive breastfeeding.[59] The researchers concluded that breastfeeding self-efficacy is a modifiable factor associated with exclusive breastfeeding so efforts to improve breastfeeding self-efficacy may help support breastfeeding.[59]

There is conflicting evidence regarding whether in-hospital formula supplementation is associated with less exclusive breastfeeding/subsequent use of formula and conflicting evidence regarding whether formula supplementation decreases breastfeeding self-efficacy. While more research is needed, it appears increasing breastfeeding self-efficacy could have a positive effect on breastfeeding. Therefore, limiting use of formula in the hospital to situations when it is medically necessary, discontinuing supplementation when lactogenesis 2 begins, and increasing prenatal and postpartum breastfeeding education and support are important strategies that can potentially increase exclusive breastfeeding for a longer duration and also increase breastfeeding self-efficacy.

Research on Prenatal Expression of Colostrum

Another way to potentially decrease in-hospital formula supplementation and to increase breastfeeding self-efficacy is to teach prenatal breast milk expression (PBME). A review article

by Chapman et al. (2013)[60] identified that PBME was taught to women in late pregnancy for three main reasons: as a form of breast preparation prior to birth; for collection and storage in late pregnancy to be fed to the newborn in order to prevent hypoglycemia; and for the expression and discarding of colostrum while pregnant to decrease the amount of time to reach stage 2 lactogenesis after delivery. Teaching pregnant women PBME can also increase their feelings of self-efficacy in that they are becoming more familiar with the anatomy of their breasts as well as developing a skill.[61] Women who are taught PBME often have a sense of increased confidence and preparedness for breastfeeding.[11] In addition, the experience of expressing the colostrum can provide confidence that the pregnant women's breasts are capable of providing nourishment for their babies, and having a supply of breast milk that can be used in case of neonatal feeding problems can be reassuring.[14] Learning to be skillful at hand expressing breast milk before giving birth is also helpful if hand expression is necessary after the baby is born[62]–e.g. for increasing milk supply especially if the baby is sleepy and not breastfeeding well, for dealing with engorgement so the baby can latch on properly, for reassurance about the BMo's milk supply, or to provide relief if the BMo has a blocked milk duct.[26] Women are often taught how to hand express in the immediate postpartum period when they are exhausted and emotional. Since hand expression is a skill that needs to be practiced and since the first attempt will often produce little colostrum, the new BMo may experience frustration and be worried about being able to produce an adequate milk supply for her baby.[26]

In a qualitative study that involved 12 in-depth interviews, Brisbane and Giglia (2015)[14] postulated that successful prenatal expression of colostrum may contribute towards mastery of breastfeeding and thus improve breastfeeding outcomes. A cross-sectional survey of 688 mothers (the majority of whom were either currently breastfeeding or who had breastfed their babies) found that many had heard of PBME, compliance with advice to perform PBME was relatively high, PBME was considered an acceptable practice, and PBME can potentially be helpful in avoiding the use of formula. Women in the overweight or obese subgroups were significantly more likely to have heard of PBME and a positive opinion of PBME was also

increased in these subgroups.[63] Since obese mothers may experience delayed stage 2 lactogenesis[3], overweight and obese pregnant women could be an important target group for PBME.[63]

A recent study examining the perceptions and experiences of first-time mothers in the United States who participated in a pilot RCT of PBME found the views of the women who participated in PBME to be similar to the studies mentioned above. Of the 22 women assigned to the PBME group, 19 completed interviews.[64] The interviewed women held positive views of PBME and did not find the practice to be burdensome or time-consuming.[64] PBME was attributed to evoking a sense of appreciation for their breasts, helped prepare them for the physical and psychological challenges of breastfeeding, increased women's confidence in their capability to produce milk, provided reassurance that they would be able to express breast milk after birth in case of breastfeeding difficulties, and increased their commitment to breastfeeding.[64] The study findings showed that some of the expressed milk was used in the case of pregnancy and labor complications such as prolonged labor, preeclampsia in the mother and infant NICU admittance, and the use of this milk led to decreased formula use.[64] In addition, several women felt that performing PBME contributed to more abundant colostrum before stage 2 lactogenesis and that their milk "came in" sooner.[64] The authors expressed that the inclusion of PBME education and demonstrations in prenatal care could benefit not only women who intend to breastfeed but also encourage women who are unsure about breastfeeding to consider it further.[64]

Two weak studies report that PBME is associated with establishing "full" lactation sooner likely through the production of more colostrum. A prospective study by Singh et al. (2009)[65] found that a significantly higher percentage of the 90 women randomized to the PBME group (beginning after 37 completed weeks of pregnancy) had established "full" lactation (defined as no top feed required and baby did not cry for at least two hours after feeding) within half an hour of initiation of breastfeeding compared to the 90 mothers in the control group (94.4% vs. 70.0%). There was no increase in any delivery complications in the PBME expression group.[65] A

similar study by Lamba et al. (2016)[65] confirmed these results. A significantly higher percentage of the women in the PBME group had established full lactation within six hours of delivery compared to the control group (89% vs. 72%).[66] The authors concluded that PBME at term pregnancy helps prepare mothers both physically and psychologically for breastfeeding as well as boosts their confidence. PBME is technically very easy to teach and is safe, effective, involves no cost, and has good acceptance among women.[66] In a pilot study by Forster et al. (2011)[11], 95% of the women in the PBME group stated that they would be willing to express prenatally again if this process was shown to be beneficial, especially so that they would have a supply of breast milk for their newborn in case it was needed.

The practice of PBME decreased during the late 1970s after concerns that nipple stimulation followed by the release of oxytocin could potentially induce uterine contractions and lead to pre-term labor.[62] However, two small studies found that women who performed PBME gave birth to their infants at or after 37 weeks, on average. Soltani and Scott (2012)[67] conducted a small-sized retrospective cohort study of pregnant women with diabetes (type 1, type 2 and gestational) from one hospital to determine if there was a difference in neonatal outcomes and gestational age at birth in women who prenatally hand-expressed breast milk (beginning at a mean gestational age of 36 weeks with a range of 33-38 weeks) and women who did not hand-express breast milk. The study indicated that PBME and a lower gestational age at birth are associated and that there was a higher rate of SCBU admission for babies born to mothers in the PBME group, although neither of these were statistically significant.[67] However, the mean gestational age was 37.1 weeks in the group that hand expressed [n = 16] and 38.2 weeks in the group who did not express [n = 69][67] so the babies were considered to be full-term if they were born at 37 weeks or later. The pilot study conducted by Forster et al. (2011)[11] recruited women at a mean gestation of 36 weeks (range 33-39 weeks), and all of the infants were born at or after 37 weeks gestation. The researchers found that infants born to women in the PBME group (who froze the expressed colostrum to give to their babies after birth if needed) were less likely to receive formula compared to the audit “control” infants; however, special care admissions

were higher in the pilot infants (30%) than for the audited infants (17%). However, this study was not adequately powered to make meaningful conclusions.[11]

Meanwhile, the DAME multi-center randomized controlled trial provides the best high quality research to date on the safety and efficiacy of PBME.[12] The exclusion criteria included: history of prenatal hemorrhage, placenta previa or other placental abnormality that increases risk for bleeding; unknown or classical C-section scar or more than one lower segment C-section scar; suspicion of fetal compromise including intra-uterine growth restriction, macrosomia, polyhydramnios or any abnormal tests of fetal well-being; any known fetal anomaly; hypertension and proteinuria—if any concerns about fetal well-being; and a serious maternal mental health issue or other severe maternal obstetric/medical issue.[12] Eligible women were assigned (1:1) to either a PBME group (expressing breast milk two times/day for no more than ten minutes from 36 weeks gestation) or to a standard care group (usual midwifery and obstetric care with support from diabetes educators). The women in the expressing group froze the breast milk to bring to the hospital when they delivered.[12] The proportion of infants admitted to the NICU did not differ between the two groups, the mean gestational age at birth was not different, and there was moderate evidence of an association between allocation to prenatal expressing group and the proportion of infants receiving exclusive breast milk during the initial hospital stay. The authors concluded that there is no harm in advising women with diabetes in pregnancy at low risk of complications to express breast milk from 36 weeks gestation.[12] Further research is needed among other groups of women who are at risk of low levels of lactation to determine if they would benefit from PBME and subsequent usage to supplement breastfeeding.

A very recent article discussed lessons learned from the introduction of a Prenatal Human Milk Expression (PHME) Clinic in South Australia. This clinic was started by a group of midwives who were concerned about the high incidence of newborn infants with hypoglycemia being transferred to the Special Care Nursery (SCN), which is the next level down from a NICU. These infants are often born to mothers with pre-existing Type 1, Type 2, or gestational diabetes.[68]

The purpose of the PHME Clinic is to teach the women how to express and store their colostrum starting at 36 weeks, to supply them with the required equipment, and to promote breastfeeding in general.[68] The mothers who collect colostrum can give this to their newborn infants if they have hypoglycemia to stabilize their blood sugar and likely prevent the introduction of formula.[68] Between August 2013 and August 2016, 207 women participated in the PHME Clinic, and 141 of these women were contacted by telephone by a midwife from the clinic 4-8 weeks after delivery to gather feedback about their experience and to determine if these women were still breastfeeding.[68] Three in four women (105) were still breastfeeding. Based on the midwives' experiences establishing the clinic and on the feedback from the 141 women who were contacted, several recommendations were developed to help ensure the success of the clinic.[68] These recommendations included using a peer education approach which would involve having women who previously attended the clinic discuss their PHME experiences with women currently in attendance and to use visual aids (such as knitted breasts and examples of an infant's stomach size over the first few weeks of life); providing easy to read information sheets; and having plenty of supplies (syringes and labels) available.[68] Based on the results of the research described in this section, it seems likely that PBME will become more widespread in the future.

Conclusion

The strength of the evidence that prenatal hand expression of breast milk is safe for women who are at low risk of pregnancy complications starting at 36 weeks gestation is fair. Several studies that interviewed women who had participated in prenatal hand expression have shown that women's confidence in their ability to breastfeed and provide adequate nourishment for their infants is increased, they often have an increase in their commitment to breastfeeding, and that the women have an overall positive attitude about prenatal hand expression.[14,61,63,64] In addition, hand expression of breast milk may encourage women who are unsure about breastfeeding to consider it further.[64] Another possible benefit to prenatal hand expression of breast milk is a decrease in the amount of time required to establish full lactation.[65,66] There is

also some limited evidence that prenatal hand expression may reduce the need for formula supplementation in newborns.[11,12] Although two studies concluded that limited formula supplementation is not associated with a reduction in breastfeeding duration[37,57] and that this supplementation is not associated with significant changes in the infants' gut microbiota[37], formula supplementation could potentially be avoided and exclusive breastfeeding maintained through the use of prenatal hand expression and storage of the breast milk for use after birth if needed. The avoidance of formula supplementation is still a good goal since Chantry et al. (2014)[10] found that formula supplementation in the hospital is associated with an increased risk of not fully breastfeeding 30-60 days after birth and an increased risk of breastfeeding cessation by day 60. Additionally, Nguyen et al. (2016)[58] reported that infant formula feeding during the first three days after birth was associated with a higher prevalence of subsequent infant formula feeding and with a higher prevalence of early breastfeeding cessation.

Hand expression of breast milk may be even more important for certain populations of women who may experience delayed stage 2 lactogenesis such as women with diabetes in pregnancy and women with overweight or obesity.[3,6] Infants born to mothers with diabetes during pregnancy are at an increased risk of RDS and hypoglycemia which often lead to NICU admissions[43] and potentially formula supplementation. In women at low risk of pregnancy complications, prenatal hand expression of breast milk appears to have more benefits than disadvantages and could potentially lead to a decrease in the use of formula supplementation. In cases where formula supplementation is unavoidable, it is important to make sure BMos realize that they can continue to breastfeed even if their infant is receiving some medically necessary formula supplementation and then resume exclusive breastfeeding once the medical issue is resolved.[57] All BMos should receive lactation services and support, especially if they are experiencing any issues with breastfeeding, to help prevent further problems and to assist in the resolution of any issues in a more-timely manner. If formula has been used, it is even more important to ensure BMos are receiving the lactation services and support they need in order to help them achieve their breastfeeding goals. Ultimately, prenatal hand expression of breast milk is one strategy to help achieve the *Healthy People 2020* goal of decreasing formula

supplementation during the first two days of life[17] and of increasing exclusive breastfeeding in general.

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Chapter III. Analysis of Evidence

The evidence grade for the following questions was determined using the Academy of Nutrition and Dietetics' Evidence Analysis Library. The evidence analysis drove the development of the protocol and patient education handout along with guidance from Capstone Mentor, Ginna Wall.

Question	Conclusion and Evidence Grade
Do pregnant women who practice prenatal breast milk expression decrease the amount of time required to establish full lactation after giving birth?	Based on evidence from two weak studies (Singh et al., 2009; Lamba et al., 2016), pregnant women who perform prenatal breast milk expression after completing 37 weeks gestation have a shorter time from initiation to full establishment of lactation thus improving breastfeeding success. **Grade III- Limited**
Is prenatal breast milk expression safe for late-term pregnant women who are at low risk for complications including women who have diabetes in pregnancy?	Two small studies of moderate quality (Forster et al., 2011; Soltani and Scott, 2012) reported that special care admissions were higher for infants born to mothers with diabetes who had prenatally hand expressed breast milk. However, a large, well-designed, multi-center RCT (Forster et al., 2017) reported no difference in the proportion of infants admitted to the NICU between two groups of mothers with diabetes: prenatal hand expressing group and standard care group. No research has been conducted using women without diabetes in pregnancy. **Grade II-Fair**
Does prenatal breast milk expression increase women's feelings of self-efficacy and confidence in their ability to breastfeed their newborns?	The available research is limited to several qualitative interviews, surveys and expert opinions (Chapman et al., 2013; Brisbane and Giglia, 2015; Wszolek, 2015; Demirci et al., 2019). **Grade III-Limited**
Does prenatal hand expression of breast milk reduce the need for formula supplementation in newborns?	One small study of moderate quality (Forster et al., 2011) reported that less infants in the prenatal hand expression group received formula in the first 24 hours and less infants

	received formula during the hospital stay (although not statistically significant). A large, well-designed, multi-center RCT (Forster et al., 2017) reported moderate evidence of association between allocation to the prenatal hand expression group and proportion of infants receiving exclusive breast milk during the hospital stay. **Grade III-Limited**
Is formula supplementation shortly after birth associated with decreased breastfeeding?	A high quality large-scale longitudinal cohort study reported an association between in-hospital formula supplementation and a risk of decreased breastfeeding (Chantry et al., 2014). A high quality large-scale cross-sectional survey showed that infant formula feeding during the first three days after birth was associated with a higher prevalence of subsequent infant formula feeding and early breastfeeding cessation (Nguyen et al., 2016). One small RCT found that limited in-hospital formula supplementation may reduce longer-term formula use at one week and increase exclusive breastfeeding at three months (Flaherman et al., 2013), while one moderately sized RCT showed no differences in partial breastfeeding rates at one month or in breastfeeding without formula rates at one month for the group who received limited in-hospital formula supplementation compared to the exclusive breastfeeding group (Flaherman et al., 2018). **Grade II-Fair**

Chapter IV. Development of Protocol and Patient Education Handout

This project was developed out of a need for more information for pregnant women who are interested in prenatal hand expression of breast milk, particularly women with diabetes during pregnancy. My Capstone Mentor, Ginna Wall RN, MN, IBCLC attended several recent lactation conferences where this topic was discussed. In addition, Ginna has had a number of patients asking her about this in the last couple of years, and she heard from several of her patients that there are Facebook groups sharing information about prenatal hand expression. It became clear to Ginna and other UWMC lactation consultants that a protocol and patient education handout should be developed for UWMC to ensure health care staff is made aware of and provided with information about this practice and to ensure that patients are performing this practice in a safe manner.

The development of the Prenatal Hand Expression of Breast Milk protocol and the "Expressing Milk Before Giving Birth" patient education handout were based on the evidence analysis from the Position Paper (see Chapter III) with guidance from Ginna. The protocol "Breastfeeding: Prenatal Hand Expression of Breast Milk" (Appendix C) provides information on the policy, exclusion criteria, procedure (including 3 videos that show how to perform hand expression of breast milk), and background information (benefits of prenatal breast milk expression, common reasons why newborns may need supplementation, reasons to avoid formula supplementation, and evidence of safety for the pregnant woman and fetus). The patient education handout "Expressing Milk Before Giving Birth" (Appendix D) provides the following information: explanation of what prenatal hand expression is; why a pregnant woman should consider doing this; information on the safety of this practice and problems to watch for; a step by step description of how to do this; a listing of the 3 videos showing how to perform hand expression; how to safely store the expressed breast milk at home and how to safely transport the milk to the hospital; reasons newborns are given formula and risks associated with the formula supplementation; and a hand expression record sheet to help keep track of how often the woman is expressing.

Both the protocol and the patient education handout went through multiple revisions. The patient education handout was revised to decrease the reading level. The Flesch-Kinkaid reading level of the patient education handout was assessed at 7.6 grade level while the SMOG Readability Formula assessed the reading level as 9th grade level. At this point, the patient education information was given to Pam Younghans who is the Health Editor for Patient and Family Education Services at the University of Washington Medical Center. Pam is in charge of formatting all of the patient education handouts for UWMC. She was able to bring the reading level down to a 5.6 grade level.

Chapter V. Evaluation of Protocol and Patient Education Handout

A short survey (17 questions) (Appendix E) was developed to evaluate the protocol and patient education handout using guidance from Michelle Averill and Ginna Wall. Several revisions were made to the survey questions. The main purpose of the survey was to obtain feedback from the patients in order to revise and improve the protocol and patient education handout rather than looking at specific outcomes. Therefore, data from the surveys were to be used internally for quality improvement. Ginna Wall asked a pregnant patient who had been doing prenatal hand expression of breast milk to read through a draft version of the patient education handout and then complete the draft version of the survey by hand. Based on several comments and questions this patient had, the survey questions were revised again. The survey is available on paper for those patients wanting to fill out the survey by hand. In addition, a link to the online survey on Catalyst is also provided to the patients.

In January 2019, the nursing staff at the Maternal and Infant Care Clinic (MICC) at UWMC were given a short PowerPoint presentation about prenatal hand expression of breast milk and were given the opportunity to review the "Breastfeeding: Prenatal Hand Expression of Breast Milk" protocol, the patient education handout "Expressing Milk Before Giving Birth", and the patient survey "Hand Expression of Breast Milk Before Giving Birth". The questions that were asked included: why the majority of the studies mentioned in the presentation used women with diabetes during pregnancy (increased risk of hypoglycemia); how long this practice has been happening, how much colostrum can be collected; whether the expressed colostrum could be donated to a breast milk bank if not used for supplementation after birth (Ginna addressed this); logistics of the patient education handouts, surveys and syringes for collecting the colostrum (location of these items and how to deal with the return of the surveys); why women with infants with known fetal anomalies or with maternal mental health issues shouldn't perform prenatal hand expression (2 of the exclusion criteria on the protocol); and whether the doctors who work at MICC had been informed about this practice since the nurses felt the doctors needed education about this.

Several doctors had been emailed drafts of the protocol but had not provided any feedback. Two doctors were emailed again and given the updated protocol, patient education handout, survey and PowerPoint presentation. The doctors were specifically asked to provide feedback on the exclusion criteria: whether any of the criteria should be deleted or whether any additional criteria should be added to the list. In addition, the doctors were told that the PowerPoint could be given at one of their upcoming meetings so that they could find out more information about prenatal hand expression of breast milk and ask questions. Unfortunately, no feedback was received. During the January meeting with MICC, there was some discussion among the nursing staff about the logistics of the forms and syringes and how best to distribute them to the patients. One nurse recommended that each of the nurses could keep track of which patients they gave the patient education handouts to and then attempt to follow up with them within a few weeks after giving birth to provide a reminder about completing the survey.

At the time of the writing of this section only one survey response via Catalyst was available. The patient had not received a copy of the patient education handout "Expressing Milk Before Giving Birth". The patient felt "somewhat supported" in hand expressing breast milk, she expressed one time/day and collected 25 mL of breast milk overall (over a two week period), her infant received the expressed breast milk in the hospital, and her infant did not receive any formula in the hospital. In addition, the patient felt more confident performing hand expression after giving birth, would do hand expression again if she had another baby, and would recommend prenatal hand expression to a friend. However, the patient did not provide any responses to the following questions: "What other information/support would have been helpful to you?" and "What would you like your healthcare providers to know about your experience with hand expression of breast milk?" nor did she provide any comments regarding "How supported did you feel in hand expressing breast milk?"

Chapter VI. Next Steps

The next steps for this project should involve obtaining Institutional Review Board (IRB) approval for contacting the pregnant women after they give birth to remind them to fill out the survey or to just ask them the survey questions over the phone. This would likely increase the number of survey responses from pregnant women participating in prenatal hand expression of breast milk. It would be important to collect feedback from a number of women in order to determine if any changes should be made to the protocol, patient education handout or patient survey. One change to the patient education handout that should be considered is providing information to patients on the process for donating any unused prenatally expressed breast milk to Northwest Mothers Milk Bank in Portland, Oregon. Additionally, if a BMo indicated on the survey that her infant received formula in the hospital, it would be important to know why this occurred. Therefore, modifying the survey to include a question about why their infant received formula would be another important change.

If additional work were done on this project, it would be essential to reach a larger number of pregnant women with the information about prenatal hand expression of breast milk, and it would be valuable to obtain feedback from them. This could be accomplished through providing the patient education handouts and surveys at a prenatal breastfeeding class or through childbirth education classes that have a breastfeeding education component. Working directly with doctors at an obstetrics clinic like MICC to try and incorporate the introduction of the patient education handout during a patient's appointment around 36 weeks gestation could also be a good way to accomplish this. After improving the protocol, patient education handout, and survey, the next steps could involve conducting a publishable research study to determine whether women who perform prenatal hand expression of breast milk and take the breast milk to the hospital have less use of formula when supplementation is medically necessary and whether these women have increased breastfeeding self-efficacy.

Appendix A.

Search terms used to locate articles on prenatal hand expression of breast milk:

colostrum
express
expression
milk
breast milk
breastmilk
pregnant women
pregnancy
mother
infant
newborn
neonate
neonatal
antenatal
prenatal
diabetes
diabetic

Appendix B.

Quality Criteria Checklist: Primary Research (Chantry et al., 2014)

Symbols Used

+ **Positive:** Indicates that the report has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

-- **Negative:** Indicates that these issues have not been adequately addressed.

∅ **Neutral:** Indicates that the report is neither exceptionally strong nor exceptionally weak.

Quality Criteria Checklist: Primary Research

RELEVANCE QUESTIONS		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (NA for some Epi studies)	Yes X No Unclear N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes X No Unclear N/A
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?	Yes X No Unclear N/A
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes X No Unclear N/A
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.		
VALIDITY QUESTIONS		
1.	**Was the research question clearly stated?**	Yes X No Unclear N/A
1.1	Was the specific intervention(s) or procedure (independent variable(s)) identified?	
1.2	Was the outcome(s) (dependent variable(s)) clearly indicated?	
1.3	Were the target population and setting specified?	
2.	**Was the selection of study subjects/patients free from bias?**	Yes X No Unclear N/A
2.1	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	
2.2	Were criteria applied equally to all study groups?	
2.3	Were health, demographics, and other characteristics of subjects described?	
2.4	Were the subjects/patients a representative sample of the relevant population?	
3.	**Were study groups comparable?**	Yes X No Unclear N/A
3.1	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	
3.2	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	
3.3	Were concurrent controls used? (Concurrent preferred over historical controls.)	
3.4	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	
3.5	If case control study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	
3.6	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	
4.	**Was method of handling withdrawals described?**	Yes X No Unclear N/A
4.1	Were follow up methods described and the same for all groups?	
4.2	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	
4.3	Were all enrolled subjects/patients (in the original sample) accounted for?	
4.4	Were reasons for withdrawals similar across groups?	
4.5	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	
5.	**Was blinding used to prevent introduction of bias?**	Yes No Unclear N/A

	5.1	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	X
	5.2	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	
	5.3	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	
	5.4	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	
	5.5	In diagnostic study, were test results blinded to patient history and other test results?	
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?**		Yes No Unclear N/A X
	6.1	In RCT or other intervention trial, were protocols described for all regimens studied?	
	6.2	n observational study, were interventions, study settings, and clinicians/provider described?	
	6.3	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	
	6.4	Was the amount of exposure and, if relevant, subject/patient compliance measured?	
	6.5	Were co-interventions (e.g., ancillary treatments, other therapies) described?	
	6.6	Were extra or unplanned treatments described?	
	6.7	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	
	6.8	In diagnostic study, were details of test administration and replication sufficient?	
7.	**Were outcomes clearly defined and the measurements valid and reliable?**		Yes No Unclear N/A X
	7.1	Were primary and secondary endpoints described and relevant to the question?	
	7.2	Were nutrition measures appropriate to question and outcomes of concern?	
	7.3	Was the period of follow-up long enough for important outcome(s) to occur?	
	7.4	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	
	7.5	Was the measurement of effect at an appropriate level of precision?	
	7.6	Were other factors accounted for (measured) that could affect outcomes?	
	7.7	Were the measurements conducted consistently across groups?	
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		Yes No Unclear N/A X
	8.1	Were statistical analyses adequately described the results reported appropriately?	
	8.2	Were correct statistical tests used and assumptions of test not violated?	
	8.3	Were statistics reported with levels of significance and/or confidence intervals?	
	8.4	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	
	8.5	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	
	8.6	Was clinical significance as well as statistical significance reported?	
	8.7	If negative findings, was a power calculation reported to address type 2 error?	
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes No Unclear N/A X
	9.1	Is there a discussion of findings?	
	9.2	Are biases and study limitations identified and discussed?	
10.	**Is bias due to study's funding or sponsorship unlikely?**		Yes No Unclear N/A
	10.1	Were sources of funding and investigators' affiliations described?	X
	10.2	Was there no apparent conflict of interest?	

MINUS/NEGATIVE (-)

If most (six or more) of the answers to the above validity questions are "No," the report should be designated with a minus (-) symbol on the Evidence Worksheet.

NEUTRAL (∅)

If the answers to validity criteria questions 2, 3, 6, and 7 do not indicate that the study is exceptionally strong, the report should be designated with a neutral (∅) symbol on the Evidence Worksheet.

PLUS/POSITIVE (+)

If most of the answers to the above validity questions are "Yes" (including criteria 2, 3, 6, 7 and at least one additional "Yes"), the report should be designated with a plus symbol (+) on the Evidence Worksheet.

Quality Criteria Checklist: Primary Research (Flaherman et al., 2013)

Symbols Used

+ **Positive:** Indicates that the report has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

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Quality Criteria Checklist: Primary Research

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1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (NA for some Epi studies)	Yes No Unclear N/A X
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes No Unclear N/A X
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?	Yes No Unclear N/A X
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes No Unclear N/A X
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.		
VALIDITY QUESTIONS		
1.	**Was the research question clearly stated?**	Yes No Unclear N/A
1.1	Was the specific intervention(s) or procedure (independent variable(s)) identified?	X
1.2	Was the outcome(s) (dependent variable(s)) clearly indicated?	
1.3	Were the target population and setting specified?	
2.	**Was the selection of study subjects/patients free from bias?**	Yes No Unclear N/A
2.1	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	X
2.2	Were criteria applied equally to all study groups?	
2.3	Were health, demographics, and other characteristics of subjects described?	
2.4	Were the subjects/patients a representative sample of the relevant population?	
3.	**Were study groups comparable?**	Yes No Unclear N/A
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3.2	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	
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3.6	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	
4.	**Was method of handling withdrawals described?**	Yes No Unclear N/A
4.1	Were follow up methods described and the same for all groups?	X
4.2	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	
4.3	Were all enrolled subjects/patients (in the original sample) accounted for?	
4.4	Were reasons for withdrawals similar across groups?	
4.5	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	
5.	**Was blinding used to prevent introduction of bias?**	Yes No Unclear N/A

	5.1	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	X
	5.2	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	
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6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?**		Yes No Unclear N/A X
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7.	**Were outcomes clearly defined and the measurements valid and reliable?**		Yes No Unclear N/A X
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	8.7	If negative findings, was a power calculation reported to address type 2 error?	
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes No Unclear N/A X
	9.1	Is there a discussion of findings?	
	9.2	Are biases and study limitations identified and discussed?	
10.	**Is bias due to study’s funding or sponsorship unlikely?**		Yes No Unclear N/A
	10.1	Were sources of funding and investigators’ affiliations described?	X
	10.2	Was there no apparent conflict of interest?	

MINUS/NEGATIVE (-)

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PLUS/POSITIVE (+)

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3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?	Yes X No Unclear N/A
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes X No Unclear N/A
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2.3	Were health, demographics, and other characteristics of subjects described?	
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3.	**Were study groups comparable?**	Yes X No Unclear N/A
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4.5	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	
5.	**Was blinding used to prevent introduction of bias?**	Yes No Unclear N/A

	5.1	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	X
	5.2	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	
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6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?**		Yes No Unclear N/A X
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7.	**Were outcomes clearly defined and the measurements valid and reliable?**		Yes No Unclear N/A X
	7.1	Were primary and secondary endpoints described and relevant to the question?	
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	7.7	Were the measurements conducted consistently across groups?	
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		Yes No Unclear N/A X
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	8.7	If negative findings, was a power calculation reported to address type 2 error?	
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes No Unclear N/A X
	9.1	Is there a discussion of findings?	
	9.2	Are biases and study limitations identified and discussed?	
10.	**Is bias due to study’s funding or sponsorship unlikely?**		Yes No Unclear N/A
	10.1	Were sources of funding and investigators’ affiliations described?	X
	10.2	Was there no apparent conflict of interest?	

MINUS/NEGATIVE (-)

If most (six or more) of the answers to the above validity questions are “No,” the report should be designated with a minus (-) symbol on the Evidence Worksheet.

NEUTRAL (∅)

If the answers to validity criteria questions 2, 3, 6, and 7 do not indicate that the study is exceptionally strong, the report should be designated with a neutral (∅) symbol on the Evidence Worksheet.

PLUS/POSITIVE (+)

If most of the answers to the above validity questions are “Yes” (including criteria 2, 3, 6, 7 and at least one additional “Yes”), the report should be designated with a plus symbol (+) on the Evidence Worksheet.

Quality Criteria Checklist: Primary Research (Forster et al., 2011)

Symbols Used

+ **Positive:** Indicates that the report has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

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Quality Criteria Checklist: Primary Research

RELEVANCE QUESTIONS			
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (NA for some Epi studies)	**Yes** X	No Unclear N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	**Yes** X	No Unclear N/A
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?	**Yes** X	No Unclear N/A
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	**Yes** X	No Unclear N/A
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.			
VALIDITY QUESTIONS			
1.	**Was the research question clearly stated?**	**Yes**	No Unclear N/A
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1.2	Was the outcome(s) (dependent variable(s)) clearly indicated?		
1.3	Were the target population and setting specified?		
2.	**Was the selection of study subjects/patients free from bias?**	Yes	**No** Unclear N/A
2.1	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?		X
2.2	Were criteria applied equally to all study groups?		
2.3	Were health, demographics, and other characteristics of subjects described?		
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3.	**Were study groups comparable?**	Yes	No **Unclear** N/A
3.1	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)		X
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	5.1	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	X
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	6.6	Were extra or unplanned treatments described?	
	6.7	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	
	6.8	In diagnostic study, were details of test administration and replication sufficient?	
7.	**Were outcomes clearly defined and the measurements valid and reliable?**		**Yes** No Unclear N/A X
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	7.6	Were other factors accounted for (measured) that could affect outcomes?	
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8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		**Yes** No Unclear N/A X
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	8.4	Was “intent to treat” analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	
	8.5	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	
	8.6	Was clinical significance as well as statistical significance reported?	
	8.7	If negative findings, was a power calculation reported to address type 2 error?	
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes **No** Unclear N/A X
	9.1	Is there a discussion of findings?	
	9.2	Are biases and study limitations identified and discussed?	
10.	**Is bias due to study’s funding or sponsorship unlikely?**		**Yes** No Unclear N/A X
	10.1	Were sources of funding and investigators’ affiliations described?	
	10.2	Was there no apparent conflict of interest?	

MINUS/NEGATIVE (-)

If most (six or more) of the answers to the above validity questions are “No,” the report should be designated with a minus (-) symbol on the Evidence Worksheet.

NEUTRAL (∅)

If the answers to validity criteria questions 2, 3, 6, and 7 do not indicate that the study is exceptionally strong, the report should be designated with a neutral (∅) symbol on the Evidence Worksheet.

PLUS/POSITIVE (+)

If most of the answers to the above validity questions are “Yes” (including criteria 2, 3, 6, 7 and at least one additional “Yes”), the report should be designated with a plus symbol (+) on the Evidence Worksheet.

Quality Criteria Checklist: Primary Research (Forster et al. 2017)

Symbols Used

+ **Positive:** Indicates that the report has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

-- **Negative:** Indicates that these issues have not been adequately addressed.

∅ **Neutral:** Indicates that the report is neither exceptionally strong nor exceptionally weak.

Quality Criteria Checklist: Primary Research

RELEVANCE QUESTIONS			
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (NA for some Epi studies)	**Yes** X	No Unclear N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	**Yes** X	No Unclear N/A
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?	**Yes** X	No Unclear N/A
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	**Yes** X	No Unclear N/A
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.			
VALIDITY QUESTIONS			
1.	**Was the research question clearly stated?**	**Yes**	No Unclear N/A
1.1	Was the specific intervention(s) or procedure (independent variable(s)) identified?	X	
1.2	Was the outcome(s) (dependent variable(s)) clearly indicated?		
1.3	Were the target population and setting specified?		
2.	**Was the selection of study subjects/patients free from bias?**	**Yes**	No Unclear N/A
2.1	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	X	
2.2	Were criteria applied equally to all study groups?		
2.3	Were health, demographics, and other characteristics of subjects described?		
2.4	Were the subjects/patients a representative sample of the relevant population?		
3.	**Were study groups comparable?**	**Yes**	No Unclear N/A
3.1	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	X	
3.2	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?		
3.3	Were concurrent controls used? (Concurrent preferred over historical controls.)		
3.4	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?		
3.5	If case control study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)		
3.6	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?		
4.	**Was method of handling withdrawals described?**	**Yes**	No Unclear N/A
4.1	Were follow up methods described and the same for all groups?	X	
4.2	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)		
4.3	Were all enrolled subjects/patients (in the original sample) accounted for?		
4.4	Were reasons for withdrawals similar across groups?		
4.5	If diagnostic test, was decision to perform reference test not dependent on results of test under study?		
5.	**Was blinding used to prevent introduction of bias?**	**Yes**	No Unclear N/A

	5.1	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	X
	5.2	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	
	5.3	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	
	5.4	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	
	5.5	In diagnostic study, were test results blinded to patient history and other test results?	
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?**		**Yes** No Unclear N/A X
	6.1	In RCT or other intervention trial, were protocols described for all regimens studied?	
	6.2	n observational study, were interventions, study settings, and clinicians/provider described?	
	6.3	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	
	6.4	Was the amount of exposure and, if relevant, subject/patient compliance measured?	
	6.5	Were co-interventions (e.g., ancillary treatments, other therapies) described?	
	6.6	Were extra or unplanned treatments described?	
	6.7	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	
	6.8	In diagnostic study, were details of test administration and replication sufficient?	
7.	**Were outcomes clearly defined and the measurements valid and reliable?**		**Yes** No Unclear N/A X
	7.1	Were primary and secondary endpoints described and relevant to the question?	
	7.2	Were nutrition measures appropriate to question and outcomes of concern?	
	7.3	Was the period of follow-up long enough for important outcome(s) to occur?	
	7.4	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	
	7.5	Was the measurement of effect at an appropriate level of precision?	
	7.6	Were other factors accounted for (measured) that could affect outcomes?	
	7.7	Were the measurements conducted consistently across groups?	
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		**Yes** No Unclear N/A X
	8.1	Were statistical analyses adequately described the results reported appropriately?	
	8.2	Were correct statistical tests used and assumptions of test not violated?	
	8.3	Were statistics reported with levels of significance and/or confidence intervals?	
	8.4	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	
	8.5	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	
	8.6	Was clinical significance as well as statistical significance reported?	
	8.7	If negative findings, was a power calculation reported to address type 2 error?	
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		**Yes** No Unclear N/A X
	9.1	Is there a discussion of findings?	
	9.2	Are biases and study limitations identified and discussed?	
10.	**Is bias due to study's funding or sponsorship unlikely?**		**Yes** No Unclear N/A
	10.1	Were sources of funding and investigators' affiliations described?	X
	10.2	Was there no apparent conflict of interest?	

MINUS/NEGATIVE (-)

If most (six or more) of the answers to the above validity questions are "No," the report should be designated with a minus (-) symbol on the Evidence Worksheet.

NEUTRAL (∅)

If the answers to validity criteria questions 2, 3, 6, and 7 do not indicate that the study is exceptionally strong, the report should be designated with a neutral (∅) symbol on the Evidence Worksheet.

PLUS/POSITIVE (+)

If most of the answers to the above validity questions are "Yes" (including criteria 2, 3, 6, 7 and at least one additional "Yes"), the report should be designated with a plus symbol (+) on the Evidence Worksheet.

Quality Criteria Checklist: Primary Research (Lamba et al., 2016)

Symbols Used

+ **Positive:** Indicates that the report has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

-- **Negative:** Indicates that these issues have not been adequately addressed.

∅ **Neutral:** Indicates that the report is neither exceptionally strong nor exceptionally weak.

Quality Criteria Checklist: Primary Research

RELEVANCE QUESTIONS					
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (NA for some Epi studies)	Yes X	No	Unclear	N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes X	No	Unclear	N/A
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?	Yes X	No	Unclear	N/A
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes X	No	Unclear	N/A
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.					
VALIDITY QUESTIONS					
1.	**Was the research question clearly stated?**	Yes	No	Unclear	N/A
1.1	Was the specific intervention(s) or procedure (independent variable(s)) identified?		X		
1.2	Was the outcome(s) (dependent variable(s)) clearly indicated?				
1.3	Were the target population and setting specified?				
2.	**Was the selection of study subjects/patients free from bias?**	Yes	No	Unclear	N/A
2.1	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	X			
2.2	Were criteria applied equally to all study groups?				
2.3	Were health, demographics, and other characteristics of subjects described?				
2.4	Were the subjects/patients a representative sample of the relevant population?				
3.	**Were study groups comparable?**	Yes	No	Unclear	N/A
3.1	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)		X		
3.2	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?				
3.3	Were concurrent controls used? (Concurrent preferred over historical controls.)				
3.4	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?				
3.5	If case control study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)				
3.6	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?				
4.	**Was method of handling withdrawals described?**	Yes	No	Unclear	N/A
4.1	Were follow up methods described and the same for all groups?		X		
4.2	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)				
4.3	Were all enrolled subjects/patients (in the original sample) accounted for?				
4.4	Were reasons for withdrawals similar across groups?				
4.5	If diagnostic test, was decision to perform reference test not dependent on results of test under study?				
5.	**Was blinding used to prevent introduction of bias?**	Yes	No	Unclear	N/A

	5.1	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	X
	5.2	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	
	5.3	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	
	5.4	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	
	5.5	In diagnostic study, were test results blinded to patient history and other test results?	
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?**		Yes X / No / Unclear / N/A
	6.1	In RCT or other intervention trial, were protocols described for all regimens studied?	
	6.2	n observational study, were interventions, study settings, and clinicians/provider described?	
	6.3	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	
	6.4	Was the amount of exposure and, if relevant, subject/patient compliance measured?	
	6.5	Were co-interventions (e.g., ancillary treatments, other therapies) described?	
	6.6	Were extra or unplanned treatments described?	
	6.7	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	
	6.8	In diagnostic study, were details of test administration and replication sufficient?	
7.	**Were outcomes clearly defined and the measurements valid and reliable?**		Yes X / No / Unclear / N/A
	7.1	Were primary and secondary endpoints described and relevant to the question?	
	7.2	Were nutrition measures appropriate to question and outcomes of concern?	
	7.3	Was the period of follow-up long enough for important outcome(s) to occur?	
	7.4	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	
	7.5	Was the measurement of effect at an appropriate level of precision?	
	7.6	Were other factors accounted for (measured) that could affect outcomes?	
	7.7	Were the measurements conducted consistently across groups?	
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		Yes X / No / Unclear / N/A
	8.1	Were statistical analyses adequately described the results reported appropriately?	
	8.2	Were correct statistical tests used and assumptions of test not violated?	
	8.3	Were statistics reported with levels of significance and/or confidence intervals?	
	8.4	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	
	8.5	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	
	8.6	Was clinical significance as well as statistical significance reported?	
	8.7	If negative findings, was a power calculation reported to address type 2 error?	
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes X / No / Unclear / N/A
	9.1	Is there a discussion of findings?	
	9.2	Are biases and study limitations identified and discussed?	
10.	**Is bias due to study's funding or sponsorship unlikely?**		Yes X / No / Unclear / N/A
	10.1	Were sources of funding and investigators' affiliations described?	
	10.2	Was there no apparent conflict of interest?	

MINUS/NEGATIVE (-)

If most (six or more) of the answers to the above validity questions are "No," the report should be designated with a minus (-) symbol on the Evidence Worksheet.

NEUTRAL (∅)

If the answers to validity criteria questions 2, 3, 6, and 7 do not indicate that the study is exceptionally strong, the report should be designated with a neutral (∅) symbol on the Evidence Worksheet.

PLUS/POSITIVE (+)

If most of the answers to the above validity questions are "Yes" (including criteria 2, 3, 6, 7 and at least one additional "Yes"), the report should be designated with a plus symbol (+) on the Evidence Worksheet.

Quality Criteria Checklist: Primary Research (Nguyen et al., 2016

Symbols Used

+ **Positive:** Indicates that the report has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

-- **Negative:** Indicates that these issues have not been adequately addressed.

∅ **Neutral:** Indicates that the report is neither exceptionally strong nor exceptionally weak.

Quality Criteria Checklist: Primary Research

RELEVANCE QUESTIONS			
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (NA for some Epi studies)	Yes X	No Unclear N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes X	No Unclear N/A
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?	Yes X	No Unclear N/A
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes X	No Unclear N/A
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.			
VALIDITY QUESTIONS			
1.	**Was the research question clearly stated?**	Yes	No Unclear N/A
1.1	Was the specific intervention(s) or procedure (independent variable(s)) identified?	X	
1.2	Was the outcome(s) (dependent variable(s)) clearly indicated?		
1.3	Were the target population and setting specified?		
2.	**Was the selection of study subjects/patients free from bias?**	Yes	No Unclear N/A
2.1	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	X	
2.2	Were criteria applied equally to all study groups?		
2.3	Were health, demographics, and other characteristics of subjects described?		
2.4	Were the subjects/patients a representative sample of the relevant population?		
3.	**Were study groups comparable?**	Yes	No Unclear N/A
3.1	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	X	
3.2	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?		
3.3	Were concurrent controls used? (Concurrent preferred over historical controls.)		
3.4	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?		
3.5	If case control study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)		
3.6	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?		
4.	**Was method of handling withdrawals described?**	Yes	No Unclear N/A
4.1	Were follow up methods described and the same for all groups?	X	
4.2	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)		
4.3	Were all enrolled subjects/patients (in the original sample) accounted for?		
4.4	Were reasons for withdrawals similar across groups?		
4.5	If diagnostic test, was decision to perform reference test not dependent on results of test under study?		
5.	**Was blinding used to prevent introduction of bias?**	Yes	No Unclear N/A

	5.1	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	X
	5.2	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	
	5.3	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	
	5.4	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	
	5.5	In diagnostic study, were test results blinded to patient history and other test results?	
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?**		Yes No Unclear N/A X
	6.1	In RCT or other intervention trial, were protocols described for all regimens studied?	
	6.2	n observational study, were interventions, study settings, and clinicians/provider described?	
	6.3	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	
	6.4	Was the amount of exposure and, if relevant, subject/patient compliance measured?	
	6.5	Were co-interventions (e.g., ancillary treatments, other therapies) described?	
	6.6	Were extra or unplanned treatments described?	
	6.7	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	
	6.8	In diagnostic study, were details of test administration and replication sufficient?	
7.	**Were outcomes clearly defined and the measurements valid and reliable?**		Yes No Unclear N/A X
	7.1	Were primary and secondary endpoints described and relevant to the question?	
	7.2	Were nutrition measures appropriate to question and outcomes of concern?	
	7.3	Was the period of follow-up long enough for important outcome(s) to occur?	
	7.4	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	
	7.5	Was the measurement of effect at an appropriate level of precision?	
	7.6	Were other factors accounted for (measured) that could affect outcomes?	
	7.7	Were the measurements conducted consistently across groups?	
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		Yes No Unclear N/A X
	8.1	Were statistical analyses adequately described the results reported appropriately?	
	8.2	Were correct statistical tests used and assumptions of test not violated?	
	8.3	Were statistics reported with levels of significance and/or confidence intervals?	
	8.4	Was “intent to treat” analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	
	8.5	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	
	8.6	Was clinical significance as well as statistical significance reported?	
	8.7	If negative findings, was a power calculation reported to address type 2 error?	
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes No Unclear N/A X
	9.1	Is there a discussion of findings?	
	9.2	Are biases and study limitations identified and discussed?	
10.	**Is bias due to study’s funding or sponsorship unlikely?**		Yes No Unclear N/A
	10.1	Were sources of funding and investigators’ affiliations described?	X
	10.2	Was there no apparent conflict of interest?	

MINUS/NEGATIVE (-)

If most (six or more) of the answers to the above validity questions are “No,” the report should be designated with a minus (-) symbol on the Evidence Worksheet.

NEUTRAL (∅)

If the answers to validity criteria questions 2, 3, 6, and 7 do not indicate that the study is exceptionally strong, the report should be designated with a neutral (∅) symbol on the Evidence Worksheet.

PLUS/POSITIVE (+)

If most of the answers to the above validity questions are “Yes” (including criteria 2, 3, 6, 7 and at least one additional “Yes”), the report should be designated with a plus symbol (+) on the Evidence Worksheet.

Quality Criteria Checklist: Primary Research (Singh et al., 2009)

Symbols Used

+ **Positive:** Indicates that the report has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

-- **Negative:** Indicates that these issues have not been adequately addressed.

∅ **Neutral:** Indicates that the report is neither exceptionally strong nor exceptionally weak.

Quality Criteria Checklist: Primary Research

RELEVANCE QUESTIONS					
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (NA for some Epi studies)	Yes X	No	Unclear	N/A
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes X	No	Unclear	N/A
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?	Yes X	No	Unclear	N/A
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes X	No	Unclear	N/A
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.					
VALIDITY QUESTIONS					
1.	**Was the research question clearly stated?**	Yes	No	Unclear	N/A
1.1	Was the specific intervention(s) or procedure (independent variable(s)) identified?		X		
1.2	Was the outcome(s) (dependent variable(s)) clearly indicated?				
1.3	Were the target population and setting specified?				
2.	**Was the selection of study subjects/patients free from bias?**	Yes	No	Unclear	N/A
2.1	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?		X		
2.2	Were criteria applied equally to all study groups?				
2.3	Were health, demographics, and other characteristics of subjects described?				
2.4	Were the subjects/patients a representative sample of the relevant population?				
3.	**Were study groups comparable?**	Yes	No	Unclear	N/A
3.1	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)		X		
3.2	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?				
3.3	Were concurrent controls used? (Concurrent preferred over historical controls.)				
3.4	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?				
3.5	If case control study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)				
3.6	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?				
4.	**Was method of handling withdrawals described?**	Yes	No	Unclear	N/A
4.1	Were follow up methods described and the same for all groups?		X		
4.2	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)				
4.3	Were all enrolled subjects/patients (in the original sample) accounted for?				
4.4	Were reasons for withdrawals similar across groups?				
4.5	If diagnostic test, was decision to perform reference test not dependent on results of test under study?				
5.	**Was blinding used to prevent introduction of bias?**	Yes	No	Unclear	N/A

	5.1	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	X
	5.2	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	
	5.3	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	
	5.4	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	
	5.5	In diagnostic study, were test results blinded to patient history and other test results?	
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?**		Yes No Unclear N/A X
	6.1	In RCT or other intervention trial, were protocols described for all regimens studied?	
	6.2	n observational study, were interventions, study settings, and clinicians/provider described?	
	6.3	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	
	6.4	Was the amount of exposure and, if relevant, subject/patient compliance measured?	
	6.5	Were co-interventions (e.g., ancillary treatments, other therapies) described?	
	6.6	Were extra or unplanned treatments described?	
	6.7	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	
	6.8	In diagnostic study, were details of test administration and replication sufficient?	
7.	**Were outcomes clearly defined and the measurements valid and reliable?**		Yes No Unclear N/A X
	7.1	Were primary and secondary endpoints described and relevant to the question?	
	7.2	Were nutrition measures appropriate to question and outcomes of concern?	
	7.3	Was the period of follow-up long enough for important outcome(s) to occur?	
	7.4	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	
	7.5	Was the measurement of effect at an appropriate level of precision?	
	7.6	Were other factors accounted for (measured) that could affect outcomes?	
	7.7	Were the measurements conducted consistently across groups?	
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		Yes No Unclear N/A X
	8.1	Were statistical analyses adequately described the results reported appropriately?	
	8.2	Were correct statistical tests used and assumptions of test not violated?	
	8.3	Were statistics reported with levels of significance and/or confidence intervals?	
	8.4	Was “intent to treat” analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	
	8.5	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	
	8.6	Was clinical significance as well as statistical significance reported?	
	8.7	If negative findings, was a power calculation reported to address type 2 error?	
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes No Unclear N/A X
	9.1	Is there a discussion of findings?	
	9.2	Are biases and study limitations identified and discussed?	
10.	**Is bias due to study’s funding or sponsorship unlikely?**		Yes No Unclear N/A
	10.1	Were sources of funding and investigators’ affiliations described?	X
	10.2	Was there no apparent conflict of interest?	

MINUS/NEGATIVE (-)

If most (six or more) of the answers to the above validity questions are “No,” the report should be designated with a minus (-) symbol on the Evidence Worksheet.

NEUTRAL (∅)

If the answers to validity criteria questions 2, 3, 6, and 7 do not indicate that the study is exceptionally strong, the report should be designated with a neutral (∅) symbol on the Evidence Worksheet.

PLUS/POSITIVE (+)

If most of the answers to the above validity questions are “Yes” (including criteria 2, 3, 6, 7 and at least one additional “Yes”), the report should be designated with a plus symbol (+) on the Evidence Worksheet.

Quality Criteria Checklist: Primary Research (Soltani and Scott, 2012)

Symbols Used

+ **Positive:** Indicates that the report has clearly addressed issues of inclusion/exclusion, bias, generalizability, and data collection and analysis.

-- **Negative:** Indicates that these issues have not been adequately addressed.

∅ **Neutral:** Indicates that the report is neither exceptionally strong nor exceptionally weak.

Quality Criteria Checklist: Primary Research

RELEVANCE QUESTIONS		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (NA for some Epi studies)	**Yes** No Unclear N/A X
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	**Yes** No Unclear N/A X
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to dietetics practice?	**Yes** No Unclear N/A X
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	**Yes** No Unclear N/A X
If the answers to all of the above relevance questions are "Yes," the report is eligible for designation with a plus (+) on the Evidence Quality Worksheet, depending on answers to the following validity questions.		
VALIDITY QUESTIONS		
1.	**Was the research question clearly stated?**	**Yes** No Unclear N/A
1.1	Was the specific intervention(s) or procedure (independent variable(s)) identified?	X
1.2	Was the outcome(s) (dependent variable(s)) clearly indicated?	
1.3	Were the target population and setting specified?	
2.	**Was the selection of study subjects/patients free from bias?**	Yes **No** Unclear N/A
2.1	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	X
2.2	Were criteria applied equally to all study groups?	
2.3	Were health, demographics, and other characteristics of subjects described?	
2.4	Were the subjects/patients a representative sample of the relevant population?	
3.	**Were study groups comparable?**	**Yes** No Unclear N/A
3.1	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	X
3.2	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	
3.3	Were concurrent controls used? (Concurrent preferred over historical controls.)	
3.4	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	
3.5	If case control study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	
3.6	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	
4.	**Was method of handling withdrawals described?**	**Yes** No Unclear N/A
4.1	Were follow up methods described and the same for all groups?	X
4.2	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	
4.3	Were all enrolled subjects/patients (in the original sample) accounted for?	
4.4	Were reasons for withdrawals similar across groups?	
4.5	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	
5.	**Was blinding used to prevent introduction of bias?**	Yes **No** Unclear N/A

	5.1	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	X
	5.2	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	
	5.3	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	
	5.4	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	
	5.5	In diagnostic study, were test results blinded to patient history and other test results?	
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were intervening factors described?**		Yes **No** Unclear N/A X
	6.1	In RCT or other intervention trial, were protocols described for all regimens studied?	
	6.2	n observational study, were interventions, study settings, and clinicians/provider described?	
	6.3	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	
	6.4	Was the amount of exposure and, if relevant, subject/patient compliance measured?	
	6.5	Were co-interventions (e.g., ancillary treatments, other therapies) described?	
	6.6	Were extra or unplanned treatments described?	
	6.7	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	
	6.8	In diagnostic study, were details of test administration and replication sufficient?	
7.	**Were outcomes clearly defined and the measurements valid and reliable?**		**Yes** No Unclear N/A X
	7.1	Were primary and secondary endpoints described and relevant to the question?	
	7.2	Were nutrition measures appropriate to question and outcomes of concern?	
	7.3	Was the period of follow-up long enough for important outcome(s) to occur?	
	7.4	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	
	7.5	Was the measurement of effect at an appropriate level of precision?	
	7.6	Were other factors accounted for (measured) that could affect outcomes?	
	7.7	Were the measurements conducted consistently across groups?	
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		**Yes** No Unclear N/A X
	8.1	Were statistical analyses adequately described the results reported appropriately?	
	8.2	Were correct statistical tests used and assumptions of test not violated?	
	8.3	Were statistics reported with levels of significance and/or confidence intervals?	
	8.4	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	
	8.5	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	
	8.6	Was clinical significance as well as statistical significance reported?	
	8.7	If negative findings, was a power calculation reported to address type 2 error?	
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		**Yes** No Unclear N/A X
	9.1	Is there a discussion of findings?	
	9.2	Are biases and study limitations identified and discussed?	
10.	**Is bias due to study's funding or sponsorship unlikely?**		**Yes** No Unclear N/A
	10.1	Were sources of funding and investigators' affiliations described?	X
	10.2	Was there no apparent conflict of interest?	

MINUS/NEGATIVE (-)

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PLUS/POSITIVE (+)

If most of the answers to the above validity questions are "Yes" (including criteria 2, 3, 6, 7 and at least one additional "Yes"), the report should be designated with a plus symbol (+) on the Evidence Worksheet.

Appendix C.

Breastfeeding: Prenatal Hand Expression of Breast Milk

Department / Section: Patient Care Services
Effective Date:
Review Date:
Reviewer:

To guide staff in the safe and appropriate recommendation for prenatal hand expression of breast milk.

A. POLICY

Teach low-risk pregnant women to perform prenatal breast milk expression beginning at 36 weeks gestation, especially those with risk factors for supplementation (unless woman meets criteria listed in **section B**) and encourage those who perform the expression to collect and freeze the expressed breast milk to be used if needed to supplement breastfeedings after birth.

B. EXCLUSION CRITERIA

Prenatal breast milk expression is **not recommended** for women with:

- History of prenatal hemorrhage, placenta previa or other placental abnormality that increases risk for bleeding
- Unknown or classical C-section scar or more than one lower segment C-section scar
- Suspicion of fetal compromise including IUGR, macrosomia, polyhydramnios or any abnormal tests of fetal well-being
- Known fetal anomaly
- Hypertension and proteinuria—if any concerns about fetal well-being
- A serious maternal mental health issue, or other severe maternal obstetric/medical issue

C. PROCEDURE

1. Give pregnant women educational handout “Expressing Milk Before Giving Birth” (available on Health Online) and review the handout with them paying particular attention to: when to start (36 weeks gestation or later), situations that warrant discontinuing hand expressing (“What problems should I watch for?”) and how to safely store the breast milk.
2. Remind pregnant women to watch one or more of the following videos:
    - “Expressing the First Milk” by Global Health Media: https://globalhealthmedia.org/portfolio-items/expressing-the-first-milk/?portfolioID=5623
    - “Early Hand Expression Increases Later Milk Production” by Stanford Breastfeeding: https://med.stanford.edu/newborns/professional-education/breastfeeding/hand-expressing-milk.html

- "The Basics of Breast Massage and Hand Expression" by Maya Bolman: https://vimeo.com/73054360

3. Provide 1 mL and 6 mL syringes and patient labels for patients to take home. Let patients know how to obtain more syringes when needed.
4. Patients may call UWMC Lactation Services (206-598-4628) with questions. If patients would like an appointment to meet with a lactation consultant, providers need to provide a referral.
5. Remind women to bring stored breast milk with them to the hospital when they give birth.

D. BACKGROUND INFORMATION

Why do hand expression prenatally? Mothers' own milk can be collected before delivery and given to the newborn if supplementation is medically necessary, thereby avoiding formula.

Benefits of prenatal breast milk expression

- Teaching prenatal breast milk expression can increase pregnant women's feelings of self-efficacy in that they are becoming more familiar with the anatomy of their breasts as well as developing a skill (1) and can provide confidence that the pregnant women's breasts are capable of providing nourishment for their babies (2).
- Having a supply of breast milk that can be used in case of neonatal feeding problems can be reassuring for the new mothers (2).
- Learning to be skillful at hand expressing breast milk before giving birth is also helpful if hand expression is necessary after the baby is born (3):
    - for increasing milk supply especially if the baby is sleepy and not breastfeeding well
    - for dealing with engorgement so baby can latch on properly
    - for reassurance about the mother's milk supply
    - to provide relief if the mother has a blocked milk duct (4)
- Since hand expression is a skill that needs to be practiced and since the first attempts will often produce little breast milk, the new mother may experience frustration and be worried about being able to produce an adequate milk supply for her baby if taught how to hand express after giving birth (4).

Common reasons why newborns may need supplementation:

- Hypoglycemia in newborn due to:
    - mother having diabetes in pregnancy (5)
    - baby being small or large for gestational age (6)
    - baby being born late preterm (6)
- Delayed lactogenesis II in women with diabetes in pregnancy (7) or in obese mothers (8)
- New mothers may have risk factors for breastfeeding difficulties (9):
    - Large intrapartum blood loss
    - Delay in first holding the infant or first breastfeeding
    - Maternal-infant separation
- Low breast milk production caused by one or more of the following factors (10):

- Maternal Endocrine Disorders
  - Hypothyroidism
  - Polycystic ovarian syndrome
  - Pituitary disorders
- Maternal Physical Conditions
  - Anemia
  - Retained placenta
  - Eating disorder or over-dieting
  - Obesity/high BMI
  - Gastric bypass surgery
  - Infection
  - Advanced maternal age
- Maternal Breast Problems (Primary or Secondary)
  - Abnormal breast appearance, size, or shape; or little or no growth in puberty
  - Little or no growth in pregnancy
  - Breast surgery, biopsy, or other trauma to the breast
  - Radiation to the chest
  - No fullness by the 6th day after birth or prolonged, unrelieved engorgement
- Medicines or Drugs Taken by the Mother
  - Alcohol
  - Nicotine
  - Certain prescription medications
- Infant Conditions (which can lead to low milk production if the mother is not pumping 8 times a day)
  - Cleft of the hard or soft palate
  - Very small chin (micrognathia) or other craniofacial abnormalities
  - Immature or disorganized suck
  - Prematurity (less than 37 weeks gestation)
  - Being "tongue-tied" (ankyloglossia*),* caused by a short frenulum, the tissue that connects the bottom of the tongue to the floor of the mouth

Reasons to avoid formula supplementation

- Formula supplementation in the hospital is associated with a nearly 2-fold greater risk of not fully breastfeeding 30-60 days later and a nearly 3-fold risk of breastfeeding cessation by day 60 even when new mothers intend to exclusively breastfeed (9).
- Formula supplementation may interfere with a woman's milk supply, especially if the mother doesn't express her milk, and breastfed infants who are supplemented using a bottle may have problems latching onto the breast correctly (11).
- Infants who were exclusively fed colostrum had no difference in blood glucose levels when compared to formula-fed infants; colostrum stabilizes infant glucose levels as effectively as formula in the first 6 hours after birth (12).

- The Sugar Babies Study showed that treatment of infants with hypoglycemia with dextrose gel or formula is associated with significantly increased blood glucose levels while neither breastfeeding nor expressed breast milk was associated with a significantly greater change in blood glucose levels. However, breastfeeding is associated with a reduced need for a second treatment with the dextrose gel, and these findings suggest that breastfeeding may have a slower but more sustained effect on blood glucose concentrations compared to infant formula or dextrose gel (13).

Evidence of safety for the pregnant woman and fetus

The DAME randomized controlled trial provides the best high quality research to date on the safety and efficacy of prenatal breast milk expression (14). Eligible women were assigned to either a prenatal breast milk expressing group (hand expressed breast milk 2 times/day for no more than 10 minutes from 36 weeks gestation) or to a standard care group (usual midwifery and obstetric care with support from diabetes educator) (14). The proportion of infants admitted to the NICU did not differ between the 2 groups, and the mean gestational age at birth was not different. In addition, there was moderate evidence of an association between allocation to the prenatal expressing group and the proportion of infants receiving exclusive breast milk during the initial hospital stay. The authors concluded that there is no harm in advising women with diabetes in pregnancy at low risk of complications to hand express breast milk from 36 weeks gestation (14).

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REVIEW/REVISION DATES:

SIGNATURE:

UW Medicine
UNIVERSITY OF WASHINGTON MEDICAL CENTER

Expressing Milk Before Giving Birth

About prenatal breast milk expression

This handout explains why and how to express milk before having your baby. Talk with your provider before you start to hand express your breast milk, to make sure it is a good option for you.

What is prenatal breast milk expression?

In the 12th to 16th week of pregnancy, your breasts will start to produce an early form of breast milk called *colostrum*. Colostrum is a thick, yellowish-white fluid that provides extra nutrients to a newborn. Most women can start to collect this early breast milk at about 36 weeks gestation.

To hand express colostrum, follow the steps on pages 2 and 3 of this handout.

Why should I express milk before giving birth?

Expressing milk before your baby is born:

- Allows you to collect and store breast milk to feed to your newborn instead of formula, if needed for any reason
- May help your breast milk "come in" more quickly after birth

Learning prenatal breast milk expression can:

- Help you get to know your breasts
- Help you feel more ready for breastfeeding
- Increase your confidence that your breasts will provide food for your baby
- Save time and frustration after your baby is born

Learning to hand express breast milk is one way to help you get ready for your baby's birth.

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Why would I hand express after my baby is born?

After birth, you can use hand expression:

- To encourage your baby to latch on. The smell and taste of your breast milk can help your baby open their mouth wide.
- To increase your milk supply. This can be very helpful if your baby is sleepy and not breastfeeding well.
- To deal with full breasts, so your baby can latch on well.

Is it safe to do prenatal breast milk expression?

Healthcare providers used to think that prenatal breast milk expression would increase the risks of preterm labor, abdominal contractions, and vaginal bleeding in the mother. They were also concerned that prenatal expression could decrease fetal movement and increase the risk that the baby would need care in the Neonatal Intensive Care Unit (NICU) after birth.

But, a recent study followed women who hand expressed breast milk starting at 36 weeks gestation. The women in this study did **not** have an increased risk of their babies being born early. And, there was **no increase** in the number of infants admitted to the NICU among these women.

Before you start expressing milk, talk with your provider to make sure you are at low risk for preterm birth and other pregnancy problems.

What problems should I watch for?

Stop doing prenatal breast milk expression and call your doctor if you have any of these symptoms:

- 6 or more contractions in 1 hour
- Stomach cramps, or cramps that feel like your period
- Lower backache
- A feeling of pressure in your stomach or pelvic area
- Increase in vaginal discharge – it may be watery, mucus-like, or bloody
- Your baby is moving less than before
- Signs of low blood sugar, especially if you have diabetes

To learn more, please read our handout, "Recognizing Preterm Labor and Preventing Preterm Birth." You can access the handout online at *https://healthonline.washington.edu/document/health_online/pdf/W1Y-Recognizing-Preterm-Labor.pdf*

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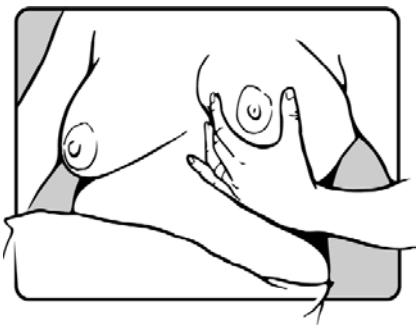
How do I do prenatal breast milk expression?

For best results, practice hand expression after you take a warm bath or shower. Hand express 2 times a day, once in the morning and once in the evening. Each time you express, spend about 5 minutes on each breast, for a total of 10 minutes.

To hand express breast milk, follow these steps:

1. Gather your supplies. You will need:
   - A clean spoon or small container
   - A small syringe
   - A plastic Ziploc bag
   - A label with your name and the date you expressed the milk
2. Wash your hands.
3. Massage one of your breasts toward the nipple for a few minutes.
4. Then, "walk" your fingers down your breast toward the nipple. Stop where you feel a change in the breast tissue. This will be about 1 to 1½ inches before you reach the nipple.
5. Place your thumb above the nipple and your fingers below the nipple in a "U" or "C" shape (see drawing at left).
6. Press back toward your chest wall and then press your thumb and finger toward each other. Do **not** squeeze the nipple itself, since you can make it sore.
7. Repeat the squeezing motion a few times until some drops of milk appear. Collect the milk on the spoon or in the small container. Then suck up the milk into the syringe.
8. When no more drops appear, move your fingers around and try a different part of the breast. Repeat until no more drops appear.
9. Follow steps 3 through 8 with the other breast.
10. Place the syringe containing your breast milk in the refrigerator. Use the same syringe to collect your breast milk later that day.
11. At the end of the day:
    - Label the syringe with your name and the date.
    - Place the syringe in the Ziploc bag. You will use a different syringe every day, but you can place more than one syringe in the same bag.
    - Place the bag with the syringe(s) in the freezer.



Place your thumb above the nipple and your fingers below the nipple.

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What if I cannot express milk?

Hand expression is a skill that needs to be practiced. Your first tries will often produce very little milk. Practice every day for a few days. If there is still no milk, try again next week.

Over time and with practice, it will get easier and faster to hand express. You will also see an increase in the amount of breast milk you express. If you need more syringes and labels, please ask your clinic staff.

How can I learn more?

You may want to watch one or more of these videos:

- "Expressing the First Milk" by Global Health Media: *https://globalhealthmedia.org/portfolio-items/expressing-the-first-milk/?portfolioID=5623*
- "Early Hand Expression Increases Later Milk Production" by Stanford Breastfeeding: *https://med.stanford.edu/newborns/professional-education/breastfeeding/hand-expressing-milk.html*
- "The Basics of Breast Massage and Hand Expression" by Maya Bolman: *https://vimeo.com/73054360*

How do I store breast milk?

This table shows how long you can safely store breast milk.

When breast milk is:	***It is safe for:***
Room temperature Freshly expressed only.	6 hours
Refrigerated at 36 to 40°F (2.2 to 4.4°C)	Up to 6 days
Frozen The freezer must have its own door, and not open when the refrigerator is opened.	6 months
Deep frozen at 0°F (-17.8°C)	12 months
Thawed, but not warmed up Thawing should be done inside the refrigerator, for about 12 hours.	24 hours in the refrigerator (do **not** refreeze)
Warmed for a feeding Place in medium-warm water to heat. Do **not** boil or heat in a microwave.	1 hour

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How do I take my expressed milk to the hospital when I am in labor?

- Place the Ziploc bags containing the frozen syringes in an insulated bag with some frozen gel packs.
- Do **not** use ice cubes to keep the milk frozen. Ice will make the milk thaw faster.
- As soon as you arrive at the hospital, ask a nurse to put the breast milk in a freezer.

When are breastfed infants given formula?

Breastfed infants may be given formula if their mothers have problems breastfeeding. These problems may be related to:

- Large blood loss during delivery
- Delay in first holding the infant or in the first breastfeeding, or not being able to be with their baby for some reason

A breastfed baby may also be given formula if:

- The baby has low blood sugar. This is often due to the mother having diabetes in pregnancy.
- The baby is small or large for their gestational age.
- The baby is born early.
- There is a delay in the mother's milk coming in.
- The mother's breast milk production is low. To learn more about low milk production, please read our handout, "Low Milk Production": *http://healthonline.washington.edu/document/health_online/pdf/Low-Milk-Production.pdf*.

If you have one of the situations listed above, your baby could be given the prenatally expressed breast milk you bring to the hospital. This would be done after you breastfeed, if possible. Having your expressed breast milk may keep us from having to supplement with formula.

What are the risks of giving breastfed newborns some formula in the hospital?

When a newborn receives formula from a bottle in the hospital, it can:

- Lead to less exclusive breastfeeding 1 to 2 months after birth, and to mothers no longer breastfeeding at all when their baby is 2 months old.
- Disrupt a mother's milk supply, especially if the mother doesn't express her milk.
- Lead to problems with getting a good latch onto the breast.

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- Affect a baby's long-term health. If a baby receives formula in the first 7 days of life, the acidity of their gut changes. This means that less of the "good" bacteria can grow in their gut. These helpful bacteria keep germs and infections from entering the baby's body and causing illness.

Tracking When You Hand Express

Use the form below to track when you hand express and how much breast milk you express each time. This form is for your records only. But, writing down when you hand express will also help you remember to do it.

Reminders:

- Try to hand express 2 times a day, once in the morning and once in the evening.
- Spend about 5 minutes on each breast, for no more than 10 minutes total each time.

Breast Milk Hand Expressing Record

Today's Date	Time (a.m.)	How Much Breast Milk	Time (p.m.)	How Much Breast Milk

Questions?

Your questions are important. Call your doctor or healthcare provider if you have questions or concerns.

UWMC Lactation Services: Call 206.598.4628 between 9 a.m. and 5 p.m., 7 days a week.

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Reprints on Health Online: https://healthonline.washington.edu

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Appendix E.

SURVEY
Hand Expression of Breast Milk Before Giving Birth

Please fill out this short survey to give us information about your experience with hand expressing breast milk before giving birth. We would like to know how to better educate and support pregnant women in this process.
If you would prefer to fill out this survey online please go to: https://tinyurl.com/ybmcnffv

1. **Did you receive a Patient Education Handout called "Expressing Milk Before Giving Birth"?**
____ Yes
____ No
____ I Don't Remember

2. **Did you try hand expressing breast milk before giving birth?**
____ Yes (*Skip to question #4)*
____ No (*Please answer question #3*)

---

3. **If your answer to Question #2 is "No", why didn't you try hand expressing breast milk? (Mark all that apply)**
____I was not aware that I could hand express before giving birth
____I was not comfortable trying this
____I did not have time to try this
Other
_____

What would you like your health care providers to know about why you didn't hand express?

THANK YOU FOR COMPLETING THE SURVEY

---

4. **How many weeks pregnant were you when you started hand expressing?** _____

5. **How often did you hand express?**
____ Twice a day
____ 8-12 times a week
____ Once a day
____ 3-5 times a week
____ Other Please fill in frequency _____

6. **Did you measure the expressed breast milk?**
____ Yes
   - What was the highest amount you collected in one session? _____

- About how much did you collect in total (if known)? _____

____ No

7. How many weeks pregnant were you when you gave birth to your baby? _____

8. Did you bring the breast milk to the hospital with you when you delivered your baby?

____ Yes

____ No (*Skip to question #10)*

9. Was the prenatally expressed breast milk fed to your baby at the hospital?

____ Yes

____ No

10. Did your baby receive formula in the hospital?

____ Yes

____ No

11. Did you feel more confident about doing hand expression after giving birth?

____ Yes

____ No

12. If you have a future pregnancy, would you do prenatal hand expression of breast milk?

____ Yes

____ No

Please add any comments regarding your answer

_____

_____

_____

13. How well supported did you feel in hand expressing breast milk?

____Well supported

____Somewhat supported

____Not well supported

Please add any comments regarding your answer

_____

_____

_____

14. Did you seek extra assistance?

____ Yes

Please explain how you received extra help

_____

_____

_____

____ No

15. Would you recommend prenatal hand expression of breast milk to a friend?

____ Yes

____ No

Please add any comments regarding your answer

_____

_____

_____

16. What other information/support would have been helpful for you?

17. What would you like your health care providers to know about your experience with prenatal hand expression of breast milk?

THANK YOU FOR COMPLETING THE SURVEY!

Please return the completed survey to MICC front desk or to one of the UWMC Lactation Consultants. If you have any questions or comments, please email/call Dr. Michelle Averill [206-221-6554 or carrots@uw.edu].