

## Academy of Breastfeeding Medicine Annotated Bibliography:

### HOSPITAL GUIDELINES FOR THE USE OF SUPPLEMENTARY FEEDINGS IN THE HEALTHY TERM BREASTFED NEONATE February 2008

Reference	Content	Level of Evidence*
<b>General Review Articles</b>		
Horvath A, Koletzko B, Kalisz M, Szajewska H. The Effect of Supplemental Fluids or Feedings During the First Days of Life on the Success and Duration of Breastfeeding: A Systematic Review of Randomized Controlled Trials. Arch Pediatr Adolesc Med June 2005; 159:597-598	Of 58 potentially relevant trials identified, only 1 met their criteria for systematic review. That study was noted to have methodologic flaws but the result was that supplementation with ad libitum amounts of 5% glucose water was associated with decreased exclusive and any breastfeeding at 4 weeks and 5 months. They recommended further RCTs, addressing outcomes other than breastfeeding, such as alteration of gut microflora, GI development and immune function, and risk of diabetes mellitus.	II-1
California WIC Association, UC Davis Human Lactation Center. A Fair Start for better Health: California Hospitals Must Close the Gap in Exclusive Breastfeeding Rates.; November 2007, <a href="http://www.calwic.org">www.calwic.org</a> .	Presentation and discussion of in-hospital exclusive and any breastfeeding rates at hospital discharge derived from newborn screening form data. Data down to the County and hospital level are available by ethnicity. Average any breastfeeding rate in all California hospitals is 86.5%, but exclusive breastfeeding is only 42.8%. Half of all breastfed California infants are receiving supplementation! Multiple references.	II-2
Gagnon AJ, Leduc G, Waghorn K, Yang H, Platt RW. In-hospital formula supplementation of healthy breastfeeding newborns. J Hum Lact 2005;21(4):397-405.	The authors analyzed 564 Canadian mother-infant pairs and interviewed nurses. Half of the study infants (47.9%) received formula in hospital; the median age at first supplementation was 8.4 hours. Risk for supplementation was affected by birth occurring between 7 PM and 9 AM (hazard ratio [HR] varied with time) and high maternal trait anxiety (HR=1.61, 95% confidence interval [CI]=1.01, 2.59). The following variables were protective against supplementation: planning to exclusively breastfeed (HR=0.46, 95% CI=0.33, 0.64), planning to breastfeed for >or=3 months (HR=0.56, 95% CI=0.37-0.86), childbirth education (HR=0.61, 95% CI=0.43, 0.86), mother born in Canada (HR=0.68, 95% CI=0.53, 0.87), completion of community college (HR=0.76, 95% CI=0.59, 0.98), male infant (HR=0.78, 95% CI=0.61, 0.99), and breastfeeding at delivery (HR varied with time). Nurses reported breastfeeding problems, infant behavior, and maternal fatigue as reasons for supplementing.	II-2
Scariati P, Grummer-Strawn L, Fein S. Water supplementation of infants in the first month of life. Arch Pediatr Adolesc Med 1997;151(8):830-2.	Evaluation of data from the Food and Drug Administration's Infant Feeding Practices Study, a panel study of US women of fairly high socioeconomic status who were followed up from late pregnancy through their infants' first year of life. The sample (1677 mothers of infants who were neonates in April through November 1993) was drawn from a nationally distributed consumer mail panel. About one fourth (24.7%) of the mothers reported giving their neonates water at least 3 times per week. Water supplementation of neonates was a prevalent practice in this cohort of women. Feeding practices (formula), maternal education (low), and family income (low) were all significant risk factors associated with this behavior.	II-2
Ip S, Chung M, Raman G, et al. Breastfeeding and Maternal and Infant Health Outcomes in Developed Countries. Evidence Report/Technology	Meta-analyses of both short-term and long-term outcomes for both mothers and infants regarding breastfeeding in developed countries. For some outcomes, dose-response assessments are available. Confirmation of risks of not breastfeeding.	III

<p>Assessment No. 153 (Prepared by Tufts-New England Medical Center Evidence-based Practice Center, under Contract No. 290-02-0022. AHRQ Publication No. 07-E007. Rockville, MD: Agency for Healthcare Research and Quality, April 2007. <a href="http://www.ahrq.gov">www.ahrq.gov</a>. 2007.</p>		
<b>Benefits of Exclusive Breastfeeding</b>		
<p>Heinig M. Host defense benefits of breastfeeding for the infant. Effect of breastfeeding duration and exclusivity. <i>Pediatric Clinics of North America</i> 2001;48(1):105-23.</p>	<p>Review article regarding the evidence of the host defense benefits of breastfeeding for term infants of normal birth weight, with an emphasis on information from industrialized countries regarding how the degree and duration of breastfeeding affect infant health.</p>	III
<p>Kramer MS, Kakuma R. The optimal duration of exclusive breastfeeding: a systematic review. <i>Adv Exp Med Biol</i> 2004;554:63-77.</p>	<p>Systematic review of available evidence concerning the effects on child health, growth, and development and on maternal health of exclusive breastfeeding for 6 months vs. exclusive breastfeeding for 3-4 months followed by mixed breastfeeding (introduction of complementary liquid or solid foods with continued breastfeeding) to 6 months. Infants who are breastfed exclusively for 6 months experience less morbidity from gastrointestinal tract infection than infants who were mixed breastfed as of 3 or 4 months of age. No deficits have been demonstrated in growth among infants from either developing or developed countries who are exclusively breastfed for 6 months or longer. Moreover, the mothers of such infants have more prolonged lactational amenorrhea and faster postpartum weight loss. Based on the results of this review, the World Health Assembly adopted a resolution to recommend exclusive breastfeeding for 6 months to its member countries.</p>	III
<p>Mihrshahi S, Ichikawa N, Shuaib M, et al. Prevalence of exclusive breastfeeding in Bangladesh and its association with diarrhoea and acute respiratory infection: results of the multiple indicator cluster survey 2003. <i>J Health Popul Nutr</i> 2007;25(2):195-204.</p>	<p>The objective of this study was to investigate the association between the prevalence of exclusive breastfeeding and morbidity (diarrheal diseases and acute respiratory infection) in infants (N=1633) aged 0-3 month(s) using the Multiple Indicator Cluster Survey (MICS) 2003 data from Bangladesh. The prevalence of diarrhea and acute respiratory infection was 14.3% and 31.2% respectively and was significantly associated with lack of exclusive breastfeeding. The adjusted odds ratio for diarrhea was 0.69 (95% confidence interval [CI] 0.49-0.98, p = 0.039), and the adjusted odds ratio for acute respiratory infection was 0.69 (95% CI 0.54-0.88, p = 0.003). Only 192 infants (11.7% of total sample) were exclusively breastfed at the time of interview, and 823 infants (50.3%) were never exclusively breastfed. The prevalence of prelacteal feeding was 66.6%. The results confirmed a protective effect of exclusive breastfeeding against infectious diseases-related morbidity in infancy and showed that frequently-collected cross-sectional datasets could be used for estimating effects.</p>	II-2
<b>Newborn Transitional Physiology</b>		
<p>Naveed M, Manjunath C, Sreenivas V. An autopsy study of relationship between perinatal stomach capacity and birth weight. <i>Indian J Gastroenterology</i> 1992;11(4):156-8.</p>	<p>Stomach capacity was measured at autopsy in 63 stillborn and 37 newborn infants with birth weights ranging from 500 g to 3500 g. who died at <math>\leq 1</math> week of age. The distal and proximal ends of the stomachs were tied and the stomachs filled with water to obliterate gastric curvatures. The water was then retrieved and volume measured. Stomach capacity had a significant positive correlation with birth weight (<math>r = 0.56</math>, <math>p &lt; 0.001</math>). Mean stomach capacity for <math>&gt; 2500g</math> stillborns (N=11) was <math>19.6 \pm 7.8</math> (SD) mL (range 10-35) and for liveborn/neonatal deaths (N=9) <math>17.8 \pm 7.5</math> (SD) mL (range 10-25). Using this method, one would expect an overestimation of newborn stomach volumes.</p>	II-1

Scammon R, Doyle L. Observations on the capacity of the stomach in the first ten days of postnatal life. <i>Am J Dis Child</i> 1920;20:516-38	“Physiologic” stomach capacity was measured by pre-post breastfeed weighing of 323 infants in the first 10 days of life. Only infants with a birth weight >2000g were included with a mean weight of 3315g. The mean stomach capacity varied slightly with birth weight, but increased significantly over the first 10 days of life with a mean g/feed of 7 on day 1, 13 on day 2, 27 on day 3, 46 on day 4, 57 on day 5, gradually increasing to 81 g/feed on day 10. There is extensive discussion and multiple graphs of the factors affecting variation in stomach size. The average “anatomic capacity” (stretched stomach capacity at autopsy), from 38 infants of weights 1500g to > 4000g (combining their own and others’ data) increased steadily from 33 mL on day 1 to 70 mL on day 10.	II-2
Zangen S, DiLorenzo C, Zangen T, mertz H, Schwankovsky L, Hyman P. Rapid maturation of gastric relaxation in newborn infants. <i>Pediatr Res</i> 2001;50(5):629-532.	Study of gastric volume, wall compliance, sensory perception, and receptive relaxation during the first postnatal 80 h in 17 healthy term infants, using a computer-driven air pump, simultaneously measuring pressure and volume within a latex balloon placed through the oropharynx into the stomach. To evaluate gastric compliance, they measured pressures while infusing air into the intragastric balloon at different rates (10, 20, and 60 mL/min) in random sequence. In all infants, there was a linear relationship between intragastric pressure and volume to the maximum pressure tested (30 mm Hg). Gastric compliance ranged from 0.2 mL/mm Hg to 3.8 mL/mm Hg. Different infusion rates had no effect on compliance. They calculated gastric receptive relaxation by measuring the volume needed to maintain a constant pressure of 10 mm Hg within the balloon for 5 min. Gastric receptive relaxation ranged from 0.5 mL/min to 54 mL/min. Gastric compliance and receptive relaxation increased with postnatal age ( $r = 0.70$ , $p < 0.005$ ; $r = 0.79$ , $p < 0.001$ , respectively) and with number of feedings ( $r = 0.80$ , $r = 0.88$ , respectively, both $p < 0.001$ ). There was no correlation between weight or type of feeding (breast versus formula) and either gastric compliance or relaxation. During the first 3 postnatal d, the newborn stomach becomes more compliant and develops more receptive relaxation, associated with a larger volume capacity.	I
Williams A. Hypoglycemia of the newborn: Review of the Literature. Geneva: World Health Organization; 1997.	Review of the literature on hypoglycemia in neonates	III
Wight N. Hypoglycemia In Breastfed Neonates. <i>Breastfeeding Medicine</i> 2006;1(4):253-62.	Review of the literature on hypoglycemia in neonates, concentrating on the breastfed infant.	III
Wight N, Marinelli K, ABM Protocol Committee. ABM Clinical Protocol #1: Guidelines For Glucose Monitoring And Treatment Of Hypoglycemia In Breastfed Neonates. <i>Breastfeeding Medicine</i> 2006;1(3):178-84.	Protocol for a breastfeeding-supportive approach to hypoglycemia in breastfed infants.	III
Cohen RJ, Brown K, Rivera L, Dewey K. Exclusively breastfed, low birth weight term infants do not need supplemental water. <i>Acta Paediatr</i> 2000;89:550-2.	Breast milk intake, urine volume and urine-specific gravity (USG) of exclusively breastfed, low birthweight (LBW) term male infants in Honduras were measured during 8-h periods at 2 (n = 59) and 8 (n = 68) wk of age. Ambient temperature was 22-36 degrees C and relative humidity was 37-86%. Maximum USG ranged from 1.001 to 1.012, all within normal limits. They concluded that supplemental water is not required for exclusively breastfed, LBW term infants, even in hot conditions.	II-2
Goldberg N, Adams E. Supplementary water for breast-fed babies in a hot and dry climate - not	Fifteen exclusively breastfed infants ages 1-5 months in Israel where temperatures were 32-35° C and relative humidity was 13-41% had urine osmolality measured at 55-320 mOsm/L.	II-3

really a necessity. Arch Dis Child 1983;58:73-4.	There were no controls and no measurement of milk and urine volumes.	
Marchini G, Stock S. Thirst and vasopressin secretion counteract dehydration in newborn infants. Journal of Pediatrics 1997;130(5):736-9.	The authors studied the water balance in healthy breastfed infants (n = 139) during their first 5 days, by cross-sectional measurements of body weight, serum sodium, serum osmolality, and hematocrit. The maximal body weight reduction was 5.7% +/- 1.7% (mean +/- SD) of birth weight and most infants started to gain weight when they were 3 days old. The serum sodium level at 16 +/- 4 hours (on day of birth) was 142 mmol/L; the level increased after 1 day (p < 0.01) and remained constantly high for the following 2 days (p < 0.05). The serum osmolality was increased at 1 day (p < 0.01) and 2 days (p < 0.05) compared with the value on the day of birth (296 mOsm/kg). The plasma vasopressin level was constant up to 24 hours (1 day), but decreased during the next 2 days (p < 0.01). Infants with body weight reduction exceeding 10% (n = 15) had a further elevation of the serum sodium level (p < 0.0001) and serum osmolality (p < 0.0001), and the plasma vasopressin level was twofold higher (p < 0.0001) compared with corresponding levels in infants with less weight reduction. These infants also had a reduced interval between two subsequent feedings (p < 0.001). The hematocrit remained unchanged irrespective of the degree of weight reduction. They concluded that when the reduction of body weight exceeds 10%, the newborn infant releases vasopressin in response to fluid hypertonicity.	II-2
Rodriguez G, Ventura P, Samper M, Moreno L, Sarria A, Perez-Gonzalez J. Changes in body composition during the initial hours of life in breast-fed healthy term newborns. . Biology of the Neonate 2000;77(1):12-6.	The authors studied body composition changes of AGA healthy term newborns (N=43) using bioelectrical impedance (BI). Weight and BI were taken on the 1st, 2nd, and 3rd days of life, always at the same time of the day. Total body water (TBW), percentage of total body mass hydration (%TBW), and amount of body solids were calculated. Average weight at birth was 3,297+/-381 g, length 50.04+/-1.75 cm, and gestational age 39.9+/-0.84 weeks. Weight, TBW, and body solids decreased progressively during the first 3 days of life (p<0.000). By day 3, weight loss represented 5.67+/-1.98% of birth weight, but %TBW increased slightly (1.72%; p<0.000). These results suggest that, during physiological weight loss, body composition modifications are produced in the term newborn by a decrease in TBW and loss of body solids. The level of body hydration increases slightly, since the loss of body solids is greater than the loss of TBW.	II-2
Sachdev H, Krishna J, Puri R. Do exclusively breast fed infants need fluid supplementation? Indian Pediatrics 1992;29:535-40.	Exclusive breast feeding in developing countries is used by women for a very short period. The major reason given for supplementation with other fluid is the maintenance of water homeostasis. This paper reviews both physiologic and interview studies of fluid supplementation. There were 6 studies which tested the validity of water need based on different methodologies: Almroth (2 studies), Armelini, Goldberg, Brown, and Sachdev. The conclusion is that water supplementation in the first 6 months is not necessary, even in hot climates, and should be actively discouraged. Evidence from surveys of physicians and nurses revealed that all considered breastmilk superior to bottle feeding but almost all of nurses and a majority of doctors thought that water supplementation was necessary during the summer. Nurses recommended supplementation 1-24 times a day, while doctors suggested adopting it 2-10 times a day. The authors concluded that education of the general public and health personnel was urgently needed. Supplementation is associated with health risks such as diarrheal morbidity or mortality, decreased milk intake, and early stops to breast feeding.	III
Shrago L. Glucose water supplementation of the breastfed infant during the first three days of life. J	Review article noting that when babies satisfy their hunger and thirst with glucose water (6 cal/oz) feeding frequency decreases and there is less opportunity to consume higher calorie	III

Hum Lact 1987;3:82-6.	colostrum (18 cal/oz).	
Sachdev H, Krishna J, Puri R, Satyanarayana L, Kumar S. Water supplementation in exclusively breastfed infants during summer in the tropics. Lancet 1991;337(8747):929-33.	This study was designed to determine the need for water supplementation to maintain water homeostasis in exclusively breastfed infants during summer in a tropical country (India). 45 healthy, male, exclusively breastfed babies, aged 1-4 months, were recruited from a well-baby clinic. 23 to group I (breastmilk only); the remaining 22 infants were allocated to group II (breastmilk plus supplemental fluid according to the mother's usual practice). The babies were studied at the hospital for 8 h; breastmilk intake was measured by weighing the infant before and after each feed, water intake by calibrated bottles, and urine output by accurate collection and measurement. The maximum room temperatures were 34-41 degrees C and relative humidities 9-60% (below 50% in all but 3 infants). In group II the mean water intake was 11% (95% confidence interval 7-16%) of the total fluid intake. Both breastmilk intake (274 vs 210 ml) and total fluid intake (274 vs 233 ml) were higher in group I than in group II (p = 0.003, p = 0.073, respectively), after adjustment for age, weight, length, room temperature, and humidity. However, there were no significant differences between the groups in urine output, urine or serum osmolality, weight change, or rectal temperature whether or not the factors adjusted for included total fluid intake. Thus, exclusively breastfed infants do not need supplemental water to maintain water homeostasis.	II-1
MacDonald P, Ross S, Grant L, Yound D. Neonatal weight loss in breast and formula fed infants. Arch Dis Child Fetal Neonatal Ed 2003;88(6):F472-6.	Retrospective observational cohort study of 937 consecutive term newborns of birth weight > or = 2500 g during the first 2-3 weeks of life in a maternity service providing geographically defined, community based newborn follow up: 45% breastfed, 42% formula fed, 13% breast and formula fed. Median weight loss: formula fed 3.5%, breastfed 6.6%. Upper centiles for maximum weight loss differed considerably (95th centiles: breast fed = 11.8%, formula fed = 8.4%; 97.5th centiles: breast fed = 12.8%, formula fed = 9.5%). Median time of maximum weight loss: 2.7 days for breastfed and formula fed. Recovery of birth weight: breastfed median 8.3 days, 95th centile 18.7 days, 97.5th centile 21.0 days; formula fed median 6.5 days, 95th centile 14.5 days, 97.5th centile 16.7 days. The time taken to regain birth weight correlates with both the degree and timing of initial weight loss for all groups. Early neonatal weight loss was defined allowing identification of infants who merit closer assessment and support.	II-2
Martens PJ, Romphf L. Factors associated with newborn in-hospital weight loss: comparisons by feeding method, demographics, and birthing procedures. J Hum Lact 2007;23(3):233-241.	Full-term newborn normative weight loss and factors influencing this were determined through chart audits (n = 812) at 6 hospitals in Manitoba, Canada. The effects of parity, gestational age, birth weight, sex, length of stay, type of delivery (cesarean vs vaginal), epidural use, and type of infant feeding (exclusively breastfed, partially breastfed, exclusively formula-fed) on percentage weight loss in hospital were analyzed using multiple regression analysis. In-hospital weight loss was 5.09% +/- 2.89% (95% CI, 4.89-5.29), varying by feeding category: exclusively breastfed 5.49% +/- 2.60% (95% CI, 5.23-5.74), partially breastfed 5.52% +/- 3.02% (95% CI, 5.16-5.88), and formula-fed 2.43% +/- 2.12% (95% CI, 2.02-2.85). Factors significantly increasing the percentage weight loss included higher birth weight, female sex, epidural use, and longer hospital stay. Lower percentage weight loss was associated with greater gestational age and exclusive formula feeding.	II-2
Cavell B. Gastric emptying in infants fed human milk or infant formula. . Acta Paediatr Scand 1981;70:639-41.	Gastric emptying of meals of human milk or infant formula was studied in 17 healthy infants aged 4 weeks to 6 months using a marker dilution technique. In the 24 studies performed gastric emptying followed a biphasic pattern in 11 and a linear pattern in 12 studies. The average gastric half-emptying time for meals of human milk was 48 min, and for meals of	I

	infant formula 78 min. After 1 hour an average of 29.5 ml of human milk and 22.7 ml of infant formula per 0.1 m <sup>2</sup> of body surface area had emptied from the stomach.	
Van Den Driessche M, Peeters K, Marien P, Ghoos Y, Devlieger H, Veereman-Wauters G. Gastric emptying in formula-fed and breast-fed infants measured with the 13C-octanoic acid breath test. <i>J Pediatr Gastroenterol Nutr</i> 1999;29(1):46-51.	The 13C-octanoic acid breath test, a noninvasive method for measuring gastric emptying, was used to compare the gastric-emptying rate of formula-fed and breast-fed infants. Twenty-nine newborn infants with a mean gestational age at birth of 34.5 weeks (range, 27-41 weeks) and a birth weight of 2148 g (range, 960-4100 g). Their mean weight on the day of the test was 2496 g (range, 1998-4140 g), and their mean age was 23 days (range, 7-74 days). Each infant received a test meal after a maximum fasting period of 3 hours. Fourteen infants were fed formula milk and 15 infants received expressed mother's milk, both mixed with 13C-octanoic acid. The mean half-emptying time was 65 minutes (range, 27-98 minutes) for the formula fed infants and 47 minutes (range, 16-86 minutes) for the breastmilk fed infants ( $p < 0.05$ ).	I
<b>Risks of Inappropriate Supplementation</b>		
Martens PJ, Phillips SJ, Cheang MS, Rosolowich V. How Baby-Friendly are Manitoba hospitals? The Provincial Infant Feeding Study. Breastfeeding Promotion Steering Committee of Manitoba. <i>Can J Public Health</i> 2000;91(1):51-7.	The Breastfeeding Promotion Steering Committee of Manitoba conducted the cross-sectional Provincial Infant Feeding Study in 1996 to examine: correlation between breastfeeding policies and actual practices in Manitoba hospitals; compliance with Baby-Friendly Hospital Initiative (BFHI) criteria; and associations between hospital practices and two-week breastfeeding duration. Three separate surveys obtained information from: administrators concerning hospital policy; nursing staff concerning hospital practices; and all women giving birth in a five-week period, concerning breastfeeding rates and maternal perceptions of hospital practices. The results highlighted the need for policy and practice changes to comply with BFHI criteria. 92% initiated breastfeeding, and 84% were breastfeeding at two weeks postpartum. Independent predictors of weaning included: in-hospital supplementation (adjusted RR = 2.1, 95% CI 1.02-4.36, $p = 0.04$ ); temporarily interrupting breastfeeding while in hospital (adjusted RR = 4.9, 95% CI 2.7-8.9, $p = 0.0001$ ); no previous breastfeeding experience (adjusted RR = 2.5, 95% CI 1.4-4.4, $p = 0.002$ ); and Grade 12 or less maternal education.	II-2
Rubaltelli F, Biadaioli R, Pecile P, Nicoletti P. Intestinal flora in breast- and bottle-fed infants. <i>J Perinatal Med</i> 1998;26(3):186-91.	Stool specimens were taken and cultured at the fourth day of life from vaginally born neonates. Twenty-two were breast-fed and 20 were fed with formula. In breast-fed infants, the Bifidobacterium was significantly prevalent expressed in percentage (47.6% vs 15%) and in mean bacterial fecal counts/g (7.1 +/- 0.8 vs 5.3 +/- 0.6). Enterococci prevailed in formula-fed infants (mean counts 6.7 +/- 0.9 vs 7.4 +/- 0.5). Of interest is the significant and simultaneous presence of Bifidobacteria and Bacteroides in breast-fed infants. Our study indicates that flora with a diet-dependent pattern is present from the fourth day of life. These results support a preference for breast feeding over formula feeding.	II-1
Bullen C, Tearle P, Stewart M. The Effect of "Humanized" Milks and Supplemented Breast Feeding on the Faecal Flora of Infants. <i>J Medical Microbiology</i> 1977;10(4):403-13.	The authors investigated the microbiological and physiochemical properties of the feces from infants fed breastmilk only, various formulas and breastmilk supplemented with cow's milk preparations over 6 weeks. Breastmilk feces have a lower pH, more acetic acid and less pathogenic bacteria. When supplements were fed during the first 7 days of life the production of a strongly acidic environment was delayed and its full potential never reached.	II-1
Saarinen K, Juntunen-Backman K, Jarvenpaa A, et al. Supplementary feeding in maternity hospitals and the risk of cow's milk allergy: A prospective study of 6209 infants. <i>J Allergy Clin Immunol</i> 1999;104(2 Pt	The authors studied 6209 unselected healthy, full-term infants, of whom 5385 (87%) required supplementary milk while in the hospital. The infants were randomly assigned to receive routine cow's milk formula (1789 infants), pasteurized human milk (1859 infants), or whey hydrolysate formula (1737 infants). The comparison group (824 infants)	I

1):457-61.	were exclusively breast-fed infants. The infants were followed for 18 to 34 months for symptoms suggestive of cow's milk allergy (CMA). The cumulative incidence of CMA in the infants fed routine formula was 2.4% compared with 1.7% in the pasteurized human milk group (odds ratio [OR], 0.70; 95% confidence interval [CI], 0.44-1.12) and 1.5% in the whey hydrolysate group (OR, 0.61; 95% CI, 0.38-1.00). CMA developed in 2.1% of the exclusively breastfed infants. Among the infants who required supplementary feeding in the hospital, both exposure to routine formula while in the hospital (OR, 1.54; 95% CI, 1.04-2.30; P =.03) and obvious parental atopy (OR, 2.32; 95% CI, 1.53-3.52; P <.001) increased the risk of CMA. Feeding of routine formula at maternity hospitals increases the risk of CMA when compared with feeding of other supplements, but exclusive breast-feeding does not eliminate the risk.	
Saarinen U, Kajosaari M. Breastfeeding as prophylaxis against atopic disease: prospective follow-up study until 17 years old. <i>Lancet</i> 1995;346(8982):1065-9.	The authors followed up 150 healthy infants during their first year, and then at ages 1, 3, 5, 10, and 17 years to determine the effect on atopic disease of breastfeeding. The subjects were divided into three groups: prolonged (> 6 months), intermediate (1-6 months), and short or no (< 1 month) breastfeeding. The prevalence of manifest atopy throughout follow-up was highest in the group who had little or no breastfeeding. Prevalence of eczema at ages 1 and 3 years was lowest in the prolonged breastfeeding group; prevalence of food allergy was highest in the little or no groups at 1-3 years, and respiratory allergy was also most prevalent in the no group. They concluded that breastfeeding is prophylactic against atopic disease--including atopic eczema, food allergy, and respiratory allergy--throughout childhood and adolescence.	II-2
Vaarala O, Knip M, Paronen J, et al. Cow's milk formula feeding induces primary immunization to insulin in infants at genetic risk for Type 1 diabetes. <i>Diabetes</i> 1999;48:1389-94.	Bovine insulin- and human insulin-binding antibodies by enzyme immunoassay and IAA by radioimmunoassay were analyzed in 200 infants carrying HLA-DQB1*0302 but no protective alleles who participated in a Finnish population-based birth-cohort study. We found that the amount of IgG-antibodies binding to bovine insulin was higher at age 3 months in infants who were exposed to cow's milk formula than in infants who were exclusively breast-fed at that age (median 0.521 vs. 0.190; P < 0.0001). The antibodies binding to bovine insulin cross-reacted with human insulin. They postulated that Cow's milk feeding is an environmental trigger of immunity to insulin in infancy that may explain the epidemiological link between the risk of type 1 diabetes and early exposure to cow's milk formulas.	II-2
Host A. Importance of the first meal on the development of cow's milk allergy and intolerance. <i>Allergy Proc</i> 1991;12(4):227-32.	A cohort of 1749 newborns from Denmark were followed prospectively for the development of cow's milk allergy (CMA)/cow's milk protein intolerance (CMI) during their first year. Thirty nine infants (2.2%) developed CMA/CMI. Infants with CMA/CMI were fed cow's milk formula daily during the first month of life significantly more often than infants in the study population (p less than .001). All 39 infants with CMA/CMI had ingested cow's milk formula (40-830 mL) neonatally, whereas none of the 210 neonates without supplements of cow's milk formula developed CMA/CMI (p < .05). The authors postulate an association between early cow's milk formula feeding and development of reproducible adverse reactions to cow's milk protein.	II-2
Chen A, Rogan WJ. Breastfeeding and the risk of postneonatal death in the United States. <i>Pediatrics</i> 2004;113(5):e435-9.	Using 1988 National Maternal and Infant Health Survey (NMIHS) data, nationally representative samples of 1204 infants who died between 28 days and 1 year from causes other than congenital anomaly or malignant tumor (cases of postneonatal death) and 7740 children who were still alive at 1 year (controls) were studied. Overall, children who were ever breastfed had 0.79 (95% confidence interval [CI]: 0.67-0.93) times the risk of never	II-2

	breastfed children for dying in the postneonatal period. Longer breastfeeding was associated with lower risk. Odds ratios by cause of death varied from 0.59 (95% CI: 0.38-0.94) for injuries, to 0.76 (0.54-1.07) for infections and 0.84 (95% CI: 0.67-1.05) for sudden infant death syndrome. Breastfeeding is associated with a reduction in risk for postneonatal death.	
Howie PW, Forsyth JS, Ogston SA, Clark A, Florey CD. Protective effect of breast feeding against infection. <i>Bmj</i> 1990;300(6716):11-6.	Prospective observational study of 618 Scottish infants for the first 2 years of life. Detailed observations of infant feeding practices and sickness episodes were made at 2 weeks and 1, 2, 3, 4, 5, 6, 9, 12, 15, 18, 21, and 24 months of age by health visitors. Of the 674 mother-infant pairs originally enrolled in the study, 267 bottle-fed from birth, 180 breastfed but weaned before their infant was 13 weeks of age, and 227 breastfed for 13 weeks or more (97 of these women exclusively breastfed their infants for the 1st 13 weeks of life). During the 1st 13 weeks, the adjusted rate (corrected for social class, maternal age, and parental smoking) for gastrointestinal illness was 2.9% among fully breastfed and 5.1% among partially breastfed infants compared with 15.7% among bottle-fed infants and 16.7% among weaned infants. In addition, the rate of respiratory illness was significantly greater in bottle-fed infants (37.0%) compared with partially (24.2%) and fully (25.6%) breastfed infants. In the period beyond the 1st 13 weeks of life, infants who had been partially or fully breastfed initially had significantly lower rates of gastrointestinal disease at 14-26 weeks, 27-39 weeks, and 40-52 weeks compared to bottle-fed infants and a lower rate of hospital admission.	II-1
Paricio Talayero JM, Lizan-Garcia M, Otero Puime A, et al. Full breastfeeding and hospitalization as a result of infections in the first year of life. <i>Pediatrics</i> 2006;118(1):e92-9.	1385 Spanish infants were followed from birth to age 1 year between 1996 and 1999. Recruitment and data collection were done at the 6-month well-infant visit under the National Child Health Program. Full breastfeeding, hospital admission, and other relevant variables related to the delivery, infant, mother, health services system, and sociologic aspects were recorded. Full breastfeeding at discharge and at 3, 4, and 6 months of age were 85%, 52%, 41%, and 15%, respectively; 78 hospital admissions as a result of infections were recorded (38 respiratory tract, 16 gastrointestinal tract). Mean age at admission was 4.1 months. After estimating the attributable risk, it was found that 30% of hospital admissions would have been avoided for each additional month of full breastfeeding.	II-2
Edmond KM, Kirkwood BR, Amenga-Etego S, Owusu-Agyei S, Hurt LS. Effect of early infant feeding practices on infection-specific neonatal mortality: an investigation of the causal links with observational data from rural Ghana. <i>Am J Clin Nutr</i> 2007;86(4):1126-31.	Prospective observational cohort study of 10,942 breastfed singleton neonates born between 1 July 2003 and 30 June 2004, who survived to day 2, and whose mothers were visited in the neonatal period. One hundred forty neonates died from day 2 to day 28; 93 died of infection and 47 of noninfectious causes. The risk of death as a result of infection increased with increasing delay in initiation of breastfeeding from 1 hr to day 7; overall late initiation (after day 1) was associated with a 2.6-fold risk [adjusted odds ratio (adj OR): 2.61; 95% CI: 1.68, 4.04]. Partial breastfeeding was associated with a 5.7-fold adjusted risk of death as a result of infectious disease (adj OR: 5.73; 95% CI: 2.75, 11.91). No obvious associations were observed between these feeding practices and non-infection-specific mortality. Prolactal feeding was not associated with infection (adj OR: 1.11; 95% CI: 0.66, 1.86) or non-infection-specific (adj OR: 1.33; 95% CI: 0.55, 3.22) mortality.	II-2
Victora CG, Smith PG, Vaughan JP, et al. Evidence for protection by breast-feeding against infant deaths from infectious diseases in Brazil. <i>Lancet</i>	Population-based case-control study of infant mortality in 2 urban areas of southern Brazil. Compared with infants who were breastfed with no milk supplements, and after adjusting for confounding variables, those completely weaned had 14.2 and 3.6 times the risk of death	II-2



1987;2(8554):319-22.	from diarrhea and respiratory infections, respectively. Part-weaning was associated with corresponding relative risks (RR) of 4.2 and 1.6. The risk of death from infections other than diarrhea or respiratory infection was less clearly associated with breastfeeding (completely weaned, RR=2.5; partly weaned, RR=0.4). Cow's and formula milk seemed to be equally hazardous. For deaths due to diarrhea the increased risk associated with not breastfeeding was greatest in the 1st 2 months of life (RR for completely weaned vs. breastfed without supplementary milk =23.3).	
World Health Organization. Evidence for the Ten Steps to Successful Breastfeeding. Family and Reproductive Health. Division of Child Health and Development. Geneva. WHO/CHD/98.9. 1998. Step 6:pages 48-53	Review of the literature supporting each of the 10 steps. Supplementation in hospital interferes with the normal frequency of breastfeeding and is associated with shortened duration of exclusive and any breastfeeding.	III
Kuhr M, Paneth N. Feeding practices and early neonatal jaundice. J Pediatr Gastroenterol Nutr 1982;1(4):485-8.	The authors studied rates of early neonatal jaundice in 135 consecutive well newborns in relation to feeding practice. Breast-fed infants had significantly ( $p < .01$ ) higher rates of jaundice than bottle-fed infants. In a subset of breastfed infants, sugar water intake in the first 3 days of life was significantly and inversely related to estimated volume of breast milk intake on the 4th day ( $r = -0.35$ , $p < 0.05$ ). Breastfed infants with high sugar water intake in the first 3 days, and low breast milk intake on the 4th day, tended to have higher rates of jaundice, but these results were not statistically significant. The authors postulated that in breastfed infants, sugar water intake may reduce the stimulus to nurse, and thereby increase the risk of jaundice.	II-3
de Carvalho M, Hall M, Harvey D. Effects of water supplementation on physiological jaundice in breast-fed babies. Arch Dis Child 1981;56(7):568-9.	Water supplementation was given to 120 babies and 55 received no extra fluids. There was no significant difference between the two groups when peak serum bilirubin levels and incidence of phototherapy were compared.	II-3
Nicoll A, Ginsburg R, Tripp JH. Supplementary feeding and jaundice in newborns. Acta Paediatr Scand 1982;71(5):759-61.	Breastfed babies receiving water or dextrose supplements had higher plasma bilirubins on the sixth day of life than bottle fed infants. Supplementation with water or dextrose did not reduce the hyperbilirubinemia of term, breastfed infants. The authors suggested that the practice be abandoned since it may prejudice the establishment of breastfeeding.	II-3
Nylander G, Lindemann R, Helsing E, Bendvold E. Unsupplemented breastfeeding in the maternity ward. Positive long-term effects. Acta Obstet Gynecol Scand 1991;70(3):205-9.	Feeding routines in a Norwegian maternity ward were investigated in 204 mother-infant pairs before, and in 203 pairs after a change towards earlier, more frequent breastfeeding and elimination of routine substitute feeds. In the intervention group, the volume of breast-milk increased, while the use of formula and sugar solution decreased correspondingly. The infants in the intervention group lost more weight during the first 2-3 days (6.4% versus 4.6%), but regained their birth weight faster than the supplemented control group. The incidence of hyperbilirubinemia was not significantly different in the two groups. No cases of hypoglycemia were diagnosed. At 6 months, 87% of the infants in the intervention group were still fed at the breast, compared with 66% in the control group.	II-3
Verronen P, Visakorpi JK, Lammi A, Saarikoski S, Tamminen T. Promotion of breast feeding: effect on neonates of change of feeding routine at a maternity unit. Acta Paediatr Scand 1980;69(3):279-82.	The effect on the health of neonates of a change in neonatal routine care, including general rooming-in, breastfeeding on demand and avoidance of supplementary bottle feeding was studied in conjunction to a breastfeeding campaign at a maternity unit. There was an increased weight loss in the neonatal period during ad libitum breastfeeding. The mean serum bilirubin of clinically jaundiced infants was slightly higher on a 4-hourly feeding schedule with supplementary bottles than on on demand breastfeeding. There was a similar high (32-33%) incidence of bilirubin levels greater than 205 $\mu\text{mol/l}$ (12 mg/100 ml) in both	II-3

	groups. The incidence of spontaneous hypoglycemia did not differ in the two groups. The new feeding regimen was thus considered safe by the authors.	
Glover J, Sandilands M. Supplementation of breastfeeding infants and weight loss in hospital. <i>J Hum Lact</i> 1990;6(4):163-6.	Retrospective chart review. Babies who received glucose water supplementation lost more weight ( $p < 0.03$ ) and stayed in hospital longer ( $p < 0.009$ ) than babies who did not receive supplementation. The authors concluded that routine supplementation with glucose water is unnecessary and potentially harmful to the baby. Stopping this practice may increase the mother's milk supply, increase her confidence in the adequacy of her supply and decrease the length of hospital stay.	II-3
Dollberg S, Lahav S, Mimouni FB. A comparison of intakes of breast-fed and bottle-fed infants during the first two days of life. <i>J Am Coll Nutr</i> 2001;20(3):209-11.	43 healthy, term infants were studied: by maternal choice, 15 infants were exclusively breastfed (pre-post-feeding weights) and 28 were formula-fed ad libitum every four hours. Breastfeeding on Day 1 was 9.6 +/- 10.3 (mean +/- SD) vs. 18.5 +/- 9.6 cc/kg/d in formula-fed infants ( $p = 0.011$ ); on Day 2 it was 13.0 +/- 11.3 vs. 42.2 +/- 14.2 cc/kg/d ( $p < 0.001$ ). Breastfed infants lost significantly more weight on Day 2 ( $p = 0.015$ ). Newborn infants offered formula ad libitum every four hours consumed much larger amounts than breastfed infants fed according to the same schedule.	II-3
Matheny RJ, Birch LL, Picciano MF. Control of intake by human-milk-fed infants: relationships between feeding size and interval. <i>Dev Psychobiol</i> 1990;23(6):511-8.	Amount of human milk consumed per feeding and intervals between feedings were measured over a 72-hr period at 2, 4, 6, 8, and 12 weeks. Correlation analyses revealed that volume of milk ingested at a feeding (meal size) was positively related to preprandial interval at all 5 ages ( $r = 0.39-0.47$ , $p < 0.0001$ ). Meal size was likewise related, but not as strongly, to postprandial interval at 4 of the 5 time points examined ( $r = 0.17-0.25$ , $p < 0.01$ ). Results of the correlational analyses revealed clear, consistent preprandial correlations, providing evidence for a reactive type feeding pattern among the solely breast-fed infants.	II-3
Wight NE. Management of common breastfeeding issues. <i>Pediatr Clin North Am</i> 2001;48(2):321-44.	Review of many breastfeeding issues, including a description and literature review of alternate feeding methods and possible consequences of supplementation.	III
Neifert M, Lawrence R, Seacat J. Nipple confusion: toward a formal definition. <i>J Pediatr</i> 1995;126(6):S125-9.	Review article which introduces a formal definition of nipple confusion and proposes various hypotheses concerning its cause. Many early breastfeeding failures are attributed to nipple confusion, although scientific data are lacking to document its prevalence, the mechanisms involved, or various factors that predispose an infant to this phenomenon. Maternal and infant risk factors making an infant more susceptible to nipple confusion are discussed. Alternative methods, such as cup, spoon, or dropper feeding, could be used to provide medically-indicated supplements until breastfeeding can be established.	III
Howard CR, Howard FM, Lanphear B, et al. Randomized clinical trial of pacifier use and bottle-feeding or cupfeeding and their effect on breastfeeding. <i>Pediatrics</i> 2003;111(3):511-8.	A total of 700 breastfed newborns (36-42 weeks, birth weight $\geq 2200$ g) were randomly assigned to 1 of 4 intervention groups: bottle/early pacifier ( $n = 169$ ), bottle/late pacifier ( $n = 167$ ), cup/early pacifier ( $n = 185$ ), or cup/late pacifier ( $n = 179$ ). The cup/bottle intervention was invoked for infants who received supplemental feedings: cup ( $n = 251$ ), bottle ( $n = 230$ ). Data were collected at delivery and at 2, 5, 10, 16, 24, 38, and 52 weeks' postpartum. Supplemental feedings, regardless of method (cup or bottle), had a detrimental effect on breastfeeding duration. There was no advantage to cupfeeding for providing supplements to the general population of healthy breastfed infants, but it may have benefitted mother-infant dyads who required multiple supplements or were delivered by cesarean. Pacifier use in the neonatal period was detrimental to exclusive and overall breastfeeding. These findings support recommendations to avoid exposing breastfed infants to artificial nipples in the neonatal period.	I
Feinstein JM, Berkelhamer JE, Gruszka ME, Wong	Of the 166 nursing mothers studied for 4 months postpartum, 83% breastfed for 1 month,	II-3

<p>CA, Carey AE. Factors related to early termination of breast-feeding in an urban population. <i>Pediatrics</i> 1986;78(2):210-5.</p>	<p>73% for 10 weeks, and 58% for 4 months or longer. Factors correlating significantly with improved breastfeeding rates include maternal age, maternal education, nonsmoking, previous breastfeeding, planned pregnancy, initiation of breastfeeding in the first 16 hours, and minimization of formula supplementation in the nursery. Partial breast-feeding (supplementing more than one bottle of formula per day, measured at 1 month postpartum) was associated with shorter breast-feeding duration. (Any) breastfeeding duration was not affected by formula samples given at discharge from the hospital.</p>	
<p>Bunik M, Beaty B, Dickinson M, Shobe P, Kempe A, O'Connor M. Early formula supplementation in breastfeeding mothers: How much is too much for breastfeeding success? Abstract # 18. In: 12 Annual International Meeting of the Academy of Breastfeeding Medicine: Frontiers in Breastfeeding Medicine; 2007 Oct 12-14; Ft. Worth, Texas; 2007.</p>	<p>This study evaluated the association of early formula supplementation with breastfeeding rates at 1, 2, 3 and 6 months in a cohort of 107 low income primiparous Latina mothers who received telephone-based breastfeeding support and education in the first 2 weeks postpartum. At day 4, mothers reporting 0-2 supplemental feedings of formula were more likely to breastfeed at 1 month with an OR of 7.7 (95% CI 2.4-24.3), at 2 months with OR 5.7 (95% CI 1.8-18.1), at 3 months with OR 3.1 (95% CI 1.0-9.8) and 6 months with OR 8.1 (95% CI 1.0-65.2) as compared to mothers reporting 3 or more supplementary feedings per 24 hrs. The authors suggest anticipatory guidance of no more than 2 supplementary feeds/24 hrs may prolong breastfeeding in the high risk mother and that giving 3 or more supplementary feeds may be a marker for breastfeeding difficulties.</p>	I
<p>Perez-Escamilla R, Segura-Millan S, Canahuati J, Allen H. Prelacteal feeds are negatively associated with breast-feeding outcomes in Honduras. <i>J Nutr</i> 1996;126(11):2765-73.</p>	<p>Multivariate logistic regression was used to examine the association between prelacteal feeds and breastfeeding practices among 0- to 6-mo-old infants (n = 714), and to identify factors associated with milk-based prelacteal feeds. Providing milk-based prelacteal feeds was negatively associated with both exclusive (odds ratio = 0.18) and any breast-feeding (OR 0.21). Prelacteal water was negatively associated with exclusive breast-feeding (OR 0.19). Both water- and milk-based prelacteal feeds were associated with a delayed milk arrival and a delay in the time at which the child was offered the breast for the first time. These findings suggest that prelacteal feeds have an adverse effect on breast-feeding outcomes.</p>	II-3
<p>Williams HG. 'And not a drop to drink'--why water is harmful for newborns. <i>Breastfeed Rev</i> 2006;14(2):5-9.</p>	<p>Literature review of water supplementation for newborns and infants. Supplementary water is not necessary and may be harmful.</p>	III
<p>Blomquist HK, Jonsbo F, Serenius F, Persson LA. Supplementary feeding in the maternity ward shortens the duration of breast feeding. <i>Acta Paediatr</i> 1994;83(11):1122-6.</p>	<p>Prospective study of feeding routines in a maternity unit and the subsequent feeding patterns of 521 newborns. During the stay in the maternity unit, 69% of newborns were exclusively breastfed and 1% received only donor's milk from the milk bank and/or formula. 9% received their mothers' milk by bottle at least once and 21% received one or more supplementary feedings with donor's milk from the milk bank. One-quarter of the children received supplementary feeds on the third day of life, the indications for this being birth weight less than 3.0 kg, maternal diabetes or gestational diabetes, "insufficient amounts" of milk or fussiness. At three months, 65% were being exclusively breastfed and 15% partially breast fed. The adjusted relative risk (estimated as odds ratios, OR) of not being breast fed at three months was associated with maternal age (&lt; 25 years, OR 4.2), maternal smoking (OR 4.0), neonatal feeding (supplements given, OR 3.9) and initial weight loss (10% or more, OR 2.8). Thus the administration of supplementary donor's milk or formula during the early neonatal period was associated with an increased risk of a short duration for breast feeding, even after adjustment for a number of potential confounders.</p>	II-2
<p>Blyth R, Creedy D, Dennis C, Moyle W, Pratt J,</p>	<p>A prospective survey was conducted with 300 women in the last trimester of pregnancy</p>	II-3

<p>DeVries S. Effect of maternal confidence on breastfeeding duration: An application of breastfeeding self-efficacy theory. <i>Birth</i> 2002;29(4):278-84.</p>	<p>recruited from the antenatal clinic of a large metropolitan hospital in Brisbane, Australia. Telephone interviews were conducted at 1 week and 4 months postpartum to assess infant feeding methods and breastfeeding confidence using the Breastfeeding Self-Efficacy Scale. Although 92 percent of participants initiated breastfeeding, by 4 months postpartum almost 40 percent discontinued and only 28.6 percent were breastfeeding exclusively; the most common reason for discontinuation was insufficient milk supply. Antenatal and 1-week Breastfeeding Self-Efficacy Scale scores were significantly related to breastfeeding outcomes at 1 week and 4 months. Maternal breastfeeding self-efficacy is a significant predictor of breastfeeding duration and level.</p>	
<p>Kurini N, Shiono P. Early formula supplementation of breastfeeding. <i>Pediatrics</i> 1991;88(4):745-50.</p>	<p>Factors influencing early formula supplementation in breastfed neonates were examined in 726 women who delivered their first child in one of three metropolitan Washington, DC, hospitals. Thirty-seven percent of breastfed neonates were given supplementary formula in the hospital. Mothers who gave birth at a university hospital were more likely to breastfeed exclusively (adjusted odds ratio 3.5; 95% confidence limit 2.1 to 5.9). A strong predictor of formula use was the time between birth and initiation of the first breastfeed: the longer a mother waited to initiate breastfeeding the more likely she was to use formula; AOR breastfeeding initiation 2 to 6 hours, 7 to 11 hours, and 12 or more hours postpartum were 1.1, 0.5, and 0.2, respectively. Feeding the baby on demand, having a vaginal delivery, deciding to breast-feed before pregnancy, having a college education, and being married also were moderately, though significantly, predictive of exclusive breast-feeding. The findings suggest that hospital influences can promote formula use and indirectly shorten breast-feeding duration, particularly those hospital practices that delay early initiation of breast-feeding.</p>	II-3
<p>Martin-Calama J, Bunuel J, Valero MT, et al. The effect of feeding glucose water to breastfeeding newborns on weight, body temperature, blood glucose, and breastfeeding duration. <i>J Hum Lact</i> 1997;13(3):209-13.</p>	<p>In order to determine the effect of feeding glucose water on breastfeeding newborns, 180 normal newborns were randomly assigned to two groups: a glucose water group (GW), fed 5% glucose solution during the first 3 days of life in addition to being breastfed; and an exclusively breastfed non-glucose water group (NGW). In the NGW, there was a greater weight loss at 48 hours but not at 72 hours, temperatures higher than 37.5 degrees C were more frequent, and the mean serum glucose levels at 6, 12, and 24 hours were lower, but no infants exhibited hypoglycemic symptoms. Infants in the GW received twice as many formulas during the first month and had a shorter duration of any breastfeeding. Elimination of feedings with glucose water in the first days of life increases the probability of successful breastfeeding.</p>	I
<p>Kramer MS, Chalmers B, Hodnett ED, et al. Promotion of Breastfeeding Intervention Trial (PROBIT): a randomized trial in the Republic of Belarus. <i>Jama</i> 2001;285(4):413-20.</p>	<p>The Promotion of Breastfeeding Intervention Trial (PROBIT) was a cluster-randomized trial conducted June 1996-December 1997 with a 1-year follow-up in 31 maternity hospitals and polyclinics in the Republic of Belarus. A total of 16,491 mother-infant pairs (96% of those enrolled) consisting of full-term singleton infants weighing at least 2500 g and their healthy mothers who intended to breastfeed, completed the entire 12 months of follow-up. Sites were randomly assigned to receive the BFHI experimental intervention (n = 16) or a control intervention (n = 15) of continuing usual infant feeding practices and policies. Infants from the intervention sites were significantly more likely than control infants to be breastfed to any degree at 12 months (19.7% vs 11.4%; adjusted odds ratio [OR], 0.47; 95% confidence interval [CI], 0.32-0.69), were more likely to be exclusively breastfed at 3 months (43.3% vs 6.4%; P&lt;.001) and at 6 months (7.9% vs 0.6%; P =.01), and had a significant reduction in</p>	I

	the risk of 1 or more gastrointestinal tract infections (9.1% vs 13.2%; adjusted OR, 0.60; 95% CI, 0.40-0.91) and of atopic eczema (3.3% vs 6.3%; adjusted OR, 0.54; 95% CI, 0.31-0.95), but no significant reduction in respiratory tract infection (intervention group, 39.2%; control group, 39.4%; adjusted OR, 0.87; 95% CI, 0.59-1.28). The experimental intervention increased the duration and degree (exclusivity) of breastfeeding and decreased the risk of gastrointestinal tract infection and atopic eczema in the first year of life.	
Chezem J, Friesen C, Montgomery P, Fortman T, Clark H. Lactation duration: influences of human milk replacements and formula samples on women planning postpartum employment. <i>J Obstet Gynecol Neonatal Nurs</i> 1998;27(6):646-51.	Telephone interviews were conducted prenatally and at 6 weeks, 3 months, and 6 months post-partum with 53 women planning to breastfeed and work outside the home. During hospitalization, 19% of infants received formula; the incidence of breastfeeding at 6 weeks and duration of breastfeeding were significantly shorter in these infants compared with infants who were not fed formula in the hospital. 59% of participants received formula samples from the hospital, 30% received samples from a physician's office, and 51% received samples by mail. Receipt of formula samples by mail was associated with reduced incidence of breastfeeding at 6 weeks and shortened duration of lactation.	II-3
Hill PD, Humenick SS, Brennan ML, Woolley D. Does early supplementation affect long-term breastfeeding? <i>Clin Pediatr (Phila)</i> 1997;36(6):345-50.	Secondary data analysis of 2 convenience samples of 120 and 223 breastfeeding mothers who were followed up for 20 weeks postpartum or until weaning occurred. The breastfeeding rate at 20 weeks postpartum was significantly greater for mothers who reported feeding exclusively mother's milk the second week after delivery compared with mothers who breastfed and simultaneously supplemented with manufactured infant milks. Of the mothers in samples one and two who exclusively fed human milk during week 2 postpartum, 63.0% and 59.7%, respectively, were still breastfeeding at week 20, compared with 28.1% and 24.2%, respectively, who supplemented with artificial milks. There was no significant difference between these two groups of mothers and their intended duration of breastfeeding. Early introduction of supplemental bottles of artificial milks is associated with a decrease in the amount of human milk the infant receives as well as with early weaning.	II-3
Marques NM, Lira PI, Lima MC, et al. Breastfeeding and early weaning practices in northeast Brazil: a longitudinal study. <i>Pediatrics</i> 2001;108(4):E66.	From January to August 1998, 364 mothers in urban Brazil were interviewed at delivery and twice weekly about feeding practices. When other milk was started, a second interview was conducted and reasons for starting other milk were investigated. Although few intended to breastfeed exclusively, 99% breastfed their new infant. In the first week 80% gave water/tea and 56% used a pacifier. The median duration of exclusive breastfeeding was 0 days, and the median age for starting other milk was 24 days. The median duration of breastfeeding was 65 days for mothers who started other milk within 1 month and 165 days for other mothers. After adjustment for confounding variables, the main factors associated with introduction of other milk within 1 month were pacifier use in the first week (odds ratio [OR], 4.01; 95% confidence interval [CI]: 2.07-7.78), intention to start other milk in the first month (OR, 3.79; 95% CI: 1.74-8.24), giving water/tea in the first week (OR, 3.07; 95% CI: 1.56-6.03), and leaving the maternity ward before breastfeeding was started (OR, 2.59; 95% CI: 1.34-5.04).	II-3
Hartmann PE, Cregan MD, Ramsay DT, Simmer K, Kent JC. Physiology of lactation in preterm mothers: initiation and maintenance. <i>Pediatr Ann</i> 2003;32(5):351-5.	Review of the physiological processes involved in preparing the breast for lactation, milk synthesis and milk expression. This paper also describes how preterm delivery may disturb these physiologic processes. Describes factors and causes of inhibited or delayed lactogenesis II in term and preterm mothers.	III
Moon JL, Humenick SS. Breast engorgement: contributing variables and variables amenable to	The focus of this study was to identify variables that correlate significantly with breast engorgement and that might be amenable to nursing interventions. Data on the initiation of	II-2

nursing intervention. J Obstet Gynecol Neonatal Nurs 1989;18(4):309-15.	feeding, frequency of feedings, feeding duration, rate of milk maturation, and supplementation were obtained of 54 women. Late initiation of feeding, decreased frequency of feedings, short feeding duration and supplementation were found to be significantly correlated with breast engorgement.	
Newman J. Breastfeeding problems associated with the early introduction of bottles and pacifiers. J Hum Lact 1990;6(2):59-63.	Review article suggesting the early introduction of bottles may render suckling less effective or may result in breast refusal, thus paving the way for failure to thrive, hyperbilirubinemia, "colic" and crying, prolonged and frequent feedings, sore and cracked nipples for the mother, and it may contribute to the onset of plugged ducts and mastitis. Alternatives to bottles can be used when supplementation is thought to be indicated. They include using a lactation aid, finger feeding, or feeding with a cup, spoon, or eyedropper.	III
<b>Inappropriate Reasons for Supplementation</b>		
Cloherly M, Alexander J, Holloway I. Supplementing breast-fed babies in the UK to protect their mothers from tiredness or distress. Midwifery 2004; 20:194-204	A qualitative study using participant observation and interviews. A major theme was the healthcare professionals' desire to protect the mothers from tiredness or distress, although this at times conflicted with their role of promoting breastfeeding. The categories of "protecting mother from guilt", "making it easy to give up" and "protecting the mother from distress" were linked to this theme. Healthcare professionals need to be aware that they may not be helping mothers in the longer-term when supplementation is used as a quick "solution" to a mother's tiredness or distress. However, other strategies such as providing emotional support or role modeling "settling" skills are time consuming and have resource implications for the maternity service.	II-3
Akuse R, Obinya E. Why healthcare workers give prelacteal feeds. European Journal of Clinical Nutrition 2002;56:729-34.	Survey of 1100 (68% response rate = 747) healthcare workers in primary, secondary and tertiary health facilities in Kaduna township Nigeria. Large proportions of both medical and non-medically trained healthcare workers stated they routinely give prelacteal feeds (doctors, 68.2%; nurses, 70.2%; and non-medical, 73.6%). However their reasons for doing so differed significantly (P=0.00001). Nurses gave prelacteal feeds mainly for perceived breast milk insufficiency, doctors for prevention of dehydration, hypoglycemia and neonatal jaundice and non-medical staff to prepare the gastrointestinal tract for digestion and to quench thirst. Training and retraining programs in lactation management are necessary and must include non-medical staff. These programs, while emphasizing the danger of giving prelacteal feeds, must deal with the misconceptions of each group.	II-3
Smale M. Working with breastfeeding mothers: the psychosocial context. In: Clement S, ed. Psychological Perspectives on Pregnancy and Childbirth. Edinburgh: Churchill Livingstone; 1998:183-204 (Chapter 10).	A review of the psychosocial factors involved in the breastfeeding choice and the attitudes and influence of caregivers. Caregivers find it takes more time to explain why supplement should not be given, and to help a mother breastfeed, than to just give a bottle. They also may prefer "doing" rather than listening and talking.	
Reiff MI, Essock-Vitale SM. Hospital influences on early infant-feeding practices. Pediatrics 1985;76(6):872-9.	Newborn nursery nursing staff members were surveyed to determine their attitudes and teaching practices regarding breast- and bottle-feeding. Concurrently, mothers using this nursery responded to a structured interview concerning their infant-feeding practices at 14 to 21 days postpartum and possible hospital influences on these practices. The nursing staff strongly advocated breast-feeding and did not favor specific bottle-feeding practices or products. Nursing staff counseling was generally interpreted by mothers as supporting breast-feeding, but this did not deter a large proportion of mothers who stated an initial	II-3

	preference for breast-feeding from introducing formula as a supplementary or exclusive form of infant feeding during the short study period. Almost all mothers doing any amount of bottle-feeding at the time of their interview were using the same formula brand used during their hospital stay. It is concluded that the hospital staff and routines exerted a stronger influence on mothers' infant-feeding practices by nonverbal teaching (the hospital "modeling" of infant formula products) than by verbal teaching (counseling supporting breast-feeding).	
Stettler N, Stallings VA, Troxel AB, et al. Weight gain in the first week of life and overweight in adulthood: a cohort study of European American subjects fed infant formula. <i>Circulation</i> 2005;111(15):1897-903.	A cohort of European American formula-fed subjects, measured on 7 occasions during infancy as part of several infant formula studies, were contacted at age 20 to 32 years. Data were available for 653 subjects (72% of eligible subjects). Approximately 32% of them were overweight adults. The period between birth and age 8 days was identified as potentially critical. After adjustment for important confounding factors, weight gain during the first week of life was associated with adulthood overweight status (OR for each 100-g increase 1.28, 95% CI 1.08 to 1.52), as was weight gain during the first 112 days of life (OR 1.04, 95% CI 1.01 to 1.08). Similar results were obtained after standardization with z scores from a reference population. In formula-fed infants, weight gain during the first week of life may be a critical determinant for the development of obesity several decades later.	II-2
Yamauchi Y, Yamanouchi I. Breast-feeding frequency during the first 24 hours after birth in full-term neonates. <i>Pediatrics</i> 1990;86(2):171-5.	The relation between the frequency of breastfeeding and intake, weight loss, meconium passage, and bilirubin levels was studied in 140 healthy, full-term, breastfed, Japanese neonates born vaginally without complications. Mothers nursed their neonates, on average, 4.3 +/- 2.5 (SD) times (range 0 to 11) during the first 24 hours after birth, and this frequency increased significantly to 7.4 +/- 3.9 times during the next 24 hours (P < .001). The frequency of breastfeeding during the first 24 hours correlated significantly with frequency of meconium passage (r = .37, P < .01), maximum weight loss (r = -.22, P < .05), breast milk intake on day 3 (r = .50, P < .01) and day 5 (r = .34, P < .05), transcutaneous bilirubin readings on day 6 (r = -.18, P < .05), and weight loss from birth to time of discharge (day 7) (r = -.32, P < .01). There was a strong dose-response relationship between feeding frequency and a decreased incidence of significant hyperbilirubinemia (transcutaneous bilirubin readings $\geq$ 23.5) on day 6.	II-3
De Carvalho M, Klaus MH, Merkatz RB. Frequency of breast-feeding and serum bilirubin concentration. <i>Am J Dis Child</i> 1982;136(8):737-8.	Prospective study of 55 mothers and their infants. Infants who nursed on average more than eight times per 24 hours in the first three days of life had significantly lower serum bilirubin levels (65. v 9.3 mg/dL, P < .01) than those who fed less than eight times per 24 hours. The results suggest that breastfeeding policies that reduce or limit the number of feedings may interfere with the normal processes that eliminate bilirubin from the newborn infant.	II-3
American Academy of Pediatrics. Management of hyperbilirubinemia in the newborn infant 35 or more weeks of gestation. <i>Pediatrics</i> 2004;114(1):297-316.	Review of the literature and guidelines providing a framework for the prevention and management of hyperbilirubinemia in newborn infants of 35 or more weeks of gestation. In every infant, the AAP recommends that clinicians 1) promote and support successful breastfeeding; 2) perform a systematic assessment before discharge for the risk of severe hyperbilirubinemia; 3) provide early and focused follow-up based on the risk assessment; and 4) when indicated, treat newborns with phototherapy or exchange transfusion to prevent the development of severe hyperbilirubinemia and, possibly, bilirubin encephalopathy (kernicterus). Routine supplementation is discouraged.	III
Kumar A, Pant P, Basu S, Rao GR, Khanna HD. Oxidative stress in neonatal hyperbilirubinemia. <i>J</i>	Investigation of the role of bilirubin as an antioxidant in neonatal hyperbilirubinemia (NNH) by measuring malondialdehyde (MDA) levels, a marker of oxidative stress and key	II-2

Trop Pediatr 2007;53(1):69-71.	antioxidant enzymes viz., superoxide dismutase (SOD), catalase and glutathione peroxidase (GPx) in otherwise healthy 70 term newborns with NNH and 20 control newborns without jaundice. Jaundiced newborns had significantly lower MDA but higher SOD, catalase and GPx levels. Furthermore, plasma bilirubin showed significant negative correlation with MDA but positive correlation with antioxidant enzyme activities. It was concluded that NNH is associated with lower oxidative stress.	
Keefe MR. The impact of infant rooming-in on maternal sleep at night. J Obstet Gynecol Neonatal Nurs 1988;17(2):122-6.	Two opposing issues in postpartum rooming-in are the benefits of continuous interaction and the threat of maternal sleep disruption. A two-group comparison study was designed to investigate differences in sleep patterns for a group of mothers who roomed-in with their infants at night as compared with a group who was separated from their infants at night. The data collected from the mothers in the study indicated that mothers did not sleep longer or better when their infants were returned to the nursery during the night.	II-2
Slaven S, Harvey D. Unlimited suckling time improves breast feeding. Lancet 1981;1(8216):392-3.	Cluster randomized trial of limited, timed breastfeedings (2 wards) and unlimited, untimed on-demand breastfeeding (2 wards). Structured interviews were conducted with 100 consecutive mothers in each ward on postpartum day 4, day 6-8, and at 6 weeks. At 6 weeks there was a highly significant difference ( $p < 0.0005$ ) with more women still breastfeeding in the untimed suckling group, but no significant differences in the incidence of nipple problems and breast engorgement. Mother and her baby are much better judges of suckling time than nurses and medical staff.	I
<b>Valid Medical Indications for Supplementation</b>		
American Academy of Pediatrics, Section On Breastfeeding. Policy Statement: Breastfeeding And The Use Of Human Milk. Pediatrics 2005;115(2):496-506.	"Supplements (water, glucose water, formula, and other fluids) should not be given to breastfeeding newborn infants unless ordered by a physician when a medical indication exists."	III
Powers NG, Slusser W. Breastfeeding update. 2: Clinical lactation management. Pediatr Rev 1997;18(5):147-61.	Review of the literature and recommendations for support of breastfeeding including appropriate indications for supplementation.	III
Committee on Drugs, The American Academy of Pediatrics. The transfer of drugs and other chemicals into human milk. Pediatrics 2001;108(3):776-89.	Review of the literature and recommendations in regards to drugs, medications and other substances for breastfeeding women.	III
Yaseen H, Salem M, Darwich M. Clinical presentation of hypernatremic dehydration in exclusively breast-fed neonates. Indian J Pediatr 2004;71(12):1059-62.	Out of 17,208 live births, 29 neonates between the ages of 2-13 days were admitted with weight loss of between 12 and 29% (dehydrated group). 27 patients had hypernatremic dehydration with serum sodium level ranging from 150 to 195 mmol/l. Mean age of admission was 4.9 days. Reasons for admission were: signs of dehydration (55%); hyperthermia (55%); hypoglycemia (27%) and jaundice (59%). The control group included 58 healthy neonates. Their birth weight and age were comparable to those in the dehydrated group. In comparison with the control group, delivery by cesarean section ( $P < 0.0001$ ), lower level of maternal breastfeeding knowledge ( $P=0.03$ ), transient inadequate breastmilk quantity ( $P=0.005$ ) and nipple anomalies ( $P=0.001$ ) were significantly more common in the dehydrated group. Fewer voids ( $< 6$ times /day) and stool ( $< 3$ times/day) in the previous 24 hours before admission was more frequently observed in the dehydrated	II-2



	group ( $P < 0.0001$ ) as well as failure of early postnatal follow-up.	
Neifert MR. Prevention of breastfeeding tragedies. <i>Pediatr Clin North Am</i> 2001;48(2):273-97.	Potential catastrophic infant outcomes can occur when enthusiastic promotion of breastfeeding outpaces necessary support services and management. Such cases often involve underlying maternal and infant breastfeeding risk factors, made deadly by parental and professional misconceptions and knowledge deficits or health care system failures. An early follow-up visit a few days after discharge allows at-risk infants to be identified before they lose excessive weight and at a time when intervention can easily correct most breastfeeding problems before they become complicated by insufficient milk. Those who enthusiastically promote breastfeeding for its many health benefits must confront the reality of breastfeeding failure and implement necessary changes in medical education and support services to foster successful outcomes in breastfed infants.	III
Su LL, Chong YS, Chan YH, et al. Antenatal education and postnatal support strategies for improving rates of exclusive breast feeding: randomised controlled trial. <i>Bmj</i> 2007;335(7620):596.	RCT in a tertiary hospital in Singapore of 450 women with uncomplicated pregnancies who received routine care v. antenatal education and postnatal support. Antenatal breastfeeding education and postnatal lactation support, as single interventions based in hospital both significantly improve rates of exclusive breast feeding up to six months after delivery. Postnatal support was marginally more effective than antenatal education.	I
<b>Recommendations</b>		
International Lactation Consultant Association. <i>Clinical Guidelines for the Establishment of Exclusive Breastfeeding</i> ; 2005.	Review of the literature, statement of desired outcomes and clinical guidelines for establishing successful breastfeeding.	III
Saadeh R, Akre J. Ten steps to successful breastfeeding: a summary of the rationale and scientific evidence. <i>Birth</i> 1996;23(3):154-60.	To become baby-friendly, hospitals and maternity wards around the world are giving practical effect to the principles described in the joint WHO/UNICEF statement that have been synthesized into Ten Steps To Successful Breastfeeding. This summary of the rationale and scientific basis for the Ten Steps is presented in the light of cumulative experience demonstrating the crucial importance of these principles for the successful initiation and establishment of breastfeeding.	III
Henrikson M. A policy for supplementary/complementary feedings for breastfed newborn infants. <i>J Hum Lact</i> 1990;6(1):11-4.	Examples of supplementation policy, parent information sheet regarding supplementation and discussion about the results of a change in policy at one hospital. It is the responsibility of the health professional to provide information, document parental decisions, and support the mother after she has made a decision.	III
World Health Organization. Annex to the Global criteria for the Baby Friendly Hospital Initiative (A39/8 Add.1). Geneva. 1992:122-35.	Recommendations for medically necessary supplementation. Currently in draft revision at <a href="http://www.who.int/nutrition/topics/BFHI_Revised_Section2.4.a_Handouts.pdf">http://www.who.int/nutrition/topics/BFHI_Revised_Section2.4.a_Handouts.pdf</a> .	III
<b>Quality and Quantity of Supplementation</b>		
World Health Organization, UNICEF. <i>Global Strategy for Infant and Young Child Feeding</i> . Geneva: WHO/UNICEF; 2003.	Recommendations and a guide for action for optimal infant and child feeding in no-HIV and HIV-prevalent regions of the world in an attempt to revitalize world attention to the impact feeding practices have on nutritional status, growth and development, health, and thus the very survival of infants and young children.	III
Morton J, et al. Early Hand Expression Affects Breastmilk Production in Pump-Dependent Mothers of Preterm Infants. <i>Abstr # 7720.9</i> . In: PAS; 2007 May 5-8; Toronto, Canada; 2007.	Investigation of the use of hand expression in the first 3 days to determine if this technique, when used in conjunction with electric pumping, would influence milk production at 2 wks. Sixty-six mothers of VLBW infants, who were $\leq 30\frac{6}{7}$ wks gestation, were recruited over 2 yrs. All mothers received individual hand expression instruction from one breastfeeding	II-1

	<p>expert. Mothers recorded pumping time duration and volume of milk pumped from each breast daily for 8 wks. Of these mothers, 48 (72.7%) recorded their use of hand expression in the first 3 days. They were then stratified into three groups based on the reported frequency of hand expression: Group I (no/low, &lt;2 per day, n=14); Group II (medium, 2–5 per day, n=18); and Group III (high, &gt;5 per day, n=16). The mean frequency of pumping in Groups I, II and III over the first 3 days post-partum was 3.7±0.8, 4.4±1.7, and 5.1±1.7/day, respectively, and the mean frequency over 14 days was 5.7±1.0, 5.8±1.3, and 6.5±1.3/day, respectively. By wk 2, Group I, II, and III mothers produced a mean milk volume of 444±227, 484±352, and 802±540 mL/day, respectively. There was a statistically significant difference in milk production by Group III mothers compared to Groups I and II (<math>p \leq 0.01</math> and <math>&lt; 0.03</math>, respectively). They concluded that pump-dependent mothers of VLBW preterm infants, who hand express frequently (&gt;5 per day) in the first 3 post-partum days, can produce larger than average volumes of breast milk by wk 2.</p>	
<p>Morton J, et al. Breast Massage Maximizes Milk Volumes of Pump-Dependent Mothers. Abstr # 444. In: PAS; 2007 May 5-8; Toronto, Canada; 2007.</p>	<p>36 mothers who delivered at <math>\leq 30</math> 6/7 wks and <math>\leq 1500</math>g – part of larger study – received instruction regarding breast massage during pumping at mean <math>19.8 \pm 9.9</math> days postpartum. Mean volumes 3 days before instruction were compared with mean volumes from the last 3 days of the study (end at 8 weeks). Volumes were unchanged or decreased in 14% (5/36) of mothers and increased in 86% (31/36) of mothers: mean pre-instruction <math>537 \pm 333</math> mL/day, and mean at 8 weeks <math>862 \pm 567</math> mL/day. There was no significant change in frequency or duration of pumping sessions pre- and post-instruction. The authors concluded that mothers of preterm infants can attain and sustain high production levels by combining the use of breast massage/hand expression with electrical pumping and that reliance on electrical pumping alone may compromise milk production potential in pump-dependent mothers.</p>	II-1
<p>Gourley GR, Kreamer B, Cohnen M, Kosorok MR. Neonatal jaundice and diet. Arch Pediatr Adolesc Med 1999;153(2):184-8.</p>	<p>Infants were exclusively fed human milk, Enfamil, or Nutramigen. Formulas were randomly assigned. Paired comparisons showed that the jaundice index of the Nutramigen group was significantly lower than that of the Enfamil group (on days 6-16) and the human milk group (on days 3-20). The jaundice index of the Enfamil-fed group was significantly lower than that of the human milk group on days 13 to 19. Jaundice levels were lower in neonates fed Nutramigen rather than Enfamil and both these groups have lower jaundice levels than breast-fed infants.</p>	
<p>Saint L, Smith M, Hartmann PE. The yield and nutrient content of colostrum and milk of women from giving birth to 1 month post-partum. Br J Nutr 1984;52(1):87-95.</p>	<p>The intake of mammary secretion from delivery to day 5 postpartum was determined by test-weighing nine infants using an integrating electronic balance. The mean yield of colostrum for the first 24 h after birth was 37.1 (range 7.0-122.5) g and was 408 (range 98.3-775) and 705.4 (range 452.5-876) g/24 h on days 3 and 5 post-partum respectively. The milk yield of mothers on either day 14 or 28 post-partum was determined by test-weighing the mother. The mean milk yield was 1.156 (SD 0.167) kg/24 h. A significant correlation (<math>P</math> less than 0.001; <math>r</math> 0.85, <math>n</math> 42) was found between milk yield measured by test-weighing the infant and milk yield measured by test-weighing the mother,</p>	II-2
<p>Casey CE, Neifert MR, Seacat JM, Neville MC. Nutrient intake by breast-fed infants during the first five days after birth. Am J Dis Child 1986;140(9):933-6.</p>	<p>The intakes of milk and specific nutrients during the first 120 hours after birth were measured in 11 full-term, breast-fed infants. Infants were test weighed at all feeds using an electronic balance, and milk samples were obtained from both breasts one to three times daily. The average (+/- SD) intake of milk in the first 24 hours after birth was <math>13 \pm 16</math> g/kg (range, 3 to 32 g/kg), increasing to <math>98 \pm 47</math> g/kg (50 to 163 g/kg) and <math>155 \pm 29</math> g/kg (110</p>	II-2

	to 196 g/kg) on days 3 and 5, respectively.	
Evans KC, Evans RG, Royal R, Esterman AJ, James SL. Effect of caesarean section on breast milk transfer to the normal term newborn over the first week of life. Arch Dis Child Fetal Neonatal Ed 2003;88(5):F380-2.	A sample of 88 healthy nursing mothers who had a normal vaginal delivery, and 97 mothers who had a caesarean section were recruited from a teaching hospital. The infants were weighed before and after each feed throughout the study period using calibrated portable electronic scales. The volume of milk transferred to infants born by caesarean section was significantly less than that transferred to infants born by normal vaginal delivery on days 2 to 5 ( $p < 0.05$ ), but by day 6 there was no difference between the two groups ( $p = 0.08$ ). Birth weight was regained by day 6 in 40% of infants born vaginally compared with 20% in those born by caesarean section. There is a lag in the profile of the daily volume of breast milk transferred to infants delivered by caesarean section compared with those born by normal vaginal delivery.	II-3
<b>Methods of Supplementation</b>		
Howard CR, de Blicke EA, ten Hoopen CB, Howard FM, Lanphear BP, Lawrence RA. Physiologic stability of newborns during cup- and bottle-feeding. Pediatrics 1999;104(5 Pt 2):1204-7.	A total of 98 term, healthy newborns were randomized to either cup-feeding ( $n = 51$ ) or bottle-feeding ( $n = 47$ ). There were no significant differences in administration time, amounts ingested or overall HR, RR, and O <sub>2</sub> saturation rates, between cup and bottle groups. Breastfed infants had longer administration times and lower overall HR, RR, and higher O <sub>2</sub> saturation as compared with cup- and bottle-fed infants. Breastfeeding takes longer than cup- or bottle-feeding, but infants experience less physiologic variability. These data support cup-feeding as an alternative to bottle-feeding for supplying supplements to breastfed infants.	I
Marinelli KA, Burke GS, Dodd VL. A comparison of the safety of cupfeedings and bottlefeedings in premature infants whose mothers intend to breastfeed. J Perinatol 2001;21(6):350-5.	In a prospective, randomized crossover study, 56 infants $\leq 34$ weeks at birth, whose mothers indicated a desire to breastfeed, were studied when infants were $\geq 34$ weeks' corrected gestational age. The order of the first two non-breast oral feedings was randomized to one cup-feeding and one bottle feeding. During cup-feedings, premature infants are more physiologically stable, with lower heart rates, higher oxygen saturations, and less desaturations, than during bottle feedings. However, cup-fed infants took less volume, over more time, than bottle fed for these initial feedings. Based on better physiologic stability and no difference in untoward effects, cup-feeding is at least as safe, if not safer, than bottle feeding in this population.	I
Malhotra N, Vishwambaran L, Sundaram KR, Narayanan I. A controlled trial of alternative methods of oral feeding in neonates. Early Hum Dev 1999;54(1):29-38.	Controlled trial of the use of the bottle, cup and a traditional feeding device ('paladai') in 100 infants including full-term normal weight infants ( $n = 66$ ), term growth retarded infants ( $n = 20$ ), and preterm infants ( $n = 14$ ). All three methods were tried on every infant by the same nurse for a particular baby, so that each infant served as his/her control. The infants took the maximum volume in the least time and kept quiet longest with the paladai. Spilling was the highest with the cup, especially with preterm infants.	I
Lang S, Lawrence CJ, Orme RL. Cup feeding: an alternative method of infant feeding. Arch Dis Child 1994;71(4):365-9.	Review of the literature and collective experience with cup-feeding for preterm infants. Cup feeding techniques are described and possible uses for special situations described. Point made that parents can do cup-feeding as well as health care professionals.	III
Cloherly M, Alexander J, Holloway I, Galvin K, Inch S. The cup-versus-bottle debate: a theme from an ethnographic study of the supplementation of breastfed infants in hospital in the United kingdom. J Hum Lact 2005;21(2):151-62; quiz 63-6.	Observation was conducted on the postnatal ward and the newborn infant unit, and 30 mothers, 17 midwives, 4 neonatal nurses, 3 health care assistants, 3 senior house officers, and 3 senior pediatricians gave in-depth interviews during a 9-month period in 2002. One of the major themes that emerged was the cup-versus-bottle debate. There were 3 categories strongly linked to this theme: difficulties returning to the breast, ease of use, and necessary	II-3

skills and knowledge. There is an urgent need to determine which is the best method of giving supplementary feeds, so that full, accurate information can be given to mothers, appropriate policies be devised, and the necessary resources and staff training be provided.
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**SUMMARY:**

Despite multiple recommendations to the contrary, inappropriate supplementation is common. Healthy, full-term infants are programmed to make the transition from their intrauterine constant flow of nutrients to their extra-uterine intermittent nutrient intake without the need for metabolic monitoring or interference with the natural breastfeeding process. Homeostatic mechanisms ensure adequate energy substrate is provided to the brain and other organs, even when feedings are delayed. The normal pattern of early, frequent, and exclusive breastfeeding meets the needs of healthy full-term infants. Routine supplementation is not necessary and is associated with shorter duration of exclusive and any breastfeeding as well as other risks. Most reasons given for supplementation are invalid, based on well meaning healthcare providers lack of understanding of the normal physiologic process of establishing breastfeeding. Valid indications for supplementation do exist: persistent hypoglycemia, separation of mother and infant, (rare) maternal medications, or inadequate milk transfer. When supplementation is necessary, the volume should reflect the normal amounts of colostrum available and the age and size of the infant, with mother's own milk or pasteurized donor human milk preferred over artificial milks. There is no one "right" way to provide supplementation. The method will depend on the infant, the anticipated duration of supplementation, the preferences of the mother and the region of the world involved.

**FUTURE RESEARCH:**

1. There is no research as to amounts of supplementation any given infant should be fed. Should the volume of supplement be the same or different for artificial milks vs. colostrum? Should the volume be independent of infant weight or a per kg volume? Should supplementation make up for cumulative losses? Should feeding intervals be different for different supplements?
2. What is the optimal way to provide supplements to the infant? Which methods are best for which infants or which time periods in which area of the world? Which methods interfere least with establishing direct breastfeeding?
3. RCTs, addressing outcomes other than breastfeeding, such as alteration of gut microflora, GI development and immune function, and risk of diabetes mellitus.

**\*US Preventive Services Task Force Ranking of Evidence from Scientific Studies**

- I Evidence obtained from at least one properly randomized controlled trial.
- II-1 Evidence obtained from well-designed controlled trials without randomization.
- II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.
- II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could be regarded as this type of evidence.
- III Opinions of respected authorities, based on clinical experience, descriptive studies and case reports; or reports of expert committees.

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