JOHNS HOPKINS ALL CHILDREN'S HOSPITAL

Vitamin D Deficiency and Metabolic Bone Disease in NICU Clinical Pathway

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All Children's Hospital

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Johns Hopkins All Children's Hospital

Vitamin D Deficiency and Metabolic Bone Disease in NICU

Clinical Pathway

Rationale:

This clinical pathway was developed by a consensus group of Johns Hopkins All Children's Hospital (JHACH) Neonatologists, Dietitians, Advanced Practice Providers, Pharmacists, Nurses, and Endocrinologists to standardize the evaluation and management of infants at risk for vitamin D deficiency (VDD) and metabolic bone disease (MBD) in the Level 4 Neonatal Intensive Care Unit (NICU). It addresses the following key clinical questions and problems:

1. When to evaluate: Optimal timing and indications for serum vitamin D testing, including early screening before the current 4 – 6 weeks standard, and triggers such as alkaline phosphatase (ALP) > 500 units/L or clinical signs of impaired bone homeostasis
2. When to initiate or adjust supplementation: Evidence-based dosing recommendations based on the severity of VDD (vitamin D level < 30 ng/mL) and standardized definitions of deficiency categories to guide therapy
3. When to monitor and re-test: Recommended intervals for repeat laboratory monitoring to ensure adequate vitamin D levels and timely response to therapy
4. When to consult subspecialists: Criteria for involving Endocrinology or other specialties (e.g., for persistent VDD or suspected MBD)

Background / Published Data and Levels of Evidence:

VDD:

Vitamin D is essential for the active absorption of calcium and for maintaining skeletal health [Abrams]. It plays a crucial role in bone health for all individuals, including infants, regardless of size or gestational maturity [Abrams]. Very preterm neonates, less than 32 weeks of gestation, are at higher risk of developing VDD [Kotodziejcyzk-Nowotarska]. Inadequate vitamin D levels in infants lead to an increased risk of poor bone mineralization, resulting in bone fractures, rickets, and MBD in premature infants [Abrams; Kumar]. VDD is also associated with an increased risk of hypocalcemic seizures, pulmonary function deficits, impaired neurodevelopment, and reduced bone mass in children and young adults [Kumar]. In neonates, low vitamin D levels are also linked to impaired immune function [Kumar].

Transplacental transmission of vitamin D predominantly occurs during the third trimester of pregnancy, making VDD more prevalent in preterm infants [Boskabadi]. Since neonatal vitamin D status reflects maternal levels, early supplementation has been suggested to prevent deficiency [Abrams]. Recommendations for full-term infants advise starting vitamin D supplementation within the first few weeks, if not the first days of life [Abrams]. In very low birth

weight (VLBW) infants, vitamin D introduction may begin early, ensuring that a minimal feed volume is well tolerated before supplementation [Abrams]. It is important to provide vitamin D to infants even if not yet receiving enteral nutrition to prevent extremely low levels, which can increase bone resorption and affect bone mineralization [Abrams]. A prospective cohort study by Sarıdemir et al found that administering oral vitamin D supplementation at 400 units/day once enteral feeds reached 50% of total intake (~80 mL/kg/day) led to most VLBW infants with deficient or insufficient 25-hydroxyvitamin D (25(OH)D) levels reaching sufficiency by day of life (DOL) 30.

There is a lack of consensus among professional organizations regarding the optimal level of vitamin D and ideal doses for supplementation [Stocia]. However, European studies have suggested cutoff values for defining vitamin D status based on circulating 25(OH)D levels: severe deficiency is classified as < 10 ng/mL, deficiency as < 20 ng/mL, insufficiency as 20 – 29 ng/mL, sufficiency as ≥ 30 – 100 ng/mL, and toxicity as > 100 ng/mL [Stocia; Saggese; Kotodziejcyzk-Nowotarska]. The European Society of Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) recommends prophylactic vitamin D supplementation of 800 – 1,000 units/day during the first months of life for preterm infants to quickly correct VDD [Abrams; Corsello]. Supplementing preterm infants to a total intake of 800 – 1,000 units/day is generally considered safe, with little concern for toxicity or the need for close monitoring, in European countries [Abrams]. By contrast, the standard recommendation in the United States (U.S.) remains 400 units/day. A randomized controlled trial by Aristizabal et al demonstrated that VDD in extremely preterm infants requires more than 400 units/day to correct deficiency before full enteral feeding is established. This study reported that a vitamin D dose of 800 units/day safely corrected deficiency in extremely preterm infants by DOL 14. The Endocrine Society recommends that the tolerable upper intake level for vitamin D supplementation in infants up to 6 months of age should be 1000 units/day, not to be exceeded without medical supervision. However, higher doses, up to 2000 units/day or more, may be required to correct deficiency in infants and can be used under close medical supervision with regular monitoring of vitamin D levels [Holick].

Another European randomized controlled trial by Kołodziejczyk-Nowotarska et al described a monitored therapy schedule for vitamin D supplementation in infants. It begins with assessing 25(OH)D levels within the first 7 DOL, followed by an initial dose of 500 units of vitamin D. At approximately 4 weeks of age, 25(OH)D levels are measured to determine the appropriate supplementation strategy. Infants with 25(OH)D levels < 20 ng/mL receive 1,000 units, while those with levels 20 – 30 ng/mL receive 500 units or 750 units, depending on weight. Infants with 25(OH)D levels 30 – 50 ng/mL are supplemented with 500 units, whereas those with levels 50 – 80 ng/mL receive 250 units. No supplementation is given to infants with 25(OH)D levels > 80 ng/mL. If 25(OH)D levels remain < 20 ng/mL, an additional 500 units is provided. For 25(OH)D levels 20 – 30 ng/mL, an additional 250 units is given. Infants with 25(OH)D levels 30 – 50 ng/mL continue their current dose. Those with levels 50 – 80 ng/mL have their supplementation reduced by 250 units, with a minimum of 250 units maintained beyond 40 weeks post-conceptional age (PCA). Infants with 25(OH)D levels > 80 – 100 ng/mL have their supplementation reduced by 500 units or completely discontinued. These findings suggested

that high-dose vitamin D supplementation in preterm infants should be implemented with proper monitoring to prevent overdosing [Kotodziejcyzk-Nowotarska].

MBD:

Approximately 80% of calcium and phosphorus placental transfer occurs between 24 and 40 weeks of gestation, making preterm infants vulnerable to VDD-related complications such as MBD and low bone mineral status [Ukarapong]. This disease is most common in infants born before 32 weeks of gestation, particularly those with VLBW (< 1,500 g). Additional risk factors for these preterm infants to develop MBD are intrauterine growth restriction, prolonged parenteral nutrition (PN), short bowel syndrome, exposure to chronic use of medications affecting bone metabolism, such as loop diuretics, caffeine, steroids, prostaglandins, phenobarbital, and antacids [Grover]. The peak onset of MBD typically occurs between 4 and 8 weeks of postnatal age, requiring close monitoring [Ukarapong].

There is a lack of consensus on the definition of MBD and best practices for its monitoring and treatment. Kołodziejczyk-Nowotarska et al define MBD based on biochemical criteria, including serum ALP > 500 units/L and phosphorus < 5.5 mg/dL, or ALP > 900 units/L, along with radiological findings of bone demineralization and/or fractures. Given the absence of standardized definitions and protocols, screening practices are largely influenced by individual center guidelines and physician preference.

Some institutions in the U.S. have already established MBD screening guidelines. Creed et al describe a primary and secondary screen to assess for MBD. The primary screening at 4 – 6 weeks of life includes obtaining serum calcium, phosphorus, and ALP levels. Secondary screening is conducted if ALP is > 500 units/L, phosphorus is < 5.5 mg/dL, or calcium is < 8.5 mg/dL. This includes obtaining parathyroid hormone (PTH), 25(OH)D levels, and a set of labs for calculating the tubular resorption of phosphate (TRP), which includes urine creatinine, urine phosphorus, serum creatinine, and serum phosphorus. A long bone radiograph (X-ray) of the wrist or knee should also be obtained to assess for signs of MBD. Follow-up testing is conducted within 1 – 2 weeks for calcium, phosphorus, ALP, and PTH (if initially abnormal). If primary screening results are normal, monitoring continues with repeat testing every 2 – 4 weeks [Creed].

Clinical Management:

Vitamin D deficiency screening:
Target population: all infants born between 22 – 41 weeks of gestational age (GA)

- Exclusion criteria: infants enrolled in the Intestinal Rehab (IR) Program will be managed according to IR team recommendations.

Initial screening:

- Initiate vitamin D supplementation for preterm and term infants based on current practice:

    - For infants < 1,250 grams: start 300 units/day
    - For infants ≥ 1,250 grams: start 200 units/day (*note: this amount was previously provided in 0.5 mL of the multivitamin with iron*)
    - For term infants: start 400 units/day
    - Note: This initial supplementation should begin once the infant reaches a minimum enteral feed volume of 80 mL/kg/day, rather than waiting until full enteral feeds are established
- Obtain the first 25(OH)D level between 2 – 4 weeks of age:
    - At 2 weeks of age, if the infant is receiving at least 80 mL/kg/day of enteral feeds and is on vitamin D supplementation
    - At 4 weeks of age, if the infant has not yet reached minimal enteral feeds (≥ 80 mL/kg/day) and has not started vitamin D supplementation by 2 weeks of age
    - If 25(OH)D < 30 ng/mL, increase supplementation based on severity: (*note: doses can be divided twice daily (BID) or three times daily (TID)*)
        - Severe deficiency (< 10 ng/mL): increase to 1,000 units/day
        - Moderate deficiency (10 – 19 ng/mL): increase to 800 units/day
        - Mild deficiency (20 – 29 ng/mL): increase to 600 units/day
    - If 25(OH)D ≥ 30 ng/mL: Continue current dose

Follow-up monitoring:

- If 25(OH)D < 30 ng/mL:
    - Recheck 25(OH)D level in 2 weeks
        - If still < 30 ng/mL, adjust dose according to the following protocol and repeat every 2 weeks until 25(OH)D level is normal (≥ 30 ng/mL) for two consecutive checks:
            - < 10 ng/mL: add 600 units
            - 10 – 19 ng/mL: add 600 units
            - 20 – 29 ng/mL: add 400 units
            - ≥ 30 ng/mL: maintain current dose
    - If the 25(OH)D level remains < 30 ng/mL for three or more consecutive checks after optimizing supplementation and the infant is already receiving a total of 2,000 units of vitamin D supplementation, consider an Endocrinology consult for further recommendations only if the level is not improving.
        - Note: this does not apply if the infant was placed nothing by mouth (NPO) and supplementation was discontinued for a period
- If 25(OH)D level is ≥ 30 ng/mL but ≤ 80 ng/mL:
    - Recheck 25(OH)D level every 2 weeks if the infant is receiving ≥ 1,000 units/day of supplementation
    - Recheck 25(OH)D level every 4 weeks if the infant is receiving < 1,000 units/day of supplementation
    - If two consecutive 25(OH)D levels are ≥ 30 ng/mL but ≤ 80 ng/mL:
        - Space 25(OH)D level monitoring to every 6 weeks x2, then space to every 8 weeks

- If 25(OH)D level > 80 ng/mL:
    - Decrease dose by half or reduce to the maintenance dose of 400 units/day
    - Recheck level every 2 weeks until normalized, then space to every 4 weeks

Discharge:

- If the infant is discharged on > 400 units/day of vitamin D supplementation, a prescription should be sent to the JHACH Pharmacy, as they provide a syringe for accurate dosing
- If the infant is ready for discharge on high-dose vitamin D supplementation (≥ 1,000 units/day), an Endocrinology consult is recommended for outpatient follow-up and continued management of vitamin D supplementation
- If the infant is on < 1,000 units/day of vitamin D, the primary care provider (PCP) should provide close outpatient follow-up and monitoring; recommended follow-up includes:
    - Recheck 25(OH)D level in 2 weeks if the last level obtained before discharge was low
        - If level still < 30 ng/mL, adjust dose according to the following protocol and repeat every 2 weeks until 25(OH)D level is normal (≥ 30 ng/mL)
            - < 10 ng/mL: add 600 units
            - 10 – 19 ng/mL: add 600 units
            - 20 – 29 ng/mL: add 400 units
            - ≥ 30 ng/mL: maintain current dose
    - Recheck 25(OH)D levels in 4 – 6 weeks if the last level obtained before discharge was normal
        - A normal, stable level is between 30 – 80 ng/mL
    - For formula-fed infants: if the 25(OH)D level is > 50 ng/mL and the infant is feeding well, consider reducing the dose by half
        - If the level remains > 50 ng/mL on recheck and the infant is clinically stable and feeding well, supplementation may be discontinued
    - For exclusively breastfed infants: if the 25(OH)D level is > 50 ng/mL and the infant is feeding well, consider reducing the dose to maintenance of 400 units/day
        - Repeat the 25(OH)D level in 4 – 6 weeks; if it remains in the 30 – 80 ng/mL range, continue the maintenance dose and discontinue further 25(OH)D level checks
    - Use the dotphrase .vitamindnicudischarge in the After Visit Summary (AVS) to provide these follow-up recommendations for the PCP

MBD screening:

Target population: infants born at < 32 weeks GA or VLBW (< 1,500 g)

Initial screening:

- Timing: obtain primary screening labs for MBD at 4 weeks of age
    - Labs to include ALP, phosphorus, and calcium

    - If ALP is found to be > 500 units/L before 4 weeks of age, follow the management protocol outlined below
- If any of the following criteria are met:
    - ALP > 500 units/L, calcium < 8.5 mg/dL, or phosphorus < 5.5 mg/dL
        - Actions:
            1. Optimize calcium and phosphorus intake based on the Dietitian's recommendations
                - This may include increasing fortification, adjusting PN, or starting enteral mineral supplementation
            2. If a 25(OH)D level was obtained at 4 weeks and is < 30 ng/mL, increase vitamin D supplementation as indicated:
                - Severe deficiency (< 10 ng/mL): increase to 1,000 units/day
                - Moderate deficiency (10 – 19 ng/mL): increase to 800 units/day
                - Mild deficiency (20 – 29 ng/mL): increase to 600 units/day

Follow-up monitoring:

- If initial labs are abnormal:
    - Repeat primary screening MBD labs (ALP, phosphorus, and calcium) in 2 weeks
        - If still abnormal:
            - Optimize calcium and phosphorus supplementation per the Dietitian's recommendations
            - Adjust vitamin D supplementation based on the severity, if a 25(OH)D level is obtained at this time
- If initial labs are normal:
    - Repeat primary screening MBD labs in 2 – 4 weeks to continue monitoring
- If ALP is down-trending from its peak value after calcium, phosphorus, and vitamin D optimization:
    - Continue current intake/supplementation and monitor ALP every 1 – 2 weeks
    - If ALP is < 500 units/L for 2 consecutive checks, routine MBD screening can be discontinued
- If ALP remains > 500 units/L and is not down-trending after 3 consecutive lab checks:
    - Consult Endocrinology
    - Obtain secondary screening labs: ALP (isoenzymes), parathyroid hormone (PTH) level, magnesium, urine calcium, urine phosphorus, urine creatinine, serum creatinine, and serum phosphorus
        - Urine and serum samples for creatinine and phosphorus will be used to calculate the TRP
        - The Endocrinologist should perform TRP calculation and interpretation
        - The urine and blood samples must be collected as closely in time as possible

- Obtain imaging to assess for MBD:
  - Preferred study: long bone X-ray of wrist or knee, specifically to assess for MBD
  - If a routine X-ray (e.g., chest or babygram) is already being obtained currently, please include in the indication to assess for MBD
  - If no imaging is planned within the next few days, then obtain a dedicated long bone X-ray (wrist or knee) to evaluate for signs of MBD

Diagnosis criteria:

- An infant is diagnosed with MBD if they meet the biochemical criteria, serum ALP > 500 units/L and phosphorus < 5.5 mg/dL, or ALP > 900 units/L**,** and have radiological findings of bone demineralization and/or fractures
  - Place "Fragile bones, handle with care" sign near the patient's isolette or crib
- If the infant has only biochemical abnormalities without radiological findings, the infant is considered to have impaired bone homeostasis and at risk for developing MBD
  - At this time, consider discontinuation of medications that do not promote bone mineralization as clinically appropriate (e.g., loop diuretics, caffeine, steroids, phenobarbital, antacids).

Discharge:

- Infants diagnosed with MBD should receive outpatient follow-up with Endocrinology

Summary:

Table 1. Vitamin D deficiency severity cutoff values

Vitamin D deficiency severity	Vitamin D levels (ng/mL)
Normal	≥ 30 – 100
Mild	20 – 29
Moderate	10 – 19
Severe	< 10

Table 2. Initial vitamin D supplementation based on the first screening level

Vitamin D level (ng/mL) at first check at 2 – 4 weeks of age	Vitamin D dose
< 10	Increase to 1,000 units/day
10 – 19	Increase to 800 units/day
20 – 29	Increase to 600 units/day
≥ 30	Keep the current dose

Note: doses can be divided BID or TID

Table 3. Vitamin D dose adjustment based on follow-up levels

Vitamin D level (ng/mL) in subsequent checks (every 2 – 4 weeks)	**Vitamin D dose**
< 10	Add 600 units
10 – 19	Add 600 units
20 – 29	Add 400 units
≥ 30	Keep the current dose

Note: if level > 80 ng/mL, decrease dose by ½ or keep at maintenance (400 units*), recheck level every 2 weeks until normalized*

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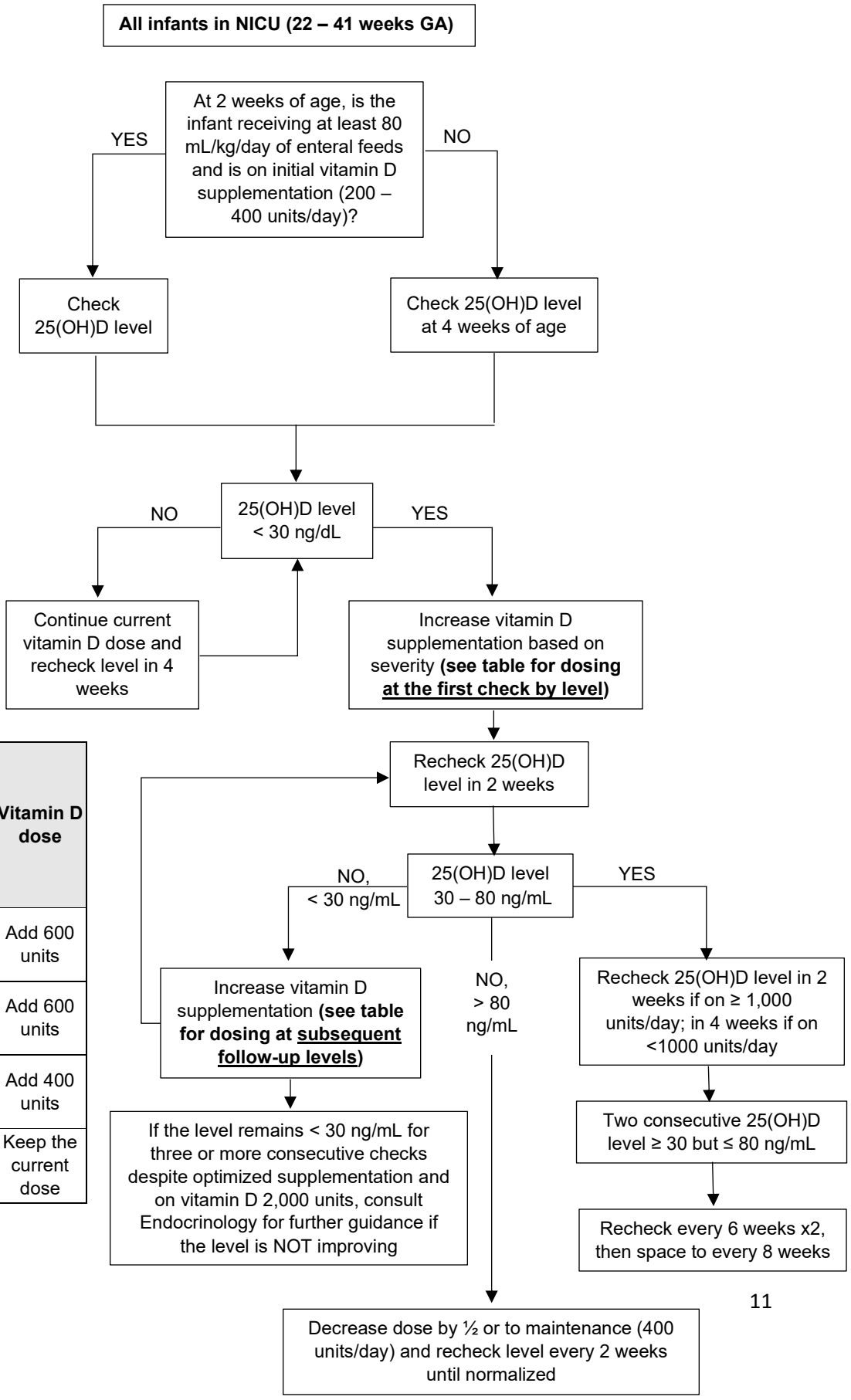
NICU Vitamin D Deficiency Screening Algorithm



Vitamin D level (ng/mL) at first check at 2 – 4 weeks of age	Vitamin D dose	Vitamin D level (ng/mL) in subsequent checks	Vitamin D dose
< 10	Increase to 1,000 units/day	< 10	Add 600 units
10 – 19	Increase to 800 units/day	10 – 19	Add 600 units
20 – 29	Increase to 600 units/day	20 – 29	Add 400 units
≥ 30	Keep the current dose	≥ 30	Keep the current dose

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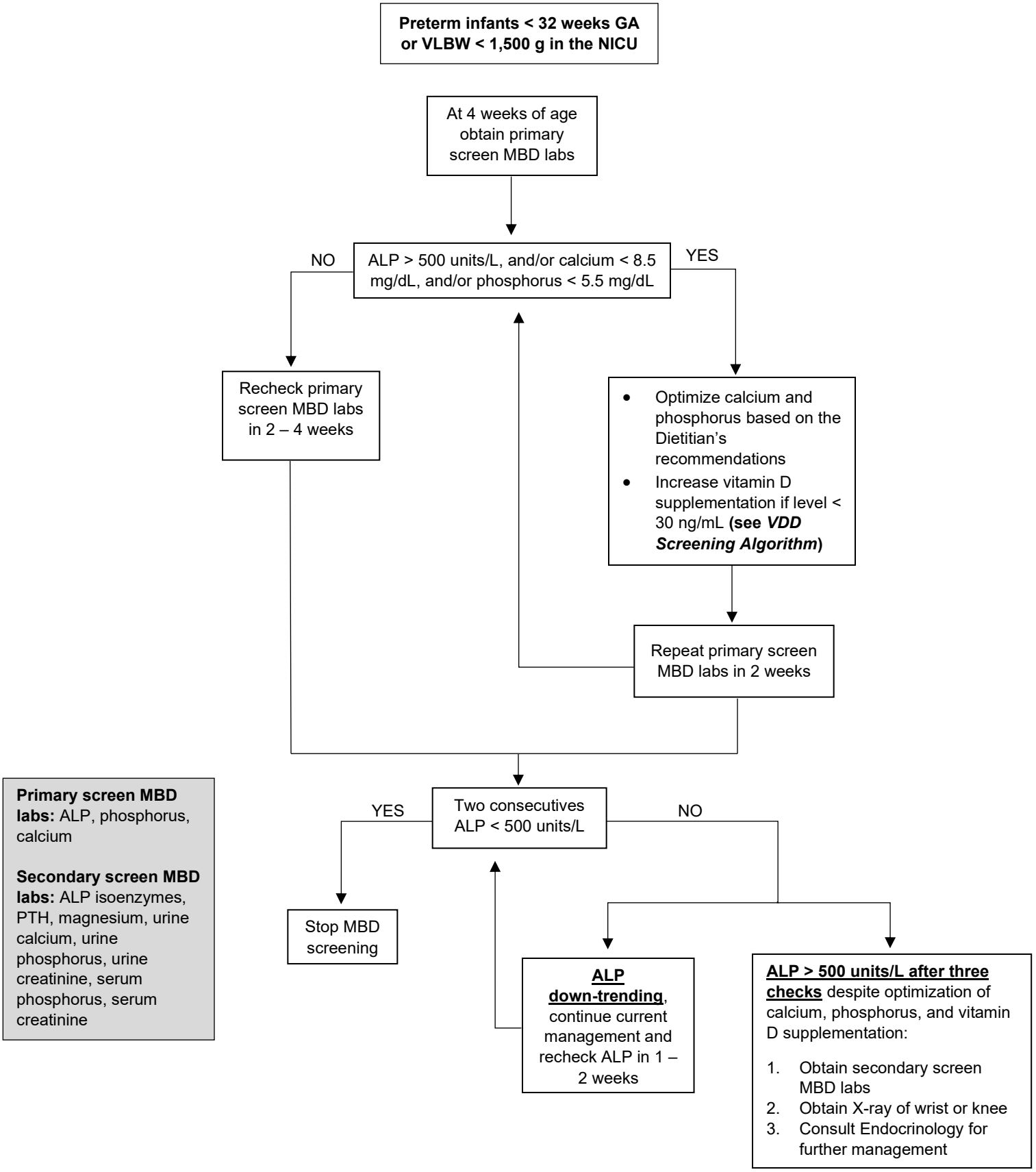
NICU Metabolic Bone Disease Screening Algorithm



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Outcome Measures:

1. Percentage of infants with vitamin D deficiency (< 30 ng/mL) whose levels normalized (≥ 30 ng/mL) after supplementation during their NICU stay
2. Percentage of infants with MBD, defined as biochemical changes (serum ALP > 500 units/L and phosphorus < 5.5 mg/dL or ALP > 900 units/L) and radiological findings related to bone demineralization and/or fractures
3. Adherence to standardized screening and supplementation protocols, including timeliness of lab monitoring and interventions

Clinical Pathway Team

Vitamin D Deficiency and Metabolic Bone Disease in NICU Clinical Pathway

Johns Hopkins All Children's Hospital

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Disclaimer:

Clinical Pathways are intended to assist physicians, physician assistants, nurse practitioners, and other health care providers in clinical decision-making by describing a range of generally acceptable approaches for the diagnosis, management, or prevention of specific diseases or conditions. The ultimate judgment regarding care of a particular patient must be made by the physician, considering the individual circumstances presented by the patient.

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