Background: Given early opportunities to breastfeed and breastfeeding assistance and instruction, the majority of mothers and babies will successfully establish breastfeeding. Most babies are able to latch and feed successfully in the first days of life, but some need extra support. Unfortunately, formula supplementation of healthy newborn infants in the hospital is commonplace, despite widespread recommendations to the contrary.\textsuperscript{[1]} The most recent scientific evidence indicates that exclusive breastfeeding (only breastmilk, no food or water except vitamins and medications) for the first 4-6 months of life is associated with the greatest protection against major health problems for both mothers and infants.\textsuperscript{[2, 3]}

Baby-Friendly Hospital Initiative: Hospital policies and routines greatly influence breastfeeding success.\textsuperscript{[1, 2, 4]} The peripartum hospital experience should include adequate support, instruction, and care to ensure the successful initiation of breastfeeding. Such management is part of a continuum of care and education that begins during the prenatal period, promotes breastfeeding as the optimal method of infant feeding, and includes information about maternal and infant benefits.

Guideline Eligibility Criteria: Healthy, term neonate

Guideline Exclusion Criteria: • infant < 37 completed weeks gestation or greater • infant < 2500 gm birth weight • infant with co-morbidities or congenital anomalies (e.g. hypoglycemia, significant jaundice, craniofacial anomalies, etc.) • maternal co-morbidities as specified in OHSU’s Breastfeeding Policy and Tuality Healthcare’s related policies

Definitions: 
Supplementary feedings: Feedings provided to infants in addition to breastfeeding. This may include pasteurized human donor milk and/or breastmilk substitutes/formula. Any foods given prior to 4-6 months of age, the recommended duration of exclusive breastfeeding, are thus defined as supplementary.\textsuperscript{[5]}

Clinical Practice Recommendations

Weight Loss Risk Assessment
Nearly all newborns lose weight in the first days after delivery, and many do not regain their birthweight until 10-14 days of age. The Newborn Early Weight Loss Tool (NEWT) allows pediatric healthcare providers and parents to see how a newborn’s weight during the first days of life compares with a large sample of newborns. The tool uses a nomogram to plot a baby’s weight percentile compared with the research population. This tool should be used across the OHSU Health System for early identification of healthy, term neonates on a trajectory for greater weight loss and related complications, and to guide appropriate management and follow-up.\textsuperscript{[6-10]}

-Strong Recommendation; Moderate Quality Evidence

PRACTICE IMPLICATIONS FOR OHSU HEALTH SYSTEM:
- The NEWT should be used for every healthy, term neonate on each day of hospitalization after birth.
- The NEWT may be accessed at: https://www.newbornweight.org/

Indications for Supplementation
Supplementation NOT necessary in:
- The healthy, term, appropriate for gestational age infant when the infant is feeding well, urinating and stooling adequately, weight loss is in the expected range, and bilirubin levels are not of concern
  • In light of new data, ten percent weight loss is not an automatic marker for the need for supplementation. The hour of life and mode of delivery must be considered.
- The infant who is fussy at night or constantly feeding for several hours.
• Cluster feeding (several short feeds close together) is normal newborn behavior, but should warrant a feeding assessment to observe the infant’s behavior at the breast and the comfort of the mother to ensure that the infant is latched effectively.

- The tired or sleeping mother
  • Fatigue is normal for new mothers. However, rooming out for maternal fatigue does not improve mothers’ sleep time and has been shown to reduce breastfeeding exclusivity. Extreme fatigue should be evaluated for the safety of mother and baby to avoid falls and suffocation.[11]
  • Breastfeeding management that optimizes the infant feeding at the breast may make for a more satisfied infant AND allow the mother to get more rest.[5]

- Consensus Statement

*Medical contraindications to breastfeeding and medical indications for supplementation:*
There are few neonatal and maternal medical contraindications to breastfeeding, which are outlined in OHSU Healthcare, and Tuality Healthcare policies. In addition, there are some situations (e.g., neonatal hypoglycemia, significant jaundice, late preterm delivery) where supplemental feedings may be clinically indicated.

- Consensus Statement

*Weight loss indications for supplementation with continued breastfeeding and careful monitoring:*
Consider feeding assessment and supplementation for weight loss greater than 75th percentile for age and mode of delivery as identified through use of the NEWT.[5, 7-9]

- Strong Recommendation; Moderate Quality Evidence

**PRACTICE IMPLICATIONS FOR OHSU HEALTH SYSTEM:**
- The infant’s medical team should be notified if the neonate or mother meets any criteria for supplementation. A feeding assessment should be conducted prior to ordering supplementation.
- If considering supplementation, first determine neonate’s weight loss percentile using the NEWT Tool.
- If infant’s weight loss is greater than or equal to 75th percentile, then conduct feeding assessment and evaluate neonate’s and mother’s medical conditions to determine if supplementation is necessary. A feeding assessment should include careful consideration of maternal and infant risk factors for delayed lactogenesis, insufficient supply, or poor transfer, physical examination of the mother’s breast and nipples, and physical examination of the infant to assess for clinical signs of dehydration and/or jaundice, and observation and assessment of a feed.
- If a decision is made to supplement, document the medical indication or reason for supplementation as well as the content, volume, and method of each feed.

*When supplementary feedings are medically necessary:*
- The primary goals are to feed the infant and to optimize the maternal milk supply while determining the cause of low milk supply, poor feeding, or inadequate milk transfer. Supplementation should be performed in ways that help preserve breastfeeding. Optimally, mothers need to express milk frequently, usually once for each time the infant receives a supplement, or at least 8 times in 24 hours if the infant is not feeding at the breast. Breasts should be fully drained each time. Maternal breast engorgement should be avoided as it will further compromise milk supply and may lead to other complications.

*When supplementary feedings are not medically indicated:*
- Discussions with the mother should be documented by the nursing and/or medical staff followed by full support of her informed decision.

*Discontinuing Supplementation:*
- Criteria for stopping supplementation should be considered from the time of the decision to supplement and should be discussed with the parents. Stopping supplementation can be a source of anxiety for parents and providers. Underlying factors should be addressed and mothers should be assisted with their milk supply, latch, and comfort with assessing the signs that their infant is adequately fed.
Choice of Supplementation
Neonates should not be given food or drink other than their mother’s breast milk, unless medically indicated. A medical provider’s order is required when supplements are medically indicated, and an informed, documented decision from the parent is required when supplements are not medically indicated. It is the responsibility of the healthcare provider to fully inform parents of the benefits and risks of supplementation, document parental decisions, and support the parents after they have made a decision.
- Consensus Statement

PRACTICE IMPLICATIONS FOR OHSU HEALTH SYSTEM:
OHSU Healthcare
- Supplemental human donor milk and formula must be ordered by a Licensed Independent Provider (LIP) as indicated.

Tuality Healthcare
- Supplemental human donor milk and formula may be ordered by a LIP, or RN as a verbal order as indicated.

Volume of Supplementation
The amount of supplement given should reflect the normal amounts of colostrum available, and the age and size of the infant. Intake on day 2 post-birth is generally higher than day 1 in relation to infant’s demand. Suggested intakes for healthy, term infants are given below:

Average Reported Intakes of Colostrum by Healthy, Term Breastfed Infants[^5]

<table>
<thead>
<tr>
<th>Time (hours)</th>
<th>Intake (mL/feed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>First 24</td>
<td>2–10</td>
</tr>
<tr>
<td>24–48</td>
<td>5–15</td>
</tr>
<tr>
<td>48–72</td>
<td>15–30</td>
</tr>
<tr>
<td>72–96</td>
<td>30–60</td>
</tr>
</tbody>
</table>

- Consensus Statement

Method of Supplementation
Any supplementation (whether medically indicated or following informed decision of the parent) should be given by tube, syringe, spoon, or cup in preference to an artificial nipple or bottle.[^5, 12-17]
- Conditional Recommendation; Low Quality Evidence

PRACTICE IMPLICATIONS FOR OHSU HEALTH SYSTEM:
- When selecting an alternative feeding method, clinicians should consider several criteria:
  a. whether the method enhances development of breastfeeding skills
  b. ease of use and cleaning
  c. stress to the infant
  d. whether adequate milk volume can be fed in 20–30 minutes
  e. whether anticipated use is short- or long-term
  f. maternal preference
  g. expertise of healthcare staff
  h. cost and availability

Consults/Referrals
A feeding assessment should be performed prior to ordering supplementation.
- Consensus Statement
PRACTICE IMPLICATIONS FOR OHSU HEALTH SYSTEM:
- A feeding assessment should be performed in all neonates with ≥ 75th percentile weight loss based on the NEWT tool.
- Consider percentile weight change and other maternal and infant factors when conducting a feeding assessment.
Quality Measures:

Process-
- provider utilization of NEWT
- documented indication for supplementation
- frequency of feeding assessment prior to supplementation order
- quantities of milk ordered during infant’s hospital stay
- age/hour of life of infant’s first supplementation

Outcome-
- percent of term, healthy neonates receiving supplementation prior to discharge
- percent of term, healthy neonates receiving supplemental human donor milk prior to discharge
- percent of term, healthy neonates receiving supplemental formula prior to discharge
- readmissions for jaundice, weight loss, or failure to thrive
- % weight loss at first newborn visit
- incidence of breastfeeding at 2 weeks, 1 month, 2 month, 4 month, 6 month follow-up visits
- # of office visits, total labs, lactation visits in first four weeks post-discharge

Recommended Strategies for Implementation:
- Direct link to Newborn Weight Loss Tool (Newt) in Epic with the ability to autopopulate score
- Updates to documentation templates, flowsheets and orders to support guideline recommendations
- Education for providers and clinicians
References

**Guideline Preparation**
This guideline was prepared by the Office of Clinical Integration (CI) and Evidence-Based Practice (EBP) in collaboration with content experts at Oregon Health and Science University.

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**Development Process**
This guideline was developed using the process outlined in the CI and EBP Manual (2016). The review summary documents the following steps:
1. **Review Preparation**
   - PICO questions established
   - Evidence search confirmed with content experts
2. **Review of Existing Internal and External Guidelines**
   - Literature Review of Relevant Evidence
3. **Critically Analyze the Evidence**
4. **Summarize the Evidence by preparing the guideline, and order sets**

- Materials used in the development of the guidelines, review summaries and content expert team meeting minutes are maintained in a Supplemental Feeding in Neonates EB review manual with the Office of CI and EBP.

**Evaluating the Quality of the Evidence**
Published clinical guidelines were evaluated for this review using the University of Pennsylvania’s Trustworthy Guideline Rating Scale. The summary of these guidelines are included in the evidence summary. The rating scale is based on the Institute of Medicine’s “Standards for Developing Trustworthy Clinical Practice Guidelines” (IOM), as well as a review of the AGREE Enterprise and Guidelines International Network domains. This scale evaluates a guideline’s transparency, conflict of interest, development group, systematic review, supporting evidence, recommendations, external review and currency and updates. The purpose of this scale is to focus on the weaknesses of a guideline that may reduce the trust a clinical user can have in the guideline, and distinguish weaknesses in documentation (e.g. guideline does not have a documented updating process) from weaknesses in the guidance itself (e.g. recommendations are outdated).

The **GRADE (Grading of Recommendations, Assessment, Development and Evaluation)** criteria were utilized to evaluate the body of evidence used to make clinical recommendations. The table below defines how the quality of the evidence is rated and how a strong versus conditional recommendation is established. The evidence summary reflects the critical points of evidence.

<table>
<thead>
<tr>
<th><strong>Recommendation</strong></th>
<th><strong>Type of Evidence</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STRONG</strong></td>
<td>Desirable effects clearly outweigh undesirable effects or vice versa</td>
</tr>
<tr>
<td><strong>CONDITIONAL</strong></td>
<td>Desirable effects closely balanced with undesirable effects</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Quality</strong></th>
<th><strong>Type of Evidence</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High</strong></td>
<td>Consistent evidence from well-performed RCTs or exceptionally strong evidence from unbiased observational studies</td>
</tr>
<tr>
<td><strong>Moderate</strong></td>
<td>Evidence from RCTs with important limitations (e.g., inconsistent results, methodological flaws, indirect evidence, or imprecise results) or unusually strong</td>
</tr>
<tr>
<td>Evidence Level</td>
<td>Description</td>
</tr>
<tr>
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<tr>
<td>Evidence from unbiased observational studies</td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>Evidence for at least 1 critical outcome from observational studies, from RCTs with serious flaws or indirect evidence</td>
</tr>
<tr>
<td>Very Low</td>
<td>Evidence for at least 1 critical outcome from unsystematic clinical observations or very indirect evidence</td>
</tr>
</tbody>
</table>

**Recommendations**

Recommendations for the guidelines were directed by the existing evidence, content experts, patient values and preferences and consensus. When evidence is lacking, options in care are provided in the guideline and the order sets that accompany the guideline.

**Approval Process**

Guidelines are reviewed and approved by the Content Expert Team, Office of CI and EBP, Clinical Knowledge and Therapeutics Executive Committee, Professional Board, and other hospital committees as deemed appropriate for the guideline’s intended use. Guidelines are reviewed and updated as necessary every 2 to 3 years within the Office of CI and EBP at OHSU. Content Expert Teams will be involved with every review and update.

**Disclaimer**

Guideline recommendations are made from the best evidence, clinical expertise and consensus, in addition to thoughtful consideration for the patients and families cared for within the Integrated Delivery System. When evidence was lacking or inconclusive, content experts made recommendations based on consensus. Expert consensus is implied when a reference is not otherwise indicated.

The guideline is not intended to impose standards of care preventing selective variation in practice that is necessary to meet the unique needs of individual patients. The physician must consider each patient and family’s circumstance to make the ultimate judgment regarding best care.