JOHNS HOPKINS ALL CHILDREN'S HOSPITAL

Enteral Vitamin and Mineral Supplementation Clinical Pathway

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Rationale

Human milk is the preferred nutrition for all infants however it does not meet the increased needs for certain vitamins and minerals in specific subgroups of neonates including preterm and medically complex term infants. Micronutrients such as vitamin D, calcium, phosphorus, iron, zinc and sodium are essential to ensure optimal nutritional status for bone mineralization, neurodevelopment and growth. The goal is to meet these needs without exceeding Tolerable Upper Intake Levels (UL) based on the clinical and medical status of the infant. Use of formula does not meet micronutrient requirements for preterm and some term infants and additional supplementation may be needed for those formula fed as well.

Background / Published Data and Levels of Evidence

Preterm Infants

Although human milk (HM) is the preferred feeding for all infants, it will not meet the increased demands of prematurity for many nutrients including protein, vitamin D, sodium, calcium, phosphorus, zinc, and iron. Unfortified HM is associated with poor growth in preterm infants.[1,2] The micronutrient composition of HM is widely variable depending on the mother and stage of lactation. Preterm infants fed unfortified HM are at risk for nutrient deficits, especially when birth weight is < 1500 grams and/or intake is < 180 mL/kg/day.[1] In addition to calories and protein, human milk fortifier (HMF) provides vitamin and minerals to mitigate nutrient deficits (LOE 1b).[1] However, fortified HM or preterm formula alone will not meet the needs of the preterm infant.[2] Refer to Table 1.

A. Vitamin D

Adequate intake of vitamin D is important due to the high rate of bone development in the early period of life. 25-Hydroxyvitamin D (25-OH-D) is the form of vitamin D that passes across the placenta.[3]

1. Vitamin D status at birth is affected by maternal vitamin D status which can be influenced mainly by sun exposure, as well as maternal diet, vitamin intake and skin color.
2. The 25(OH)D status of an infant at birth is 50-75% of the mother's vitamin D status and many preterm infants can thus have vitamin D deficiency at birth.
3. The optimal 25-OH-D level for preterm infants remains controversial, with sufficient levels usually being considered >20 ng/mL, however, a concentration of 32-80 ng/ml has been used as the preferred target for preterm infants. [4, 6,7]

4. Enteral supplementation is recommended, however, there is a discrepancy in recommended dose. The AAP recommends 200-400 IU vitamin D per day while ESPGHAN recommends 800-1000 IU per day, with Koletzko recommendations of 400-1000 IU per day. [5, 8]

B. Calcium and Phosphorus

Adequate calcium and phosphorus intake are crucial after birth in preterm infants as 80% of calcium and phosphorus transfer occurs during 24-40 weeks gestation.

1. Monitoring for metabolic bone disease via biochemical assessment of serum alkaline phosphatase (AP) along with serum phosphorus and calcium is strongly recommended.[9, 10] Laboratory monitoring for VLBW infants begins at 4 weeks (because abnormal values are uncommon in the first four weeks of life) with subsequent weekly to biweekly testing depending on risk factors (LOE 2c).[9]
   Risk Factors for metabolic bone disease include:
   a. Prematurity
   b. Very low birth weight
   c. Parenteral Nutrition use > 4 weeks
   d. Use of diuretics and fluid restriction for bronchopulmonary dysplasia (BPD) treatment
   e. Postnatal corticosteroid use
   f. Necrotizing enterocolitis
   g. Delayed/suboptimal fortification of HM[11]
2. Monitoring should be discontinued once the AP has peaked and is declining to less than about 500 IU/L (if the patient is on appropriate enteral nutrition).[9]

3. When elevated AP (≥800 IU/L) and low serum phosphorus (< 4 mg/dL) is identified in patients on full feeds, mineral supplementation of calcium and phosphorus should be considered. [12]
   a. Calcium Phosphate Tribasic provides 100 mg elemental calcium and 46 mg elemental phosphorus per 250 mg (1/8 tsp).

C. Iron

Anemia of prematurity results from decreased erythropoietin production and occurs in the weeks following early birth. Multiple blood draws also contribute to anemia. Iron accumulation occurs during the last trimester of pregnancy and therefore iron stores in premature infants are low. Insufficient intake of iron may impair recovery from anemia of prematurity when erythropoiesis begins.

1. Premature infants need 1-3 mg/kg/day of supplemental iron. The AAP recommends starting iron supplementation after 2 weeks of life. [8]
2. The combination of hemoglobin, ferritin and reticulocytes may help differentiate between iron-deficiency anemia and anemia of prematurity.
   a. Ferritin is an acute phase reactant and acute infection or inflammation may cause falsely elevated ferritin levels. A C- reactive protein level should be considered with ferritin levels to rule out infection or inflammation. Ferritin levels should be postponed until acute inflammation/infection is resolved and

repeated if already drawn.[13] Ferritin can also be elevated in patients with liver disease.[13]

3. Continue iron supplementation until 12-15 months of age.[11]

D. Zinc

Zinc is a micronutrient that plays an important role in growth and development and deficiency can lead to growth impairment. Preterm infants are especially at risk due to their rapid rate of growth and missing the in-utero accretion time of the third trimester. Due to the role of zinc in protein synthesis, enhanced nutrition early in life may further deplete zinc stores in preterm infants.[14] Prematurity associated conditions such as BPD, significant enterotomy fluid losses and wounds may require additional zinc supplementation. Zinc binds to casein limiting its bioavailability. It is estimated that ~36% of zinc in fortified breast milk and ~14-24% of zinc in preterm formula is absorbed.[15]

1. Measurement of serum zinc levels should be considered in infants with:
    a. Unexplained growth failure
    b. Failure to meet weight gain goals in spite of otherwise optimized intake
    c. Increased gastrointestinal losses [16]
    d. Exclusive HM diet (especially if mother is vegan or has discontinued prenatal vitamins)
    e. Receiving chronic administration of steroids or diuretics[18]
2. Enteral zinc supplementation should be initiated in infants with BPD on full feeds who fail to meet weight gain goals in spite of providing energy and protein intake at goal (especially in infants with AP levels lower than expected). [17]
3. Refer to *Guidelines for Nutrition, Fluid and Electrolyte Management for Patients with BPD* for more information.

E. Sodium

Preterm infants are at risk for developing hyponatremia due to immature kidney function, and frequent need for medications that can cause hyponatremia such as diuretics. Fluid and sodium balance should be assessed when evaluating hyponatremia.

1. Inadequate sodium intake can lead to impaired growth of both weight and length, rather than supplementation of sodium leading to better growth as once hypothesized.[18]
2. HM is low in sodium, though the use of HMF helps meet the sodium requirements of preterm infants.
3. Additional sodium supplementation is still frequently needed in form of sodium chloride supplementation and is determined based on serum and/or urine sodium levels.
    a. Sodium supplementation should be individualized and not started unless needed.
    b. Refer to Table 2 for more information on recommended sodium intake.
4. Refer to *Guidelines for Nutrition, Fluid and Electrolyte Management for Patients with BPD* for more information.

Term Infants

A. Vitamin D

Vitamin D (calciferol) is made of two components: Vitamin D2 (ergocalciferol) and D3 (cholecalciferol). Vitamin D2 is derived from plants, whereas vitamin D3 is synthesized in the skin from sun exposure and the fat of fish. Both vitamin D2 and D3 undergo hydroxylation in the liver to form the main circulating form of Vitamin D: 25-OH-D. 25-OH-D is then hydroxylated in the kidney to the active form 1,25-dihydroxyvitamin D (1,25-OH2-D), also known as calcitriol.

1. Human milk does not contain levels of vitamin D to meet current recommendations. Term infants receiving breastmilk require 400 IU of supplemental vitamin D daily to prevent insufficiency and maintain serum 25-OH-D of > 30 ng/mL.[19]
2. Vitamin D supplementation should start within the first few days of life, before hospital discharge per AAP recommendations.[20]
3. 1 mL of D-Vi-Sol provides 400 IU vitamin D (refer to Table 3 for more information) and is recommended for all breastfed infants (LOE 1b).[19]
4. Of note, there are “single drop” preparations of vitamin D available, however, parents should be cautioned if they choose to use these products as there is a greater chance of overdosing vitamin D.[21]
5. There is evidence that breastfeeding women supplemented with high-dose vitamin D (6400 IU daily) will provide sufficient vitamin D to infants via maternal breast milk, though currently this is not routine practice.[21]
6. Infants with fat malabsorption may require serum vitamin D level monitoring since vitamin D is a fat-soluble vitamin.
7. When Vitamin D deficiency is suspected, 25-OH-D should be ordered as it is the best nutritional indicator of vitamin D stores (LOE 2c). Measurement of 1, 25-OH2-D is not recommended to detect Vitamin D deficiency on routine basis as it can remain normal in spite of vitamin D deficiency as a result of secondary hyperparathyroidism.[20]

B. Iron

1. Iron supplementation is not typically indicated for term infants as enough iron is transferred in utero to meet the infant’s requirements for the first six months of life, assuming the mother was not iron deficient.
2. One liter of standard infant formula provides iron to meet the RDA for term infants until 1 year of age (provides 12 mg/liter). Term infants should receive 1 mg/kg/day of iron supplementation starting at 4 months of age if receiving breast milk and/or less than 1 liter of formula per day.[8]
3. Additional iron supplementation may be needed for infants requiring multiple blood draws.
4. Once an infant reaches 4-6 months of age, food sources of iron should be introduced, such as iron fortified cereal and meats.[22]

C. Zinc

Zinc supplementation is not needed before 6 months of age for normal, healthy infants.

1. For infants receiving breastmilk at 6 months, an additional source of zinc is indicated, as breast milk is lower in zinc, especially if mother is vegan or has discontinued prenatal vitamins.[17]
    a. This can be achieved by introducing complementary foods that contain zinc (ex. meat).

D. Fluoride

Infants may not receive adequate fluoride intake if only fed ready-to-feed formula or if formula is mixed with bottled water that is not fluoridated. Most hospitalized infants do not receive fluoride.

1. Fluoride supplementation should not be provided before 6 months of age (this includes mixing formula with fluoridated nursery water).[22]
2. If fluoride supplements are warranted, a typical dose is 0.25 mg per day. [16]

E. Sodium

Breast milk and formula are sufficient in sodium for healthy, term infants.

1. Infants on diuretics or with certain disease states, such as cystic fibrosis, may need additional sodium supplementation.
2. Term infants with gastrointestinal problems, such as enterostomy or poor colonic function causing total body sodium depletion, may have increased sodium needs. Refer to *the Management Guidelines for Short Bowel Syndrome and Intestinal Failure MFNI Clinical Practice Guideline* for further information.

Special Considerations

A. Infants treated with anti-epileptic medications, benzodiazepines, and phenytoin may need higher levels of vitamin D supplementation to maintain normal serum levels due to their effect on vitamin D metabolism.[23] Monitoring of 25-OH-D levels is recommended. [23]
B. Zinc deficiency can cause growth impairment and can be seen in some disease states or medical conditions such as cystic fibrosis or intestinal resections. If deficiency is confirmed, an oral solution of zinc can be given, usually 1 mg/kg/day.[8]
C. Darbepoetin: When started on darbepoetin, provide 5-6 mg/kg elemental iron enterally, including any iron provided by multivitamin, by adding needed amount of Fer-in-sol.
    a. Refer to Darbepoetin CPG for further information.

Table 1. Estimated Nutrient Needs

Nutrient	Preterm Infants [5, 11, 25]	Term infants up to 6 months of age and preterm infants once corrected to term*[18, 26, 27, 28, 29]
Iron	1-3 mg/kg/day	0.27 mg/day (11 mg/day for 7-12 months of age)
Zinc	2-3 mg/kg/day	2 mg/day
Calcium	120-220 mg/kg/day	200 mg/day
Phosphorus	70-120 mg/kg/day	100 mg/day
Fluoride	1.5-60 µg/kg/day	0.01 mg/day (0.5 mg/day 7-12 months)
Vitamin D	400-1000 IU/day	400 IU/day
Sodium	~ 3-5 mEq/kg/day (69-115 mg/kg) **Also See Chart Below**	4.8 mEq/day

*=Adequate Intake (AI)

Table 2. Recommended Sodium Intake (mEq/kg/day) According to Gestational and Postnatal Ages[18]

	Postnatal Age, days of life (DOL)				
Gestational age, in weeks	DOL 1-2	DOL 3	DOL 7	DOL 14	DOL 30
< 28 weeks	3	6-12	4-8	3-6	2-4
29-31 weeks	2	4-7	2-4	2-4	1-2
32-36 weeks	1	3-5	2-3	1-2	1-2

Table 3. Content of Common Enteral Vitamin/Mineral Supplements

Vitamin/Mineral Supplements	Iron (mg)	Calcium (mg)	Phosphorus (mg)	Vitamin D (IU)
1 ml Poly-vi-sol	0	0	0	400
1 ml Poly-vi-sol with Fe	11	0	0	400
1 ml D-vi-sol	0	0	0	400
250 mg Calcium Phosphate Tribasic	0	100	46	0

Table 4. Laboratory Assessment

Lab	Method	Interpretation (Goal Range)	Indications for Checking & Monitoring	Supplementation& Monitoring	Comments
Vitamin D	Serum or plasma 25-hydroxyvitamin D (25-OH-D)	> 30 ng/mL	Anti-seizure, or glucocorticoid medication for > 1 month Metabolic Bone Disease BPD Preterm infants (< 37 weeks): check initial level at 4-6 weeks postnatal age and on full feeds [4] Check levels every 3 months if initial level within normal limits	If levels < 30 ng/mL, add additional 4OO IU vitamin D per day. (UL for preterm infants: 1000 IU/day, UL for term: 1500 IU/day) Recheck levels every 4-6 weeks until normal, then every 3 months	Measurement of 1,25-OH2-D is not recommended to detect Vitamin D deficiency on routine basis
Phosphorus	Serum Phosphorus	Preterm 5-9 mg/dL Term 4-8 mg/dL	IUGR/SGA History of abnormal values while on TPN	Calcium Phosphate Tribasic provides 100 mg elemental calcium and 46 mg elemental phosphorus per 250 mg (1/8 tsp). There are no published recommendations for dosing, however, historically initial dosing is twice per day for metabolic bone disease, with increase to three times daily if no improvement. Monitor levels weekly. Goal is to target high end of range of estimated calcium and phosphorus needs (Table 1).	
Alkaline Phosphatase	Serum	Preterm < 800 IU/L	Prematurity Metabolic Bone Disease		

Zinc	Serum or Plasma	74-146 mcg/dL (per ASPEN Guidelines)	Not typically indicated for enterally fed preterm infants	Preterm infants: Empirically start if zinc deficiency is suspected at 1 mg/kg/day up to 4.5 mg total daily.	Use levels cautiously with hypoalbuminemia Acute phase reactant
Sodium	Serum	135-145 mEq/L	Routine monitoring; on weekly basis if on diuretics	Consider sodium and chloride supplements when serum sodium persistently less than 135 mEq/L and/or serum chloride less than 90 mEq/L Start sodium chloride supplementation with 2 mEq/kg	

Clinical Management

Recommendations for Preterm Infants

1. Once on goal volume of enteral feeds (usually breast milk/donor milk 24 kcal/oz fortified with Hydrolyzed Protein Concentrated Liquid HMF at 150 ml/kg/day: *Refer to Early Standardized Nutritional Management of the Preterm Neonate MFNI Clinical Practice Guideline for more information*):
    a. For infants < 1250 grams: Start 300 IU per day of vitamin D supplementation and 2 mg/kg/day of iron supplementation. Change to 0.5 ml of infant multivitamin with Fe once patient reaches 1250 grams.
    b. For infants ≥ 1250 grams: Start 0.5 ml of infant multivitamin with Fe (provides 5.5 mg iron and 200 IU vitamin D)
    c. Check a vitamin D 25-OH level (takes 0.1-0.6 mL of blood and can be run with anything else collected in either a SST Gold tube, Red tube or micro red tube) once infant is 4-6 weeks postnatal age and has been on full feeds for at least 2 weeks.
        i. If level is ≤ 30 ng/mL, add an additional 400 International Units per day of vitamin D. Recheck level 4 weeks after increasing supplementation.
    d. For all infants:
        - If discharged on all formula, continue 0.5 ml of infant multivitamin with Fe.
        - If discharged on breastmilk, increase to 1 ml of infant multivitamin with Fe.
        - Continue additional vitamin D supplementation as needed per labs. Recommend follow-up outpatient with pediatrician.
        - Refer to Discharge Feeding Guidelines CPG.
2. Zinc supplementation and monitoring of serum zinc levels should be considered in infants with unexplained growth failure or increased gastrointestinal losses. (Discuss with NICU nutritionist to ensure calories and protein are maximized prior to initiating zinc supplementation.)
    a. Supplementation should be considered if the infant has failure to meet growth goals (15-20 g/kg/day) despite receiving maximal calories and protein and meets 1 of the following:
        i. Infant < 1500 grams
        ii. High ostomy/GI output
        iii. Chronic use of diuretics or steroids
    b. Start with 2 mg/kg/day of zinc acetate supplementation and continue for 2 weeks then discontinue. If poor growth persists following discontinuation, restart zinc supplementation. Monitor serum copper and serum zinc levels and for anemia if on zinc supplementation for > 4 weeks. Serum zinc level requires 4 mL of blood. Optimal level for serum zinc in preterm infants is 74-146 mcg/dL.
3. Preterm infants should be monitored for evidence of metabolic bone disease, with supplementation added as needed.
    a. For infants requiring Calcium Phosphate Tribasic supplementation, order in 250 mg increments. Calcium Phosphate Tribasic provides 100 mg elemental calcium and 46 mg elemental phosphorus per 250 mg (1/8 tsp). Typically start with dosing twice per day. Refer to Table 4 for more information.
4. Serum sodium levels should be monitored as clinically appropriate, especially in infants on sodium-reducing medications and sodium supplementation added to ensure maintenance of adequate serum sodium levels.

Recommendations for Term Infants

1. Begin vitamin D supplementation to reach a total of 400 IU per day from supplementation and feeds once goal feeding volumes reached.
    a. Infants (breastfed or formula fed): require 400 IU vitamin D per day. 1 ml of infant vitamin D drops provide 400 IU Vitamin D.
        i. Formula-fed infants: continue vitamin D supplementation until the infant consumes 1 liter of infant formula daily (1 liter of infant formula provides approximately 400 IU vitamin D).
    b. Recommend checking vitamin D 25-OH levels for infants who have been on anti-epileptic medications for > 1 month.
2. Start iron supplementation at 4-6 months of age for infants receiving breast milk, unless earlier supplementation indicated. 11 mg/day is the RDA for infants 7-12 months of age. 1 mL of Poly-Vi-Sol with iron contains 11 mg of iron. Formula contains iron and further iron supplementation is usually not indicated.
3. For infants receiving breast milk at 6 months, an additional source of zinc is indicated, as breast milk is lower in zinc. This can be achieved by introducing complementary foods that contain zinc (ex. meat).
4. If an infant remains hospitalized at 6 months of age, it should be noted that patient will not have a source of fluoride.

Glossary

1. Tolerable Upper Intake Level (UL): The highest level of nutrient intake that is likely to pose no risk of adverse health effects for almost all individuals in the general population. As intake increases above the UL, the risk of adverse effects increases.
2. Very Low Birth Weight (VLBW): Infants born less than 1500 grams at birth.
3. Recommended Dietary Allowances (RDA): the average daily dietary intake level that is sufficient to meet the nutrient requirements of 97-98 percent of healthy individuals in a group.
4. MVI: Multivitamin
5. LOE – level of evidence (based on Centre for Evidence-based Medicine, United Kingdom, 2015)
    - 1a - Systematic review (with homogeneity) of randomized controlled trials (RCT)
    - 1b - Individual RCT with narrow confidence interval (CI)
    - 2a - Systematic review (with homogeneity) of cohort studies
    - 2b - Individual cohort studies and low-quality RCTs
    - 3a - Systematic review (with homogeneity) of case-control studies
    - 3b - Individual case-control studies
    - 4 - Case series, poor-quality cohort and poor-quality case-control studies
    - 5 - Expert opinion without explicit critical appraisal

    If a minus sign is suffixed (e.g., 1a− or 1b−), it denotes either a single study with wide CI or a systematic review with troublesome heterogeneity.
6. MFNI: Maternal, Fetal and Neonatal Institute

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