



FED IS BEST FOUNDATION COMMENTS TO USDA DIETARY GUIDELINES COMMITTEE

These comments are being submitted on behalf of The Fed Is Best Foundation (the “Foundation”) in response to the U.S. Department of Health and Human Services (“HHS”)/U.S. Department of Agriculture (“USDA”) 2020 Dietary Guidelines Advisory Committee (the “Committee”) request for comments on the nutritional recommendations for newborns and infants to inform the Committee’s guideline setting for newborns and infants, particularly in the first year following birth.

The Fed is Best Foundation is a national nonprofit organization of over 1200 volunteer nurses, physicians, allied health professionals and patient advocates committed to identifying gaps in current infant feeding protocols, guidelines and education programs, in order to provide families and health professionals the most up-to-date scientific research, education and resources to ensure safe infant feeding with breast milk, formula, or a combination of both. We do this in order to ensure all parents are informed about how to provide safe and sufficient feeding to their infants to prevent, especially in the days following birth, complications associated with inadequate feeding that can cause poor short- and long-term health and neurodevelopmental outcomes. The Fed is Best Foundation is evidence-based in its mission and does not accept funding from the formula or breastfeeding industries.

We submit the following summary of the current peer-reviewed literature to the Committee in order to inform the Committee’s guideline setting for newborns and infants in the Birth to 24 Month group. In particular, we provide the Committee with a summary and make recommendations regarding:

- The rising rates of infant feeding complications in exclusively breastfed newborns resulting in neonatal extended and repeat hospitalizations in the first days after birth
- The brain injury and developmental disabilities that result from insufficient feeding complications
- The data on the limitations and potential harms of the current model of exclusive breastfeeding promotion
- The health care and psychological costs of neonatal jaundice, dehydration and hypoglycemia admissions related to aggressive exclusive breastfeeding promotion as well as the cost of long-term rehabilitation and medical care for injured infants
- The ethical and psychological issues associated with a mandate on mothers to exclusively breastfeed particularly in the first days following birth when exclusive breastfeeding often provides less than the minimum caloric and fluid requirements, which increase the risk of insufficient feeding and its negative health consequences
- The medical definition of a safely and adequately fed infant from birth to one year of age required to achieve optimal health and neurocognitive development

EXECUTIVE SUMMARY

INTRODUCTION

Receiving adequate nutrition in the first days following birth is critically important for child health and brain development. Unfortunately, among the leading causes of newborn extended and repeat



hospitalizations are complications of insufficient feeding in exclusively or near-exclusively breastfed newborns.^{1,2} Among the most common reasons for excessive weight loss and dehydration readmissions are exclusive breastfeeding when colostrum or breast milk is not sufficient and copious milk production (lactogenesis II) is delayed.^{2,3,4,5} Insufficient feeding results in the complications of excessive weight loss, dehydration, hyperbilirubinemia (jaundice), hypernatremia and hypoglycemia.^{6,7,8} These complications not only can lead to preventable hospitalizations and health care costs, but also can lead to brain injury, permanent disability and rare deaths among affected newborns.^{9,10,11}

The current public health objective to increase the proportion of infants who are breastfed exclusively from birth through 6 months has received significant criticism from the general population, nurses, [pediatricians and other physicians](#)¹² in the media,¹³ in [national pediatric conferences](#)¹⁴ and in peer-reviewed publications.^{15,16,17,18,19,20} Criticisms of the objective have mostly stemmed from emerging evidence of harm caused by excessive pressure to exclusively breastfeed even when an infant is showing obvious signs of insufficient feeding, namely persistent crying, prolonged, unsatisfied nursing and other clinical markers of dehydration, jaundice and hypoglycemia, particularly in the first days after birth. Nurses and doctors have reported to us that these complications can stem from the pressure to meet the quality metric goal promoted by the [Joint Commission](#),²¹ the World Health Organization,²² the Centers for Disease Control and Prevention (“CDC”),²³ the American Academy of Pediatrics (“AAP”)²⁴ and Baby-Friendly USA²⁵ of increasing rates of exclusively breastfeeding before discharge, which have encouraged unsafe practices like allowing newborns who show signs of persistent hunger to remain unsupplemented until they develop signs of critical illness.^{26,27} Insufficient and delayed supplementation have led to exclusively breastfed newborns developing lethargy, inability to feed, seizures and even apnea and cardiac arrest from severe hyperbilirubinemia, hypernatremia and hypoglycemia.^{10, 28,29,30} These complications of insufficient feeding are known causes of brain injury and long-term disability that cannot be reversed once the infant shows enough clinical manifestations of those conditions.¹⁰ Furthermore, maternal exhaustion from 24/7 rooming-in, unsupervised breastfeeding and skin-to-skin contact along with prolonged and unsatisfied nursing have resulted in mothers accidentally falling asleep with their newborns resulting in newborn falls, asphyxiation and cardiac arrest also known as Sudden Unexpected Postnatal Collapse.³¹ These complications have gained significant media attention and has resulted in several high-profile legal cases against health professionals and hospitals across the globe from resulting neonatal deaths and brain injury.^{32,33,34,35} The [WHO/UNICEF Baby-Friendly Hospital Initiative \(“BFHI”\)](#), published in 1991, was based on the 1989 WHO Ten Steps to Successful Breastfeeding and has been primarily responsible for the national uptake by hospitals in the U.S. of the BFHI program and associated public health messaging regarding exclusive breastfeeding as ideal for the vast majority infants from birth to 6 months. It is currently being promoted as the gold-standard for breastfeeding management in health facilities across the globe. In the U.S., as noted by Baby-Friendly USA:

“In 2007, less than 3% of United States births occurred in approximately 60 Baby-Friendly designated facilities. In 2018, those numbers rose to more than 25% of births in [more than 500 Baby-Friendly designated facilities](#),²⁵ and they continue to rise. Baby-Friendly hospitals and birthing centers can be found in all 50 states, the District of Columbia, and the Commonwealth of Puerto Rico. Since 1996, when the first hospital in the United States was designated Baby-Friendly, more than 5 million babies have been born in Baby-Friendly designated facilities in the US.”³⁶

What this means is that >25% of U.S. births occur in hospitals and birthing centers that, to maintain their BFHI certification, must agree to adhere to the directive that 80% of eligible newborns must be exclusively breastfed upon discharge. However, little attention has been paid to the serious negative



health consequences of specific policies of the BFHI, like the exclusive breastfeeding quality metric, during its real-life application in health facilities until recently.

Below, we provide the Committee a summary of relevant published data regarding the limitations of the current model of exclusive breastfeeding promotion and our recommendations on safe and healthy infant feeding monitoring and practices from birth to the first year following birth along with a primer on the caloric needs of infants to ensure optimal health and neurodevelopment. We hope to refocus attention on what constitutes safe and adequate feeding with breast milk and/or formula to prevent serious feeding complications and better ensure optimal health and neurodevelopmental outcomes for all infants.

BACKGROUND ON CURRENT RESEARCH

Receiving adequate nutrition in the first days following birth and in the subsequent first 1000 days after birth is critically important for child health and development.³⁷ Feeding complications and poor growth in early life are known risk factors for impaired brain development and metabolic conditions like obesity, type 2 diabetes and cardiovascular disease.^{38,39} The higher propensity of infants whose mothers have lower than average breast milk production to develop insufficient feeding complications early in life may be a plausible mechanism through which infants who are ultimately categorized as “formula-fed” develop poor health and neurocognitive outcomes. Since public health efforts have shifted to prioritize exclusive breastfeeding for all infants from birth to 6 months, particularly before discharge from the birth hospitalization, there has been a rise in hospitalizations for infant feeding complications.^{40,41,2,42} This not only includes readmissions of previously healthy newborns but also extended hospital stays for IV fluids, dextrose and phototherapy that would be unnecessary in an infant with adequate caloric and fluid intake. Parents who express concern that their infant is not receiving sufficient milk are commonly inappropriately reassured without sufficient clinical and laboratory evaluation for feeding complications. As a result, exclusively colostrum-fed newborns who are developing hypoglycemia, hypernatremia and hyperbilirubinemia and showing signs of distress like persistent crying and prolonged nursing are commonly left unsupplemented until they develop signs of critical illness like poor feeding, lethargy, seizures and apnea which necessitate medical intervention. According to the published data:

- There are common misperceptions that insufficient breast milk is rare and that the signs of insufficient feeding are normal and necessary to encourage copious milk production. Insufficient breast milk is common, especially in the first days after birth. In a study of healthy, mothers motivated to exclusively breastfeed with excellent lactation support, 22% experienced delays in copious milk production (lactogenesis II), which increased the risk of excessive weight loss in their newborns by 7-fold.⁴
- 42–44% of first-time mothers have similar delays in copious milk production.^{43,44}
- 15% of healthy, motivated primiparous breastfeeding women delivering term babies fail to maintain lactation even with maximal lactation support.⁴⁵
- The largest and longest quantitative data on breast milk production among healthy mothers showed that insufficient breast milk supply (<440 mL/day) was common, occurring to 2/3rds of mothers between day 11 and 13 and 1/3rd of mothers between day 14 and 28.⁴⁶
- The prevalence of lactation “insufficiency” over the first 6 months following birth may be much higher, as 40–50% of women in the US cite “not producing enough milk” or “baby not satisfied with breast milk” as the primary reasons for weaning prior to 6 months.⁴⁷ There is currently no



quantitative population data on maternal breast milk production from birth to 6 months to determine how many mother-baby dyads can safely exclusively breastfeed without causing insufficient feeding complications and failure to thrive.

- The caloric and fluid yield of exclusive colostrum feeding has been over-estimated. While colostrum is commonly viewed as higher in nutritional content than mature breast milk, meta-analysis data on the caloric and fluid content of breast milk has shown that colostrum in fact has *fewer* calories than mature milk (54 Cal/dL vs. 66-77 Cal/dL) and is present in much smaller quantities.^{48,49} The low caloric and fluid yield of exclusive colostrum feeding along with high rates of delayed onset of lactogenesis II contribute to high rates of dehydration and starvation-related hypoglycemia and hyperbilirubinemia among exclusively breastfed newborns.

As a result of high rates of delayed and failed lactogenesis II and the low caloric and fluid content of colostrum, complications of insufficient feeding are common, particularly among exclusively breastfed newborns.

The most recent studies show:

- In the largest newborn weight loss study to date, 10% of healthy, term vaginally-delivered and 25% of cesarean-delivered newborns develop excessive weight loss of >10% of birth weight within the first 96 hours,⁵⁰ a condition that increase the risk for hyperbilirubinemia and hypernatremic dehydration.^{6,51} In comparison, less than 1% of newborns who are supplemented or exclusively formula-fed from birth lost >10% of birth weight.⁵²
- A follow-up study of this hospital cohort found that newborns who were exclusively breastfed before discharge had almost double the rates of hospital readmission in comparison to infants offered formula from the first feed. Overall, 6.4% of the exclusively breastfed newborns were readmitted compared to 3.6% of the formula fed newborns (4.3% EBF vs. 2.1% FF among vaginally delivered newborns and 2.1% EBF vs. 1.5% FF among cesarean-delivered newborns). The most common reasons for readmission were hyperbilirubinemia and dehydration.²
- 10% of all healthy, term exclusively breastfed (EBF) newborns and 23% of first-born exclusively breastfed newborns develop levels of hypoglycemia (<40 mg/dL)⁵³ that have been documented to increase risk of lower academic achievement⁵⁴ and developmental delay.^{55,56} At this time, healthy, term, appropriate-for-gestation-age (AGA) exclusively breastfed newborns receive no glucose monitoring unless they are symptomatic, at which time, they may already have sustained brain injury that lead to life-long impairments.^{57,10}
- Cognitive impairment from asymptomatic hypoglycemia in the hours after birth can have long-term effects as evidenced by a study of 1395 newborns showing that development of transient asymptomatic hypoglycemia of less than 40 mg/dL was associated with a 50% reduction in passing the fourth-grade proficiency test in literacy and math.⁵⁴ Glucose levels below 45 mg/dL were associated with a 38% reduction in passing rates for literacy. Asymptomatic transitional hypoglycemia has long been considered benign and not in need of correction even for levels as low as 25 mg/dL in the first hours following birth, a standard that has not been updated since the 2011 AAP guidelines.⁵⁸
- A 2019 large population study of 101,060 healthy, term non-hyperinsulinemic newborns followed to 2-6 years of age found that developing neonatal hypoglycemia of < 40 mg/dL in the days after



birth increased the risk of developmental delay by 2.5-fold, almost doubled the risk of motor delay (1.9-fold) and almost tripled the risk of cognitive developmental delay (2.8-fold) compared to newborns with normal glucose levels⁵⁵ The highest risks were recorded among newborns developing hypoglycemia before 6 hours following birth and among AGA newborns, which have been considered to be low-risk conditions that do not result in impaired brain development under the AAP neonatal hypoglycemia guidelines.⁵⁸

- The published literature has shown that 12-35% of well-monitored healthy, term exclusively breastfed newborns develop significant hyperbilirubinemia and 5.7% of newborns born in hospitals with high exclusive breastfeeding rates require phototherapy.^{59,60,61,62,63,64,65,66,67} The majority of hyperbilirubinemia is caused by non-hemolytic hyperbilirubinemia from insufficient feeding.^{68,69} In comparison, a recently published study showed breastfed newborns supplemented to satisfaction until onset of lactogenesis II have a hyperbilirubinemia rate of 1.3% and a phototherapy rate of 0.3%.⁷⁰ The AAP identifies exclusive breastfeeding as a major risk factor for severe hyperbilirubinemia, a condition that can result in moderate to severe neurodevelopmental impairments.¹¹
- A 2014 U.S. study has shown that jaundice, feeding problems, and dehydration combined are the primary cause for 37% of all readmissions within the first 30 days following birth.¹ A review by the [National Perinatal Information Center](#) of the American Hospital Association present by Joint Commission Perinatal Section member Janet Muri revealed that hyperbilirubinemia was the primary diagnosis for 48% of neonatal readmissions in 2009, which increased by 7.6% from 2005, and that 78% of all readmitted newborns required phototherapy.⁷¹
- Moderate hyperbilirubinemia in the range commonly seen among newborns requiring phototherapy (14-20 mg/dL) are associated with Bilirubin-Induced Neurological Disorder, which manifest as developmental delay, cognitive impairment, disordered executive function (i.e. ability to plan to achieve desired goal) and behavioral and psychiatric disorders.⁷²
- Severe hyperbilirubinemia (>20 mg/dL) in a 30-year follow-up study resulted in 45% of affected newborns having persistent neurobehavioral problems including difficulty with literacy and math, problems with attention and impulsivity, inability to complete secondary and tertiary education, lower life satisfaction scores and higher rates of alcoholism.⁷³
- A recently published study showed that among healthy, term newborns universally screened for hypernatremia (>145 mEq/dL), a defining condition of insufficient feeding, an alarming 36% of breastfed newborns (both exclusive and mix-fed) developed hypernatremia.^{51c} Furthermore, the study showed that hypernatremia can occur as early as 4.8% weight loss, the majority occurring above 5%, within the range of what has been considered normal, acceptable weight loss for breastfed newborns.^{51,74} In comparison, among newborns who were exclusively fed with formula, only 6% developed hypernatremia.
- More than half of newborns who develop hypernatremia > 150 mEq/L have abnormal developmental scores by 12 months of age.⁷⁵
- Exclusive breastfeeding at discharge has been associated with a 2- to 11-fold higher risk of rehospitalization for jaundice and dehydration.^{2,3}



- Symptomatic hypoglycemia from insufficient feeding in previously healthy term breastfed newborns can result in extensive brain injury and severe long-term developmental disabilities.^{10,32,76}

In the U.S., approximately 190,000 newborns require phototherapy every year (5.7% of 3.33 million breastfed newborns annually), occurring primarily to those who are exclusively breastfed. Additionally, poorly fed breastfed newborns require readmission for hypernatremia, dehydration, hypoglycemia and failure to thrive.⁷⁷ These preventable phototherapy admissions alone cost the U.S approximately \$2.7 billion dollars annually.^{1*} The care of a child who sustains brain injury from insufficient feeding complications can result in millions of dollars in rehabilitation and health care costs over their lifetime.⁷⁸

These preventable complications among previously healthy, term newborns have recently gained the attention of the Joint Commission, an independent, not-for-profit organization that accredits and certifies nearly 21,000 health care organizations and programs in the U.S. and whose mission is to continuously improve health care for the public. The Joint Commission released a new perinatal care performance measure, [“PC-06 Unexpected Complications in Term Newborns”](#) on January 1, 2019 requiring hospitals to report complications in healthy, term newborns, including hyperbilirubinemia, phototherapy admissions and severe cardiovascular and neurological complications.⁷⁹ The purpose of this new performance measure, as noted by the Joint Commission, is to “gauge adverse outcomes resulting in severe or moderate morbidity in otherwise healthy term infants without preexisting conditions.” We believe strongly that this is an important step in quantifying adverse outcomes and confronting, as a nation, preventable outcomes such as feeding-related complications and their associated outcomes.

NEONATAL CALORIC AND FLUID REQUIREMENTS AND THE EVOLUTION OF INSUFFICIENT FEEDING COMPLICATIONS IN EXCLUSIVELY BREASTFED NEWBORNS

We draw attention to the known caloric and fluid requirements of newborns to illustrate how insufficient feeding complications arise in exclusively breastfed newborns. This discussion will also help illustrate how exclusive breastfeeding before lactogenesis II may fail to safely deliver the calories and fluid necessary to protect an infant’s brain and vital organs in the first days following birth and will help the Committee inform its recommendations as to the caloric and fluid dietary needs of newborns and infants. Additionally, we believe newborns, infants and other vulnerable populations have special protection under the 1966 [International Covenant on Economic, Social and Cultural Rights \(ICESCR\)](#), part of the International Bill of Human Rights, to be protected from caloric and fluid deprivation that result in undue suffering from hunger and thirst as well as short- and long-term negative health consequences.⁸⁰

The estimated energy requirements of a healthy, term newborn, at the time of birth is approximately 100-120 Cal/kg/day.^{81,82} Currently, there is no data suggesting that the minimum energy requirements of healthy, term, breastfed and formula-fed newborns are significantly different. The exceptions to this are infants born with depleted reserve and/or are persistently crying and nursing, which is likely to increase the caloric requirement. This is the number of calories required to prevent persistent hunger, catabolism, weight loss, hypoglycemia and ultimately brain and vital organ injury. Colostrum has been previously believed to be higher in caloric content than mature milk. A [2013 meta-analysis](#) has shown that colostrum, in fact, has fewer calories than mature milk containing 54 Cal/dL vs. 66-77 Cal/dL (Figure 1).⁴⁸ The published average colostrum production of healthy exclusively breastfeeding mothers delivering term babies and the calculated caloric yield are shown below (Table 1).

* 83.2% breastfeeding initiation rate x 4,000,000 annual births = 3,328,000 breastfed newborns
3,328,000 breastfed newborns per year x 5.7% phototherapy rate = 189,696 phototherapy admissions per year
189,697 x \$14,247 average cost of admission⁵⁴ = \$2,702,598,912 per year



Meta-analysis results of preterm and term breast milk energy content over time from measured and calculated estimates

Comparison: Bomb calorimetry energy measurement (kcal/dL)♦								
Time frame:	Preterm			Term			Preterm & term compared	
	mean	SD	n	Mean	SD	n	% difference	p-value
d 1-3	49	7	12	54	8	19	-10	0.34
d 4-7	71	9	52	66	9	37	7	0.02
week 2	71	12	53	66	9	34	7	0.04
week 3-4	77	8	27	66	8	97	16	< 0.00001*

Figure 1. From Gidrewicz DA, Fenton TR. A systematic review and meta-analysis of the nutrient content of preterm and term breast milk. *BMC Pediatr.* 2014;14:216.⁸⁴

Table 1: Caloric Yield of Exclusive Colostrum Feeding for an Average 3 kg Newborn

Day of life (DOL)	Average daily colostrum production ^a	Calories provided by colostrum/mature milk ^b	Daily caloric requirement ^c	Percent of caloric requirement
Day 1	56 mL/day	30 Cal	300 Cal	10%
Day 2	185 mL/day	100 Cal	300 Cal	33%
Day 3	383 mL/day	207 Cal	300 Cal	69%
Day 4	580 mL/day	382 Cal ^d	300 Cal	128%

^aAverage colostrum production of healthy mothers the first four days of life.⁴⁹

^bCaloric content of colostrum from mothers delivering at term is an average 54 Cal/dL.⁸⁴

^cThe daily caloric requirement of newborns at birth is 100 Cal/kg/day⁴

^dUsing the caloric density of mature milk of 66 Cal/dL⁸⁴

Given this caloric density, exclusive colostrum feeding from the average mother provides a fraction of the full caloric requirement from days 1-3 of life, approximately 10-69% of the total requirement before the onset of lactogenesis II. The catabolic conditions caused by the low caloric yield of exclusive colostrum feeding commonly result in newborn hunger, catabolism and weight loss. Clinically, this results in



persistent crying and hours of nursing in an attempt to alleviate hunger and thirst, also widely known among mother-baby health professionals as “Second Night Syndrome.” Starvation-related hypoglycemia occurs among newborns, including healthy, term newborns, who have insufficient reserve and who receive the least amount of breast milk from exclusive colostrum feeding. A 2015 case series showed that infants who develop symptomatic hypoglycemia from poor breastfeeding results in extensive injury to several lobes of the brain resulting in severe long-term disability (see Table 2 and Figure 2).¹⁰

Table 2: MRI Finding of Neonates with Symptomatic Hypoglycemia from Poor Breastfeeding¹⁰

No.	Mode of Delivery	% Weight Loss	Day of Life (DOL)	Presenting Symptoms	Glucose (mg/dL)	Seizure	MRI Results
1	Vaginal	10.5	4	Lethargy, poor feeding, seizure in trauma bay of emergency department	20	Yes	Extensive areas of restricted diffusion [injury] involving the bilateral parietal and occipital lobes
2	Vaginal	7.3	4	Lethargy, poor feeding, seizures	20	Yes	Extensive severe injury to the posterior one-third of the supratentorial brain
3	Vaginal	4.2	3	Poor feeding, shallow breathing, tremors	13	Yes	Restricted diffusion in parietal and bilateral occipital lobes
4	Vaginal	16	3	Lethargy, hypotonia, apnea	<20	Yes	Diffuse brain injury involving frontal, parietal, and occipital lobes
5	Vaginal	0	3	Cyanotic episode at home, lethargy, poor feeding	<20	Yes	Restricted diffusion involving both posterior parietal, temporal, and occipital lobes
6	Cesarean	7.1	2	Apnea, hypotonia	8	No	Normal

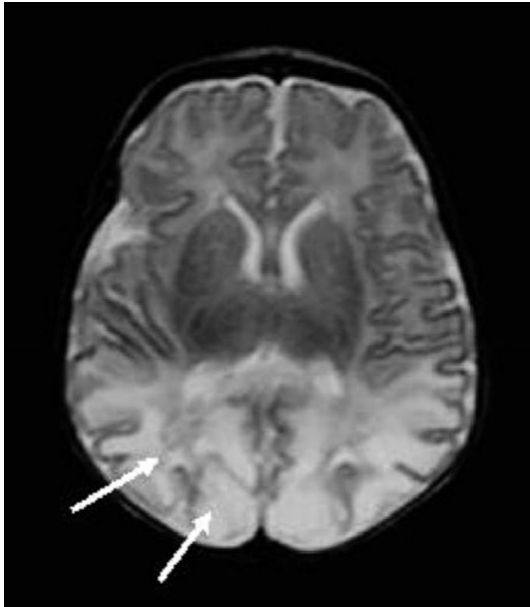


Figure 2. Neonatal hypoglycemic brain injury similar to the findings described in healthy, term newborns with symptomatic hypoglycemia from poor breastfeeding. The light appearance in the bottom half of the brain (posterior brain) are the injured areas. Image obtained from a study of previously healthy, term newborns with isolated symptomatic hypoglycemia.⁵⁷

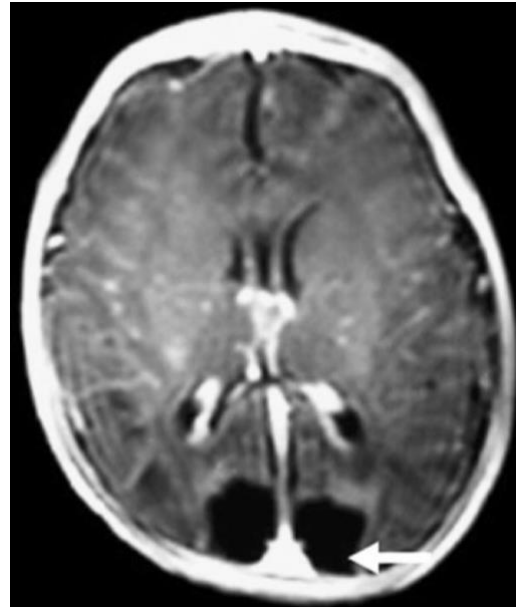


Figure 3. MRI brain of a poorly exclusively breastfed newborn one month after developing symptomatic hypoglycemia of 20 mg/dL at 9% weight loss 60 hours after birth. Dark areas show reabsorbed areas of brain after injury in bilateral occipital and parieto-occipital regions.⁷⁶

In addition to the low caloric yield of exclusive colostrum feeding, the colostrum of many mothers may not provide sufficient fluid to meet the fluid requirement of her newborn. The average mother produces a total of about 60 mL the first 24 hours, then 190 mL on the 2nd day, and then 380 mL on the 3rd day.⁴⁹ The minimum fluid requirements of newborns are less well-defined given variations in extracellular fluid volumes present at the time of delivery. The current commonly accepted neonatal fluid requirements are 60 mL/kg/day on day 1, 100 mL/kg/day on day 2 and 140-160 mL/kg/day thereafter.⁸³ Given these requirements, the average mother provides 33-90% of a 3 kg newborn's fluid requirement through day 3, which can result in persistent thirst and subsequent dehydration. This results in the low wet and dirty diaper outputs currently observed in exclusively colostrum-fed newborns, also known as anti-diuresis, a response to low fluid intake. While some newborns are born with enough extracellular fluid to compensate for such fluid restrictions, newborns who receive the least amount of colostrum, have the lowest fluid reserve and whose mothers develop delayed lactogenesis II can develop accelerated dehydration and hypernatremia.

Newborns who develop hypernatremia, severe hyperbilirubinemia and hypoglycemia during their birth hospitalization and shortly thereafter are commonly described to exhibit vigorous, high-pitched crying and near-continuous breastfeeding, which is commonly mistaken by health providers as normal newborn feeding behavior, widely called "cluster-feeding" or "Second Night Syndrome." Infants who continue to receive insufficient milk despite showing signs of persistent hunger will commonly stop crying and develop "blank staring" from encephalopathy (or decreased and abnormal brain function) due to metabolic abnormalities, which can be easily mistaken as signs of satisfaction from the current feeding regimen. Encephalopathy can result in excessive sleepiness, disinterest in feeding or short feeding durations. If these signs of insufficient feeding are missed, in the final stages of starvation and dehydration, newborns develop lethargy, seizures, apnea and hypotensive arrest. Among healthy term



newborns who develop isolated symptomatic hypoglycemia below 46 mg/dL, the data show there is a 94% chance of having brain injury visible on MRI.⁵⁹ In addition, co-morbid hypernatremia can result in venous and arterial thrombosis (blood clots), kidney failure, other vital organ injury and increased mortality.⁸⁴

There is currently poor understanding among health professionals and parents regarding what constitutes safe and sufficient feeding in exclusively breastfed newborns since the earliest signs of dehydration and hypoglycemia like persistent crying and nursing have been normalized by the breastfeeding guidelines. Misperception of what constitutes normal newborn feeding behavior primarily originates from breastfeeding education provided to health professionals and parents by the BFHI, whose primary quality metric is exclusive breastfeeding before discharge. The Academy of Breastfeeding Medicine (“ABM”) supplementation guideline for the BFHI has stated that supplementation is “not indicated” for a newborn “who is fussy at night or constantly feeding for several hours”.⁸⁵ The 2017 revision made provisions for examining breastfeeding behavior if this occurs but provided little guidance on checking for hypoglycemia or hypernatremia, which may in fact be the cause of such behavior.⁸⁶ As a result, health professionals and parents have reported to the Foundation alarming rates of serious complications occurring to previously healthy exclusively breastfed newborns caused by poor recognition of insufficient feeding and delayed or insufficient supplementation during the birth hospitalization and shortly after discharge. In all the stories of breastfeeding complications that the Foundation has received and reviewed, the root cause of every case was poor recognition of the signs of insufficient feeding by parents and health professionals.

Furthermore, the criteria by which health professionals assess safe and sufficient feeding of breastfed newborns are dangerously outdated and non-evidence based. The most common criteria used by health professionals to determine sufficient feeding of newborns is percent weight loss, the majority believing that up to 10% weight loss is normal and safe. They are not aware of the lack of evidence that supports this belief. The “10% weight loss rule” comes from a 1984 study of 7 healthy, term exclusively breastfed newborns, 2 of whom lost 10%.⁸⁷ The study provided no data on glucose, bilirubin or sodium levels and provided no neurological outcomes on the studied infants. This scant evidence established the 10% weight loss rule still followed today. While larger studies on the weight loss patterns of exclusively breastfed newborns have been done since,⁵¹ the cohorts studied have not been monitored for occult hypoglycemia, hypernatremia and the related developmental sequelae. In fact, a follow-up study of the Newborn Weight Loss Tool (NEWT) cohort showed the 6.4% of the exclusively breastfed newborns were readmitted compared to 3.6% of the formula fed newborns, the most common reasons for admission being jaundice and dehydration.² Only one study using standard developmental testing has been performed on the effect of >12% weight loss on neurodevelopment to 5 years of age.⁸⁸ This study found that while the mean developmental scores were not significantly different between the “dehydrated” and non-dehydrated newborns, the data showed that newborns that lost >12% have lower fine motor development, had higher rates of parental reports of language delay, “allergies” and “disability.” Several decades of evidence have now shown that healthy, term newborns can develop brain-threatening levels of hyperbilirubinemia, hypoglycemia and hypernatremia before 10% weight loss is reached, which is why the 2013 AAP Breastfeeding guidelines recommend weight loss no greater than 7% among breastfed newborns, a recommendation that has not been widely disseminated.²⁴ We urgently need updated neonatal hypoglycemia and breastfeeding guidelines and dietary intake recommendations that reflect current data in order to protect all infants, particularly healthy, term exclusively breastfed newborns, from feeding complications that result in impaired brain development.

Parents who subscribe to the BFHI protocol are commonly not given accurate information on the risks, the signs and consequences of insufficient feeding from early exclusive breastfeeding. Information they are given regarding infant feeding are often outdated or contrary to what scientific evidence shows. The



following are a few examples of non-evidence-based teaching that parents and health professionals are commonly taught:

- “The newborn stomach size is 5-7 mL.” The published data shows it is actually 20-30 mL.⁸⁹
- “Colostrum has more calories than mature breast milk or formula.” It has fewer calories.⁴⁸
- “Diaper counts can determine if a newborn is getting sufficient breast milk.” The data shows even newborns with excessive weight loss can produce 6-8 wet and dirty diapers on day 4.⁹⁰
- “Hours of crying and nursing are normal infant feeding behavior called ‘clusterfeeding’ and not a sign of infant hunger.” Persistent crying and nursing are signs of persistent hunger and thirst and are the earliest signs of dehydration and hypoglycemia.^{74, 58}

In the U.S. today, parents are not offered information on the benefits of supplementation to prevent feeding complications, hospitalization, and impaired brain development when breastfeeding is insufficient. They are also not informed of the benefits of supplementation to facilitate sustained breastfeeding, particularly among mothers with a partial milk supply. When requesting supplemental milk for their newborns who are showing clear signs of distress, they are commonly shamed and forced to sign informed consent forms warning that even a few bottles of formula can result in multiple lifelong illnesses that have never been linked to limited, supplemental formula feeding. They are commonly discharged before breast milk supply meets the minimum safe caloric and fluid requirements of their infant and are told to avoid formula supplementation with little to no information on when supplementation is medically necessary to prevent irreversible harm. Infants who do not receive enough milk from exclusive breastfeeding will return to the hospital critically ill from hypernatremia, dehydration, hypoglycemia and/or hyperbilirubinemia, at which time brain injury may have already occurred. Unfortunately, these breastfeeding complications have become routine admissions for pediatricians and neonatologists in the U.S., especially where Baby-Friendly practices have been implemented by certifying hospitals and birthing centers and are aggressively promoted.²

This is problematic from a medical as well as a legal perspective. Denying supplemental milk to a breastfed infant who is showing obvious signs of persistent hunger and losing weight from exclusive colostrum feeding, particularly if brain injury occurs, constitutes a serious violation of their human right to food and water. Additionally, miseducation of parents on the signs and consequences of insufficient feeding constitutes a serious violation of the patient right to accurate health information regarding preventable life- and brain-threatening complications. There is currently a dangerous lack of awareness of the signs and consequences of newborn starvation among health professionals and the general public and it is resulting in an epidemic of hospitalizations in breastfed newborns.

RATES OF INSUFFICIENT FEEDING COMPLICATIONS IN BREASTFED NEWBORNS

Baby-Friendly USA is the only private organization allowed to operate in U.S. hospitals and influence through its certification mandates and educational programs the medical judgement of nurses and physicians who are ultimately responsible for patient safety. Health professionals in the U.S. have reported being reprimanded and/or disciplined for discussing or offering formula supplementation even in cases where infants were showing persistent hunger and distress despite prolonged, well-latched breastfeeding in order to prevent complications. The Foundation has received thousands of reports from health professionals and parents regarding serious complications resulting from rigid adherence to BFHI guidelines. The current BFHI guidelines have no safety data and has resulted in tens of thousands of preventable insufficient feeding complications and newborn readmissions in the U.S. every year both at certifying facilities and more broadly in the U.S. across hospitals and birthing centers as the policies advanced by the BFHI have taken hold in societal discourse about a singular “breast is best” feeding approach following birth.



Table 1. Rates of Feeding Complications in Exclusively Breastfed Newborns

	Exclusively Breastfed Newborns	Ad-Lib Supplemented Breastfed/ Formula-Fed Newborns
Hyperbilirubinemia Rates	12-35% ⁴¹⁻⁴⁹	1.3% ⁵²
Phototherapy Rates	5.7% ⁴⁹	0.3% ⁵²
Excessive Weight Loss > 10%	10% (VD), 25% (CD) ³³	0.1% ⁵²
< 30 Day Readmissions	6.4% overall 4.3% (VD) 2.1% (CD) ¹⁹	3.6% overall 2.1% (VD) 1.5% (CD) ¹⁹
Hypernatremia (>145 mEq/L) (with universal screening)	36% ⁵⁶	6% ⁵⁶
Severe Hypernatremia (>160 mEq/L) (without universal screening)	98.3% of cases ⁹¹	1.6% of cases ⁶⁴
Hypoglycemia (<40 mg/dL)	10% ³⁶	N/A

VD – Vaginally-Delivered; CD – Cesarean-Delivered; N/A – Not Available, unrestricted feeding protects against hypoglycemia

Currently there is insufficient monitoring of healthy, term breastfed newborns for serious metabolic complications of inadequate feeding. The ABM and the AAP have made the assertion that healthy, term, appropriate-for-gestational-age (AGA) exclusively breastfed newborns are not at risk for hypoglycemia and its related brain injury despite the low calculated caloric yield of exclusive colostrum feeding. Their guidelines have not been updated to reflect published data showing that 10% of healthy, term exclusively breastfed newborns develop hypoglycemia,⁵³ are in fact at 2-fold higher risk for hypoglycemia readmission⁹², and that symptomatic hypoglycemia from poor breastfeeding results in extensive brain injury and long-term disability.¹⁰

There is also no safety data showing that the current criteria for medical indications for supplementation or the recommended supplemental volumes protect infants from negative health and neurological consequences using measurements of long-term health and neurological outcomes. Currently, persistent crying and hours of breastfeeding are regarded as normal when they are the earliest signs of hypoglycemia, dehydration and hypernatremia. There is poor understanding of when prolonged crying and nursing become abnormal signs of hypernatremia, hypoglycemia and acute bilirubin encephalopathy. Unfortunately, many newborns go on to require hospitalizations when signs of insufficient feeding are not met with timely and adequate supplementation. Health professionals have reported to the Foundation that even when medical indications for supplementation are reached, parents have become so indoctrinated to regard formula as dangerous that they commonly refuse it, which can increase their infant’s need for medical intervention and potentially increase their risk of brain injury. Research is needed on the safe minimum volumes of colostrum/breast milk per kg required to prevent hypoglycemia and hypernatremic



dehydration in *all* newborns. For now, the best estimate for the minimum caloric and fluid requirements of newborns to prevent these complications are 100-120 Calories/kg/day and 100-140 mL of fluid/kg/day, which is met by approximately 6 oz of breast milk and/or formula per kilogram per day. Unfortunately, few health professionals are aware of these important minimum requirements.

Rates of insufficient feeding among exclusively breastfed newborns have been underestimated as percent weight loss of >10% has been considered the primary defining criterion. Hypernatremic dehydration is a defining condition of insufficient feeding in breastfed newborns. It has been previously regarded as a rare complication of exclusive breastfeeding. However, data has emerged that it is in fact far more common than previously recognized and occurs at weight loss percentages that are currently regarded as safe and normal. Among healthy term newborns who were universally screened for hypernatremia (≥ 145 mEq/L), 36% of exclusively and “mix-fed” breastfed newborns developed hypernatremia before hospital discharge at 48-72 hours of life.⁵² Hypernatremia occurred as early as 4.8% weight loss, the majority occurring above 5%. This is particularly alarming as more than half of all healthy, term exclusively breastfed newborns lose greater than 7%. The finding that hypernatremia occurs at percent weight loss of greater than 5% have been described in multiple studies (see Figure 4).^{74,93} Developmental follow-up data has shown more than half of newborns who develop hypernatremia ≥ 150 mEq/L have abnormal developmental tests by 12 months of age.⁹⁴ Other follow-up data confirm that hypernatremic newborns develop long-term developmental disability.^{95,96} The true magnitude of the population effects of these common insufficient feeding-related complications in newborns have yet to be measured but the implications of the emerging data are alarming.

Figure 2. Relationship between Percentage Weight Loss and Sodium Concentration in 304 Late Preterm or Term Newborn Infants Affected with Breastfeeding-Associated Hypernatremia.

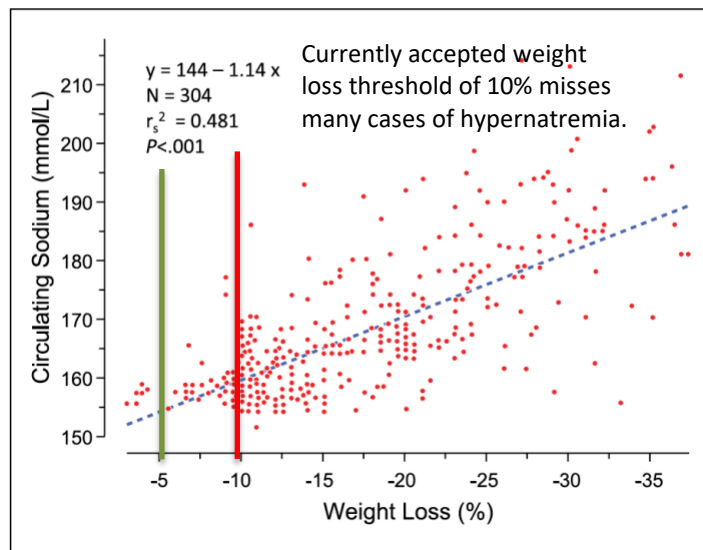


Figure 4. Relationship between percent weight loss and sodium concentration⁷⁸ The currently accepted weight loss threshold of 10% misses many cases of hypernatremia. The majority occur above 5% weight loss and a few occur before.

The goal of “exclusive” breastfeeding is the cornerstone of early breastfeeding management and is the most prominent quality metric of the BFHI.⁹⁷ This focus on avoidance of supplementation particularly in first days following birth results in tens of thousands of admissions for insufficient feeding complications



every year in the U.S. alone costing billions of dollars in preventable health care costs and long-term rehabilitation and medical care of injured infants. The exclusive breastfeeding hospital metric continues to dominate early breastfeeding management despite lack of evidence from now five randomized, controlled trials that judicious supplementation interferes with long-term breastfeeding rates^{98,99,100,101,102} and limited data in developed countries showing any difference between exclusive vs. non-exclusive breastfeeding on health outcomes. While exclusive breastfeeding status months after the newborn period may be associated with health advantages, the data show that exclusively breastfed newborns in the first days of life are at greater risk for hyperbilirubinemia, dehydration, hypernatremia and excessive weight loss and the related admissions when compared to ad-lib supplemented and exclusively-formula-fed newborns. The higher rates of feeding complications among newborns born to mothers prone to lactation failure provide a plausible mechanism through which infants who are ultimately categorized as “formula-fed” experience poorer health and neurological outcomes. The expected impact of insufficient complications to the population make prevention of these complications and reexamination of the exclusive breastfeeding hospital metric before discharge as an effective or even safe measure of quality of care.

RECOMMENDATIONS FOR THE COMMITTEE

1. Gather a multidisciplinary panel of experts in pediatric neurology, nephrology, gastroenterology, endocrinology, nutrition, breastfeeding, breastfeeding complications, neonatology and ethics in order to review current data and develop balanced, evidence-based safe newborn and infant feeding guidelines following birth centered on the minimum caloric and fluid needs for optimal health and brain development.
2. Include in the Committee’s guidelines that *safe* and *sufficient* feeding with breast milk, properly-prepared formula or both to prevent feeding complications and achieve optimal growth are medically important for protecting long-term health and neurocognitive development for all newborns and infants.
3. Address in the Committee’s guidelines the common occurrence of insufficient breast milk, both transient insufficiency in the first days after birth and thereafter. Addressing the importance of supplementation to protect infant health and brain development in cases where exclusive breastfeeding cannot safely meet an infant’s nutritional needs and that such supplementation can prevent thousands of hospitalizations for breastfeeding complications in the U.S. per year.
4. Define and educate health professionals and the public the minimum daily milk requirement from birth through 1 year of age using the most current scientific evidence on infant caloric and fluid needs. The current definition is 100-120 Cal/kg/day or 6 oz/kg/day of breast milk or formula resulting in 5-7 oz weight gain per week and optimal growth on a standardized growth chart. Infants who receive less than the minimum, particularly during the immediate postnatal period require closer clinical and laboratory monitoring for hypoglycemia, hyperbilirubinemia and hypernatremia.
5. Define the optimal growth trajectory for U.S. infants. The data has shown that the CDC growth chart outperforms the WHO growth chart in terms of protecting overall health and neurodevelopment.¹⁰³
6. Define the safe limits of postnatal weight loss, serum sodium, glucose and bilirubin levels in newborns and infants based on current neurodevelopmental outcomes data related to hypernatremia, hypoglycemia and hyperbilirubinemia as well as the clinical signs of a safely and sufficiently fed infant in terms understood by both health professionals and parents.
7. Educate health professionals and parents on the clinical signs and potential consequences of insufficient feeding complications.
8. Educate health professionals on the signs, clinical and laboratory markers and long-term consequences of insufficient feeding.



9. Support increased availability of screened, tested human milk bank milk for infants requiring supplementation for families who wish to avoid formula.
10. Reaffirm the patient right to full and unbiased information regarding risks and benefits of all infant feeding choices free from commercial-bias introduced by formula- *and* breastfeeding-related industries and interests.
11. Reaffirm the obligation of health professionals to respect patient autonomy by supporting a patient's informed decision to feed their infants through exclusive breastfeeding, temporary supplemented breastfeeding, combination feeding or exclusive formula feeding so long as it safely provides the full nutritional requirements of their newborns and infants.
12. Establish the goal of achieving low rates of insufficient-feeding-related jaundice, dehydration, hypernatremia, hypoglycemia, related neurological injury and deaths as the dominant quality metric followed by U.S. hospitals.

We need comprehensive reform and updating of the infant feeding guidelines in order truly deliver safe and optimal feeding to all U.S. infants and to reduce the associated public health risk of medical complications associated with the underfeeding of infants. Gathering a multi-disciplinary panel of experts that represent multiple perspectives on infant feeding that are free of financial conflicts of interest is vital to developing safe infant feeding guidelines. We need comprehensive review of the safe limits of infant feeding, including: the safe weight loss, hypoglycemia, hyperbilirubinemia and hypernatremia thresholds based on long-term neurocognitive data. Establishing daily caloric requirements for infants through 1 year after birth and ensuring education on the caloric and fluid requirements for *every* newborn in order to protect their brain development and vital organs may be one of the most efficient, cost-effective public health endeavors we can invest in today. Unfortunately, for an unacceptable number of infants, this minimum nutritional requirement is not part of the current lexicon for new parents and it is resulting in an epidemic of preventable injuries and newborn admissions for infant feeding complications every year.

Publicly addressing minimum caloric and dietary needs of infants and the reality of naturally occurring variations in breast milk production and breastfeeding efficacy, while educating on the importance of supplementation when breastfeeding is insufficient, can prevent hundreds of thousands of infant feeding complications and hospitalizations per year in the U.S. alone. The U.S. spends an estimated \$2.7 billion dollars annually in newborn hyperbilirubinemia admission alone (190,000 admissions per year), the vast majority caused by insufficient feeding in exclusively breastfed newborns. The rehabilitation and medical care of previously healthy infants who are disabled by breastfeeding complications can cost millions more per child.

The Committee should provide health professionals and families guidelines on the minimum macro- and micronutrient requirements to protect infant health and brain development. This includes informing the public regarding the minimum requirement of 100-120 Cal/kg/day from birth through the first year of life, which is provided by 2.7 oz/lb/day or 6 oz/kg/day of mature breast milk or formula resulting in 5-7 oz of weight gain per week or optimal growth documented on a standardized growth chart. At this time, published data suggests that the CDC growth chart outperforms the WHO growth chart in terms of improved overall infant health and neurodevelopment.¹¹⁰ This is important to examine as many parents have been encouraged to follow the WHO growth chart to reduce diagnosis of failure to thrive and to promote continued exclusive breastfeeding. This recommendation may, in the end, result in poorer health and neurodevelopmental outcomes in infants in the U.S. if failure to thrive is underdiagnosed and undertreated. The Committee, through its guideline setting, has an opportunity to address and minimize the incidence of insufficient-feeding-related complications.



The 2020-2025 Dietary Guidelines for Americans should reflect the goal of ensuring minimum dietary needs of newborns and infants are met to support and achieve optimal health for all newborns and infants and avoidance of brain- and life-threatening feeding complications, regardless of a mother's capacity (biological or otherwise) or decision to breastfeed. Such a shift in focus would raise public awareness that exclusive breastfeeding from birth to 6 months may be unattainable and potentially unsafe for a sizable proportion of mother-baby dyads and would help reduce adverse outcomes that may result. For approximately 15% of mothers who cannot sustain breastfeeding even with intensive lactation support, removing the stigma of supplementation by publicly acknowledging the benefits of supplementation when exclusive breastfeeding is unsafe, will not only protect their infant from serious harm, but also protect the mother's mental health. This can be achieved with minimal impact to sustained breastfeeding as all five of the randomized trials on supplementation in breastfed infants with higher than average weight loss have shown no reductions in long-term breastfeeding rates.⁸⁴⁻⁸⁷

Safe infant feeding guidelines should meet the ethical obligations of health professionals to 1) do no harm, 2) to act in the best interest of the patient, 3) to respect patient autonomy and 4) to protect the human rights of patients.² Encouraging parents and health professionals to allow infants who develop persistent hunger despite breastfeeding to remain unsupplemented while putting them at risk of feeding complications violates all four of these principles. This is unfortunately a common phenomenon in hospitals across the U.S. as a result of the exclusive breastfeeding metric endorsed by the BFHI. The Committee has an opportunity in its guideline setting to establish the minimum intake standards for optimal health development in newborns and infants that cuts through the messaging in hospitals today and focuses instead on setting evidence-based guidelines.

Finally, as for nutritional recommendation after the neonatal period, the AAP has publicly acknowledged and accepted evidence that delaying introduction of allergenic foods until 6 months of age as opposed to introducing it between 4 to 6 months of age, increases the risk of food allergies, which prompted revision of their guidelines.^{104,105, 106, 107} They now recommend assessing the developmental readiness of an infant between 4 and 6 months of age and making recommendations to introduce solids food, particularly allergenic foods, through shared decision-making with the parents.

Multiple studies have also shown increased risk of iron deficiency anemia in exclusively breastfed newborns between 4 and 6 months of age compared to predominantly formula-fed infants, suggesting an increased need for dietary iron from solid food in breastfed infants.^{108,109,110,111} Similar findings have been found with regard to vitamin B12 deficiency in breastfed infants between 4-6 months.^{112,113} Both iron and vitamin B12 deficiency are known causes of poor cognitive development.^{114,115} We need research on effective interventions that can reduce iron and B12 deficiency among breastfed infants (e.g. maternal and/or infant vitamin supplementation). Furthermore, mothers have inadvertently caused their infants to develop failure to thrive by attempting to adhere to the 6-month exclusive breastfeeding rule despite signs of persistent infant hunger,¹¹⁶ a condition which increases risk of lower cognitive development and other long-term negative health outcomes.^{117,118,119} Without a public health standards and a message that informs parents of the minimum dietary needs and signs and symptoms of insufficient feeding during the first 6 months of life and the importance of seeking medical evaluation to address them, parents may overlook the signs in their infants and potentially cause harm. Moreover, the 2020-2025 Dietary Guidelines for Americans should reflect the current data and the standard of care that has been adopted by the AAP to appropriately assess an infant's readiness for solid food between 4-6 months and make recommendations on introduction of solid food on a case-by-case basis. Even the 2017 WHO

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Breastfeeding Guidelines Revision acknowledged that there were no difference in health outcomes between infants who start solids at 4 months vs. 6 months of age.¹²⁰

Conclusion

Focusing on reducing infant morbidity, hospitalization, long-term disability and cost-of-care is vital to improving maternal, infant and child health outcomes. Equally important is the goal of protecting mothers from misinformation regarding the minimum dietary needs of newborns and infants and the psychologically harmful public health messages that suggest failure to adhere to the exclusive breastfeeding directive equals failure as a mother. If the goal is to provide all mothers who choose to breastfeed safe and optimal conditions to successfully achieve their goal and to equitably support and ensure infants are best-positioned to receive sufficient feeding support for optimal growth and brain development, the focus should be on **healthy, sufficient and sustained breastfeeding**, rather than exclusive breastfeeding from birth to 6 months, which for an unacceptable number of dyads, can result in infant and maternal harm. Formula-feeding families also require comprehensive infant feeding support in order to achieve optimal health and developmental outcomes for their infants. This includes education on safe preparation and storage of formula milk and monitoring of infant growth as well. The current model of exclusive breastfeeding promotion in hospitals currently has no data on safety, and peer-reviewed evidence has emerged regarding its harms. Comprehensive reforms in infant feeding education and management requires objective examination of the evidence by a multidisciplinary panel of experts without financial conflicts of interests on the benefits *and* the risks of the recommendations prescribed to support infant feeding. New parents require updated education as to minimum dietary needs and the potential harms of insufficient feeding of infants, which include but are not limited to:

- Risk of feeding complications and need for hospital treatment of hyperbilirubinemia, dehydration, hypernatremia, hypoglycemia, and failure to thrive
- Brain injury and developmental disability from insufficient feeding complications
- Sudden Unexpected Postnatal Collapse and newborn drops/falls from maternal exhaustion caused by 24/7 rooming, unsupervised skin-to-skin care and breastfeeding; and
- Rare infant deaths from the above listed conditions

Moreover, as the cost of litigation and cost of care related to insufficient feeding complications is increasingly burdening an already over-burdened health care system, these newborn and infant feeding safety issues need to be addressed urgently. We request that the Committee consider the body of peer-reviewed literature cited herein in its development of dietary feeding guidelines, particularly for newborns and infants under 1 year old.

Respectfully,

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