INPATIENT GUIDELINE

Vitamin K Refusal Guideline – Critical Care

Children's MINNESOTA

Aim: Standardize education and response to infants <6 months of age who have not received Vitamin K.

EXCLUSIONS
Patients **excluded** from this guideline:
- Already received Vitamin K

Newborn in the critical care units of Children's Minnesota (Neonatal Intensive Care Units of Minneapolis, St. Paul, and Mercy; Infant Care Center of Minneapolis; Special Care Nurseries of Minneapolis, CVICU, PICU)

Provide parents with **"Vitamin K Patient & Family Education Materials"** (Note B, page 5)

Parents provide assent to Vitamin K?

- **Yes** → Infant weight?
  - < 1 kg → 0.3 mg IM once within 6 hours of birth
  - 1-1.5 kg → 0.5 mg IM once within 6 hours of birth
  - > 1.5 kg → 1 mg IM once within 6 hours of birth
- **No**
  - Provide "**Children's Minnesota Informed Refusal of Vitamin K Form**" (Note A, page 5) and ask parents to sign. Upload to medical chart (***See Note 1 regarding oral vitamin K***). Document in healthcare maintenance section of progress note and narrative summary using dotphrase ".VKSIGN". If parents decline to sign, see Note 2.
  - Add Z53.20 to the patient's Problem List
  - Delay elective procedure or surgery until >6 months of age or 48 hours after IM vitamin K has been given to patient.

Next step:
Any of these statements TRUE?

Does the patient require intubation, chest compressions or cardiac medications during **active resuscitation**, have **acute bleeding** or **coagulopathy, or require ECMO** <u>and</u> parent(s) continue to decline vitamin K prophylaxis? (Note 4)

- **Yes** → Proceed according to the emergent management pathway on page 4
- **No**

Does the patient require an urgent surgical or invasive procedure (e.g., central line placement, arterial access, lumbar puncture, chest tube placement, peritoneal/pericardial drain placement) for which no medically reasonable alternative exists, while parent(s) continue to decline vitamin K? *(If parents refuse vitamin K and there are medically reasonable alternatives, it is appropriate to not offer the procedure. Discussion on alternative treatment options risks and benefits and why alternatives are inadequate, if applicable, should be documented in the provider's note.) (Note 4)*

- **Yes** → Evaluate and correct coagulopathy prior to the procedure when clinically feasible. Consult Hematology for recommendations regarding ongoing monitoring and management. If the procedure is emergent and cannot be delayed for correction of coagulopathy, proceed according to the emergent management pathway (see Page 4).
- **No**

Document continued declination despite change in clinical status in healthcare maintenance section of progress note and narrative summary. Contact risk on call per note 3.

Note 1: It is not recommended to offer oral vitamin K as an alternative. See Children's Minnesota Home Medication Policy for parents who bring oral vitamin K. See Note C, page 5.
Note 2. Document in chart if parents decline to sign "Children's Minnesota Refusal of Vitamin K Form." Include in documentation that healthcare provider reviewed content of "Children's Minnesota Refusal of Vitamin K Form" with legal caregiver. Use dotphrase .VKNOSIGN.
Note 3. If parents are declining additional standards of care beyond vitamin K or life-saving/sustaining treatments recommended by provider, consult risk on call.
Note 4. Coagulation studies resulting at normal do NOT rule out risk of bleeding from vitamin K deficiency.

AMBULATORY GUIDELINE

Vitamin K Refusal Guideline - Clinic

Children's MINNESOTA

Aim: To standardize offering, administration of, and ongoing refusal of Vitamin K in clinics.

EXCLUSIONS
Patients **excluded** from this guideline:
- Already received Vitamin K

Infant seen in primary care clinic that has not yet received IM Vitamin K

Offer IM Vitamin K at every clinic visit through age 6 mos and provide parents with **"Vitamin K Patient & Family Education Materials"** (Note B, page 5) if not provided already. Document education given. Did parents assent to IM Vitamin K? (Note 5 and 6)

Note 5: IM Vitamin K would be given at any time parent consents, up to 6 months of age. For timing of effectiveness, it is recommended to wait 48 hours after administration before performing elective procedures (INR will correct quickly, but this is not reflective of coagulation status).

Note 6: It is not recommended to offer oral vitamin K as an alternative. See Note C, page 5.

Yes

Does the clinic stock IM vitamin K? (Note 9)

Yes

Give Vitamin K 1 mg IM once

No

Refer to outside source (Note 10)

No

Provide "**Children's Minnesota Informed Refusal of Vitamin K Form**" (Note A, Page 5) to parents

- Ask parent to sign "**Children's Minnesota Informed Refusal of Vitamin K Form**" and upload to medical chart (done once, even if ongoing refusal) (***See Note 7 if parents decline***).
- Document declination of Vitamin K in healthcare maintenance section of clinic note (every visit up to 6 months) and use dotphrase: **.VKSIGN**
- Add Z53.20 to the patient's Problem List (every visit up to 6 months) (Note 8)

Note 7: Document in chart if parents decline to sign **"**Children's Minnesota Refusal of Vitamin K Form." Include in documentation that healthcare provider reviewed content of Children's Minnesota Refusal of Vitamin K Form" with legal caregiver. Use dotphrase **.VKNOSIGN**

Note 8: Elective outpatient surgeries/procedures will typically be postponed until 6 months or referred to the ED/hospital if infant has not received IM vitamin K (ie circumcision, frenulotomy, lumbar puncture, etc). Coagulation studies resulting as normal do NOT rule out risk of bleeding from vitamin K deficiency.

Note 9: Getting IM vitamin K in stock in clinics
- Ideally pre-filled syringes and not a vial (example: McKesson, NDC 76329-1240-01)
- Contact your distributor to start
- If needed, can connect with Children's Minnesota pharmacy department for assistance

Note 10: Outside sources for IM Vitamin K
- Children's Home Care – referral can be placed, and nursing will review and make sure family is within their radius and check with insurance. If covered, it can be prescribed to Children's Home Care Pharmacy, and they will bring it to family for administration.
- ED – can be referred to ED and have it given there.

HOSPITAL GUIDELINE

Vitamin K Refusal Guideline – ED/Med-Surg

Children's MINNESOTA

Aim: Standardize education and response to infants <6 months of age who have not received Vitamin K.

Note 11: At any point, if a parent consents, provide IM vitamin K (up to 6 months of age) if not needing urgent procedure. If needs semiurgent procedure, give IV Vitamin K (neonates 0-30 days: 2.5 mg IV; infants >30 days: 5 mg IV) daily for 5 days. Can proceed with procedure >24 hours after first IV dose. If meeting discharge criteria before 5 days are complete, give 1 mg IM Vitamin K before discharge. If needing emergent surgery, consult hematology.

Note 12: It is not recommended to offer oral vitamin K as an alternative. See Children's Minnesota Home Medication Policy for parents who bring oral vitamin K. See Note C, page 5

Note 13. Document in chart if parents decline to sign **"**Children's Minnesota Refusal of Vitamin K Form." Include in documentation that healthcare provider reviewed content of "Children's Minnesota Refusal of Vitamin K Form" with legal caregiver. Use dotphrase .VKNOSIGN.

Note 14: Coagulation studies resulting at normal do NOT rule out risk of bleeding from vitamin K deficiency.

Note 15. If parents are declining additional standards of care beyond vitamin K or life-saving/sustaining treatments recommended by provider, consult risk on call.

Patient <6 months who has not yet received IM Vitamin K

Is the patient actively bleeding AND/OR physiologically unstable or with life-threatening injuries/condition?

Yes → Proceed according to the emergent management pathway on page 4

No

Offer Vitamin K and provide parents with ***"*Vitamin K Patient & Family Education Materials**" (Note B, page 5). Parents assent to Vitamin K? (Note 11 and 12)

Yes → Give Vitamin K 1 mg IM once

No

- Provide "**Children's Minnesota Informed Refusal of Vitamin K Form**" (Note A, page 5) and ask parents to sign (once per admission). Upload to medical chart. Document in healthcare maintenance section of progress note and narrative summary using dotphrase ".VKSIGN". If parents decline to sign, see Note 13.
- Add Z53.20 to the patient's Problem List

Next step:
Any of these statements TRUE?

Does the patient require an **urgent/emergent surgical or invasive non-elective procedure** (e.g., central line placement, arterial access, lumbar puncture, chest tube placement, peritoneal/pericardial drain placement) for which no medically reasonable alternative exists, while parent(s) continue to decline vitamin K? *(If parents refuse vitamin K and there are medically reasonable alternatives, it is appropriate to not offer the procedure. Discussion on alternative treatment options risks and benefits and why alternatives are inadequate, if applicable, should be documented in the provider's note.) (Note 14)*

Yes → Evaluate and correct coagulopathy prior to the procedure when clinically feasible. Consult Hematology for recommendations regarding ongoing monitoring and management. If the procedure is emergent and cannot be delayed for correction of coagulopathy, proceed according to the emergent management pathway (see Page 4).

→ Document continued declination despite change in clinical status in healthcare maintenance section of progress note and narrative summary. Contact risk on call per note 15.

No

Does the patient have a scheduled **elective** procedure or surgery? (Note 14)

Yes → Discuss with parents that we will typically not perform **elective** procedure/surgery without Vitamin K in patients <6 mos (ultimate decision made by surgeon or proceduralist)

No

EXCLUSIONS

Patients **excluded** from this guideline:

- Already received Vitamin K

Disclaimer: This guideline is designed for general use with most patients; each clinician should use their own independent judgment to meet the needs of each individual patient. This guideline is not a substitute for professional medical advice, diagnosis or treatment.

HOSPITAL GUIDELINE

Bleeding and Emergent Procedure Pathway for Infants without Vitamin K Prophylaxis

Children's MINNESOTA

EXCLUSIONS
Patients **excluded** from this guideline:
- Already received Vitamin K

Aim: to standardize care for patients with severe vitamin K deficient bleeding.

Patient <6 months who has not yet received IM Vitamin K who is actively bleeding and/or physiology unstable and/or requiring emergent procedure per prior guideline pages?

If a cardiac patient, immediately consult pediatric cardiology and see Note 16

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- STAT IV access and CBC, plt, PT, PTT, liver panel, factor assays (5, 7, 8, 9) *[can hold factor assays if blood volume is a concern]*
- Consult hematology
- Imaging per provider discretion. STAT brain imaging if neurologic symptoms suspicious for intracranial hemorrhage. Do not delay steps in next box for imaging.

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1. Immediately administer IV Vitamin K depending upon the patient's age:
    - Neonates 0-30 days: 2.5 mg IV daily for 5 days
    - Infants >30 days: 5 mg IV daily for 5 days
2. IM Vitamin K 1 mg once
3. Per hematology discussion/recommendations, can begin one of the following for more immediate reversal:
    - If prothrombin complex concentrate (Kcentra) is available in the pharmacy, administer 30-50 units/kg IV once as soon as possible. 20 minutes following the administration, re-check PT/INR and PTT. If possible, also get factors 7, 9 to confirm reversal.

    OR
    - If prothrombin concentrate is not available, then transfuse FFP 15-20 ml/kg IV. Again, recheck PT/INR and PTT as well as factor levels as above 20 minutes following the infusion to confirm reversal.

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Further care off guideline and per consultant recommendations.

Note 16: Cardiology Patients:
- Immediately consult pediatric cardiology for all cardiology patients presenting with bleeding related to anticoagulation *prior* to reversal.
- These patients who have markedly prolonged PT/INR and serious or life-threatening bleeding clearly require reversal as noted above. It will be particularly important to consider ongoing anticoagulation as soon as possible following stabilization of the patient.
- The one exception to this is **infants with mitral valve replacement** who are at markedly increased risk of thrombosis with reversal. In these patients, prothrombin complex concentrate or FFP may be used as the primary method of reversal along with a small dose of IV Vitamin K (30 micrograms/kg). Discuss with cardiology about the reintroduction of anticoagulation as soon as it is safe.

Vitamin K Guideline - Supplemental Information

Aim: Standardize education and response to infants <6 months of age who have not received Vitamin K.

NOTES:

Note A: Vitamin K Refusal form links found on Star Net. Available in English, Hmong, Somali, and Spanish.

Note B: Vitamin K Patient & Family Education Materials: Vitamin K After Birth: Protect Your Baby from a Preventable Bleeding Disorder

Note C: Oral Vitamin K: there is lack of data showing oral is as effective as IM. It is not recommended to offer oral vitamin K as an alternative. See Children's Minnesota Home Medication Policy for parents who bring oral vitamin K.

- Absorption can be erratic
- Less effective in preventing late-onset VKDB compared to single IM dose
- Oral formulations studied in foreign countries are not available here

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