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Continuing Education | Children's Hospital Colorado

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Caregiver Refusal of Vitamin K and Vitamin K Deficient Bleeding- an evolving problem in ICUs and EDs

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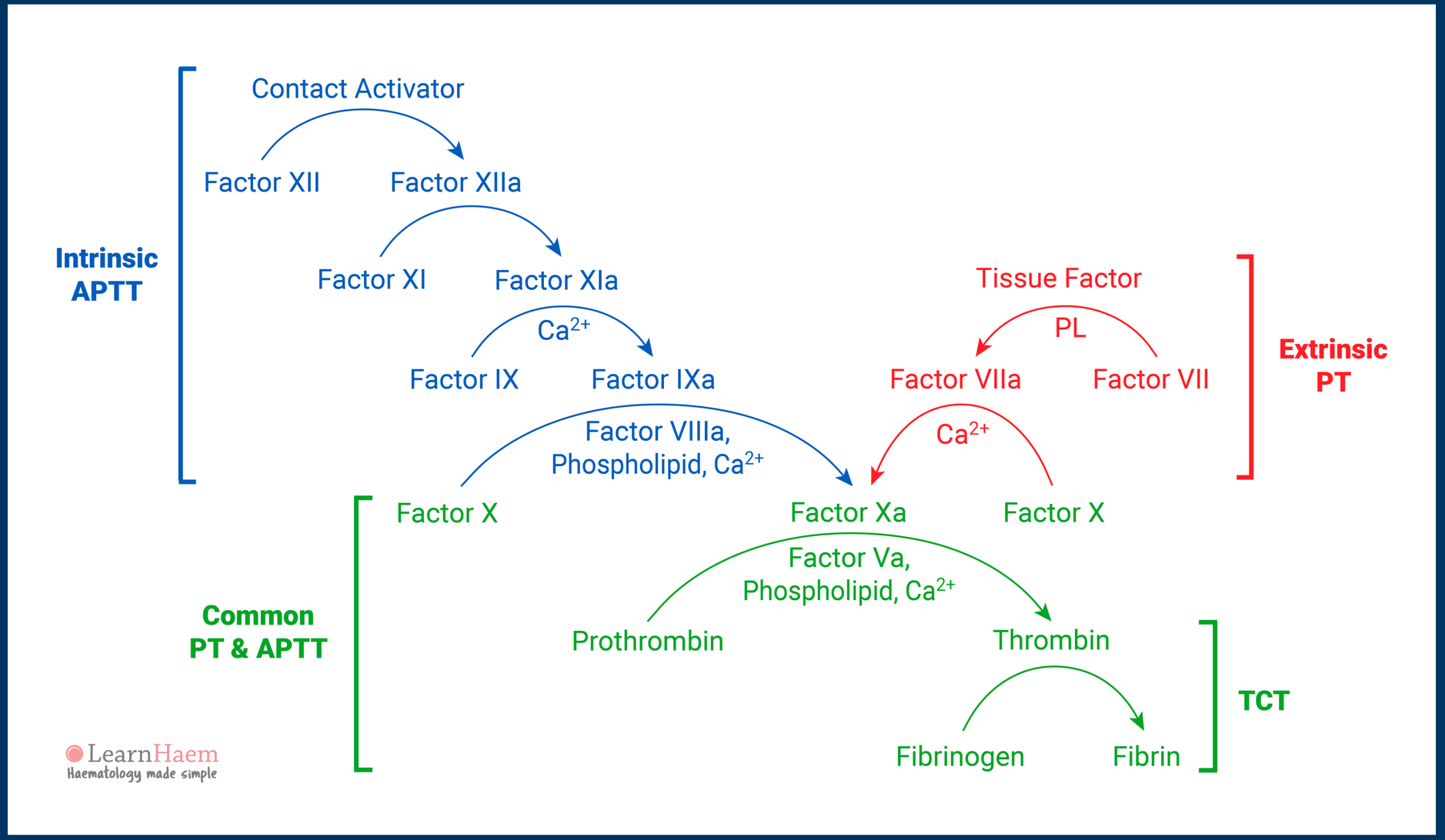
OBJECTIVES

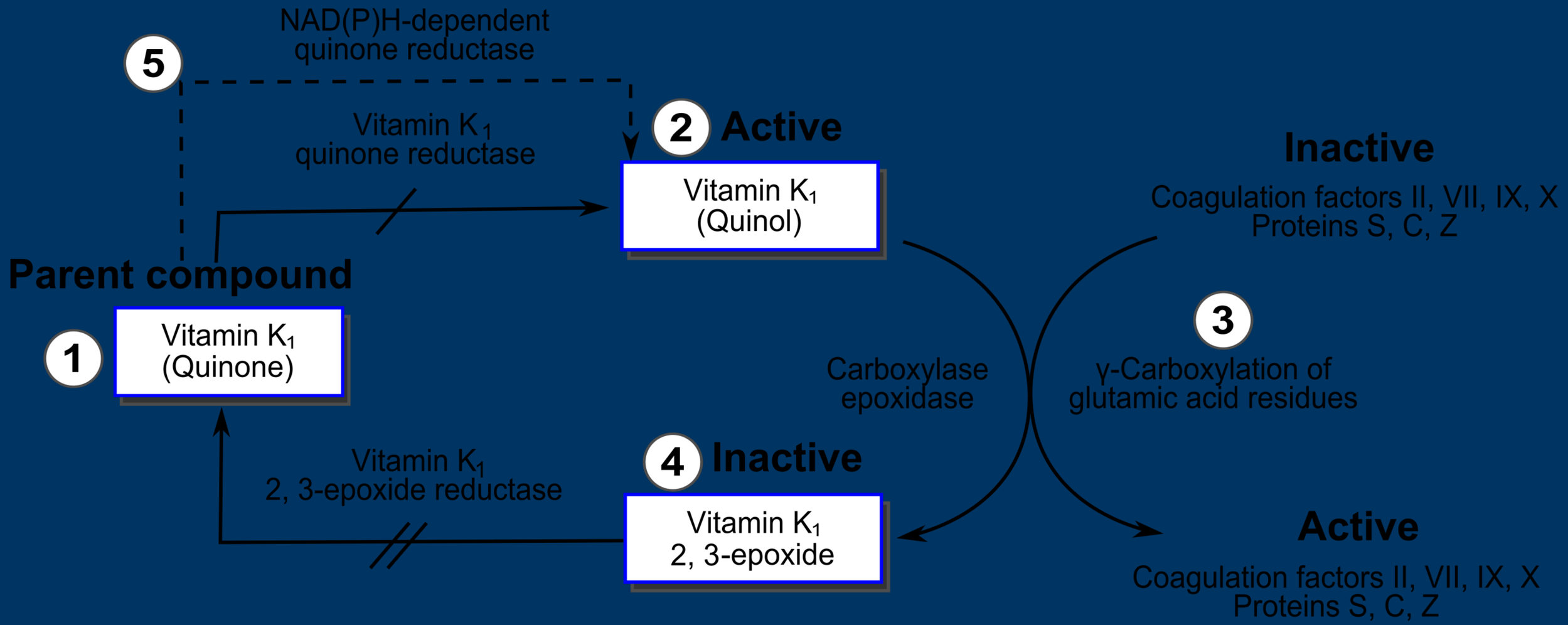
1. Review importance of the Vitamin K shot in the Newborn
2. The history of Vitamin K and Vitamin K Deficient Bleeding (VKDB)
3. Forms of VKDB
4. Parental Refusal of Vitamin K- an evolving dilemma. Reasons for refusal
5. Dispelling myths and exposing the truths
6. Differentiating VKDB from other ED presentations- Trauma and NAT
7. Strategies to discuss Vitamin K with hesitant parents

Case Study

- 6 week old former term female to ED, “not eating well” x 1 day. No fever, V/D, cough, congestion, rash, or sick contacts
  - Has not yet seen a pediatrician, religious beliefs forbade traditional medical care
  - Exclusively breastfeeding, home birth, uncomplicated L/D
  - Exam: Bulging AF, poor tone, HR 155, T 36.7, BP 121/45, no retinal hemorrhages but abnormal gaze, bruising left wrist and chest wall. Distal swelling of the left elbow.
  - Labs: Hgb 5.6, Hct 16.6%, PLT 155k, PT>130s, PTT > 96s.
  - Bleeding from all IV stick sites, CXR normal, Head CT: multiple areas of subdural and intraparenchymal hemorrhage with midline shift. Elbow: Periosteal elevation c/w healing fx

Coagulation Cascade




NAD(P)H-dependent
quinone reductase
5
Vitamin K1
quinone reductase
2 Active
Vitamin K1
(Quinol)
Inactive
Coagulation factors II, VII, IX, X
Proteins S, C, Z
Parent compound
1
Vitamin K1
(Quinone)
3
γ-Carboxylation of
glutamic acid residues
Carboxylase
epoxidase
Vitamin K1
2, 3-epoxide reductase
4 Inactive
Vitamin K1
2, 3-epoxide
Active
Coagulation factors II, VII, IX, X
Proteins S, C, Z

Vitamin K

1. Major role in coagulation pathways- cofactor to activate factors 2, 7, 9, 10 (clot)
2. Necessary to activate Proteins C and S (anti-clot)
3. Important for function of other proteins, including osteocalcin (bone formation)
4. Requires intact pancreatic and biliary function and fat absorptive mechanisms
5. Dietary Vit K is protein bound, requires pancreatic enzymes to release it for fun
6. Cofactor for gamma-glutamyl carboxylase to function

Vitamin K

**Vitamin K1: Phylloquinone, green/leafy vegetables, vegetable oils, dairy product

**AAP recommends 1mg IM x 1 within 6hrs all babies >1500g

(0.3-0.5 mg/kg in preterm infants up to 1500g)

Vitamin K2: Menaquinone, synthesized by gut flora

Vitamin K3: Menadione, synthetic, water soluble form no longer produced (caused hemolytic anemia)

Fetal Vitamin K- benefits

1. Decreases risk of fetal tumors in high mitotic environment (K induces tumors)
2. Since induces osteocalcin, lower levels make skeleton less rigid->easier delivery
3. Lower levels allow for normal growth rate and regulation

Vitamin K- factors leading to deficiency at birth and beyond

- Poor placental transfer (does not matter if mother increases intake during pregnancy
- Low Vitamin K in breast milk (even with maternal intake postnatally)
- Sterile gut at birth (bacteria can take weeks to months to colonize gut and make K-once the gut is colonized, microbial production of Vitamin K decreases VKDB risk)
- Liver immaturity at birth leading to inefficient utilization of Vitamin K and poor storage ability of neonatal liver

Vitamin K- History

1894: Dr. Charles Townsend in Boston documented 50 cases of bleeding in newborns. Referred to as Hemorrhagic Disease of the Newborn (HDN)

1930: Henrik Dam discovered Vit K deficiency in baby chicks caused bleeding

1944: Jörgen Lehmann studied 13,000 babies given 0.5mg Vitamin K on DOL 1, those who received Vitamin K had a 5-fold decrease in risk of bleeding to death in 1st week of life

1961: AAP recommends Vit K administration after birth to prevent HDN, name change to VKDB (Vitamin K deficient bleeding) because there are other causes of neonatal hemorrhages.

Vitamin K Deficient Bleeding- Scope of the Problem

~4 million babies born in the US per year. If stopped giving Vitamin K at birth, 12,000 to 18,000 babies per year would develop VKDB (>200/day)

2 of every 100 who do not get Vitamin K at birth develop VKDB

1 of every 5 babies with VKDB will die

2013, Tennessee: Cluster of infants with VKDB and ICH

3 FORMS OF VKDB:

1. EARLY

2. CLASSIC

3. LATE

VKDB- EARLY VKDB

EARLY VKDB:

- 1st 24 hrs of life, can be very serious and even fatal
- Related to maternal medications that interfere with Vitamin K metabolism, unclear

  AEDs (phenytoin, barbiturates, carbamazepine)

  Anti-TB meds (rifampin, isoniazid), Antibiotics, Warfarin

- Limited studies suggest can be prevented if give mother Vitamin K in last 2-4 weeks of pregnancy (currently not an AAP recommendation)
- Too late to give baby AFTER birth (Via K shot does not help with Early VKDB)

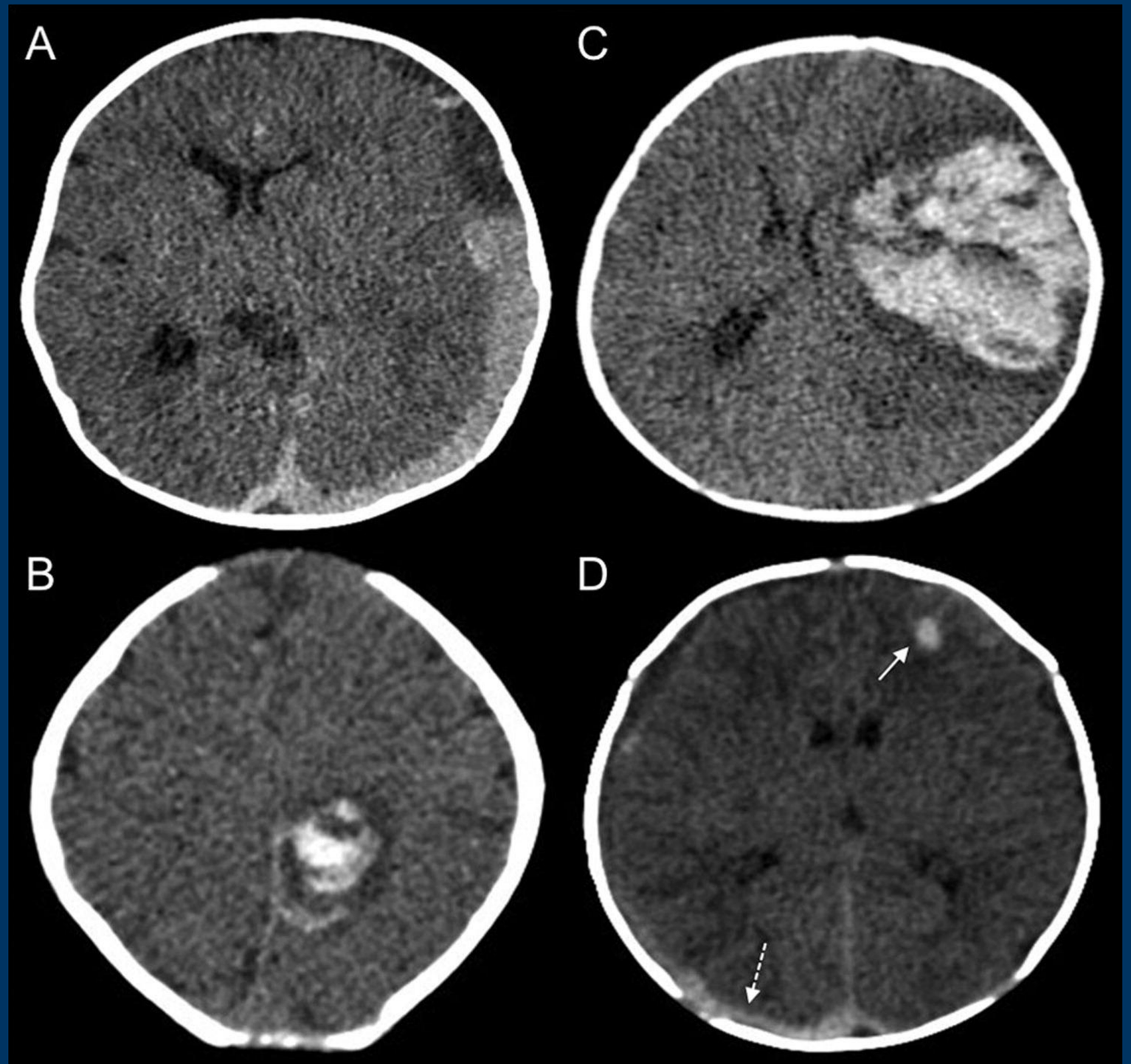

a
b

VKDB- CLASSIC VKDB

- Occurs 24 hours of life to 1 week of life, some suggest even up to 4 weeks of life and overlap with Late VKDB
- Observed in infants who have NOT received prophylactic Vitamin K at birth (0.5-1mg IM) in first 6 hrs of life
- Seen in 0.25 to 1.7 cases per 100 births
- Appear ill, usually poor feeding, bleeding at umbilicus, GI tract, skin, nose, surgical sites including circumcision

VKDB- LATE VKDB

- Occurs between 1 week of life up to 6 months of life
- Most common in the
    - Exclusively breastfed infant who did…
    - Not get the Vitamin K shot at birth
- Industrial contaminants in breast milk also implicated
- Low content of Vitamin K in breastmilk!
- More than 1/2 present with Acute intracranial hemorrhage (vomiting,seizures,fdng)
- Also seen in babies with hepatic/biliary dysfunction (hepatitis, atresias, malabsorptions)


A
C
B
D

LATE VKDB- Other risk factors

- Diarrhea
- Cystic Fibrosis
- Celiac Disease
- Alpha-1-Antitrypsin
- Short Bowel Syndrome
- Intestinal bacterial overgrowth
- Chronic exposure to broad spectrum antibiotics

VKDB

- Neonatal Morbidity, Mortality, and long-term neurologic developmental issues are a severe consequence of VKDB (motor and intellectual). Late VKDB 20-50% mortality
- Can easily be confused with NAT in presentation in infants up to 6 months of life
- Parental refusal of Vitamin K at birth is steeply not the rise, putting the lives of thousands at risk
- Even longer term developmental effects (development, learning, seizures) are thought to be on the rise, sometimes never attributed to, but actually caused by, chronic, sub- clinical ICHs throughout early infancy
- Bacteroides spp. best at synthesizing K, not E coli and NOT lactobacillus (breast-milk)
- Formula fed babies have higher fecal K1 and huge amounts K2 (vs. breastfed)

VKDB

- Frequency of Vitamin K deficiency bleeding is 1700 per 100,000 infants (1 of 59) if Vitamin K not given at birth
- When IM Vitamin K is given, risk of VKDB falls to 1 per 100,000 infants
- In absence of ICH, prognosis for VKDB is excellent if otherwise healthy
- Other sites of hemorrhage reported include adrenals and liver

Parental refusal of Vitamin K

1. MISINFORMATION is generally related to…
    - concerns about increased risk of cancer
    - Toxicity from additives
    - Increased risk of autism
2. Many parents do not have balanced information regarding benefits of vitamin K vs. limited risk of side effects
3. Incidence highest at birthing centers (vs. hospitals)
4. Birth wasn’t “traumatic”- not necessary
5. The Vitamin K shot causes cancer

- In one US Study (2016): 83% of parents reported awareness of risk of not receiving vitamin K, only 67% reported awareness of bleeding as a risk. Only 17% reported awareness of intracranial hemorrhage specifically, and 9% knew about risk of death (Hamrick et. al.)

- In this study, only 11% changes their mind after discussion (“dig in their heels”). Bed-side discussions and information sheets had little effect on changing minds.

    - Misinformation websites abound on the internet (most common source of information with those who refuse) including Dr. Mercola, Dr. Sears, and non-scientific sites. They contain biased interpretation of information obtained in their “research”

    - Most parents have made their decision to refuse Vitamin K long before delivery

    - Internet info often lacks support of peer-reviewed scientific evidence and generally presented to encourage completely natural birth experience without medical intervention

Parental Refusal of Vitamin K

- Concern for potential harm from foreign substances (e.g. benzyl alcohol)
- Desire for newborn to remain “natural”
- Influence from opinions of peers, social media
- Distrust in medical system
- Difficult to estimate rate of refusal d/t no national effort to track/record, but estimated to be as high as 3.2% of all live births in the USA in 2020, and increasing (this amounts to about 192,000 babies at risk annually with ~3 million births/yr in the US)
- Refusal of Vitamin K as high as 14.5% in home births, 31% in birthing centers
- Parents who refuse tend to also refuse Hep B vaccine, Emycin ophthalmic, and subsequent vaccinations

Parental Refusal of Vitamin K

The very success of Vitamin K supplementation in preventing VKDB may contribute to the problem, as many parents are unaware of its critical role.

Compare to car seat laws- most car trips do not end in accident, but failure to restrain your child properly IS Neglect- the potential harm is significant enough to mandate use. Why isn’t Vitamin K in most states not viewed similarly?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RESEARCH & DEVELOPMENT
ANTI-VACCINE
RESEARCH LABORATORY
200 MINUTES OF
INTENSE WEB BROWSING

Vitamin K: Myths and Truths

- ACTUAL Complications of Vitamin K include anaphylactoid reactions with IV (extremely rare), hyperbilirubinemia/hemolytic anemia with very high doses, and hematomas at site of administration

- IM dose side effects other than pain or swelling at injection site are considered “exceptionally rare”

- Anaphylaxis in neonate exceedingly rare d/t immature immune system, and benefits have been proven in millions of babies since US started recommending Vitamin K in all newborns in 1961, far outweighing the exceedingly rare risk of anaphylaxis (package insert still lists IM as having potential risk of anaphylaxis)

Myths and Truths

1. Most babies with VKDB have NO hx of traumatic birth, injury, or illness

2. The shot DOES NOT cause cancer- myth has been conclusively dispelled with large trials in multiple countries (1990s, Bristol England, single study by single researcher who claimed to find an association with childhood leukemia and Vitamin K)

3. Toxic ingredients: PF form has NO benzyl alcohol (gasping syndrome). In non-PF formulations, need 100x the amount of benzyl alcohol in shot to cause side effects

    - Vitamin K1

    - Polyoxyethylated fatty acid derivative (solvent/emulsifier)- allergic rxn in older kids

    - Hydrochloride (tiny ants)- stabilize pH

    - Dextrose

MYTHS and TRUTHS

- Trauma from Shot not nearly as traumatic physiologically on a baby than the process of labor and delivery itself.

Scope of Parental Rights

- Parents do not have UNLIMITED rights over their child
- UN Convention on Rights of the Child: Parents/legal guardians have primary responsibility for upbringing and development of the child but…
- Human Rights Committee acknowledges…this right is not absolute, as the…parental rights [cannot impede]…the child's right to safety, security, and fundamental rights"
- No reason for state to step in as long as parent adequately cares for child
- No right for parent to "neglect child", but does refusing vitamin K rise to level of neglect???

What is Parental Neglect?

- “Failure of a parent or another responsible party to provide necessary food, clothing, shelter, medical care, or supervision to the extent that the child’s health, safety, and well-being are at risk of harm”
- Medical Neglect is a hazy area of law, and refusal of Vitamin K is even more ambiguous
- No vitamin K at birth will not necessarily get sick, unlike a child denied chemotherapy or a necessary blood transfusion.
- Neglect more likely to be determined based on the OCCURRENCE of morbidity
- State dependent: IL unlawful to refuse Vitamin K, = neglect. CO- parent may refuse

Oral Vitamin K

- AAP does NOT have recommendations for oral Vitamin K, other countries do (Canada)
- France: recommends Vitamin K orally as first line
- Countries using primarily oral vitamin K used other have higher rates of Late VKDB, but this is thought to be changing d/t parental refusal in the US
- Oral vitamin K has NOT been studied in large RCTs to determine if this strategy effectively prevents Classic and Late VKDB
- No FDA-approved oral Vitamin K in the US
- Recent rec: 1mg weekly until age 12 weeks OR 2mg at birth, 1 week, 4 weeks +/- 8 weeks but NO information in preterm infants at all.

- Concerns for ongoing compliance with regimen, puts infants at risk
- Higher risk of Late VKDB with oral regimens (thought mostly to be d/t non-compliance)
- Availability of established oral option may provide an attractive choice for many parents
- Considered significantly less effective than IM
- Oral K is not consistently absorbed through the stomach and intestines and does not provide adequate amounts for the breastfed infant
- Biochemical indices of coagulation similar between the two but but no correlation with clinical indices of coagulation
- USA: reconstitute IM form, or 5mg tab divided/crushed and put into liquid

O

R

A

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K

Reasons for not giving ORAL K

1. Concerns for efficacy
2. Poor compliance
3. Lack of encounters with parents who have refused IM Vitamin K (e.g. already dis- trustful of the medical community, not likely to properly follow up to confirm compliance
4. No AAP recommendation to support use
5. Only 5mg tabs available

VKBD: Implications in the ED

- VKBD should be considered in any infant presenting in 1st 6 months of life with bleeding, bruising, lethargy, fussiness, or seizures ESPECIALLY if exclusively breastfed did not receive Vitamin K at birth
- Prolonged PT/INR (usually first lab to be abnormal)
- Directly measuring Vitamin K levels not useful
- If PLT low or aPTT abnormal, other causes should be considered
- Treatment: Vitamin K1 (phytonadione) 1 to 2 mg IV/SQ/IM
- Should see normalization of coagulation profile in 2-3 hours (confirms dx)
- Severe bleeding: FFP or prothrombin complex concentration + K
- Important to ask pre-op also

CASE STUDY, cont'd

Differential for NAT at 6 weeks: Accidental trauma, traumatic labor, sepsis, vascular malformations, DIC, ITP, metabolic, and VKDB

Coagulopathy associated with head trauma is much less severe than the coagulopathy associated with Late VKDB

NAT peak incidence between 3-8 months of life (crossover with Late VKDB) but does include neonates to children age 4 years

**Retinal hemorrhages can be associated with traumatic birth in the healthy term infant (20-49%) but usually resolve by 10 days of life

In this case, significant intracranial pathology without retinal hemorrhages was a clue for other diagnoses like VKDB

Subperiosteal bleeding resulting in elevation of periosteum mimics healing elbow fracture (pseudofracture)

	Laboratory investigations			
Health status	**Platelets**	**INR (PT)**	**APTT**	**Possible diagnosis**
Sick	↓	↑	↑	Disseminated intravascular coagulation (usually low factor VIII)
	↓	N	N	Platelet consumption (infection, necrotizing enterocolitis, renal vein thrombosis)
	N	↑	↑	Liver disease, heparinization (usually normal factor VIII)
	N	N	N	Altered vascular integrity (eg, extreme prematurity, severe hypoxia and acidosis
Healthy	↓	N	N	Immune thrombocytopenia, occult infection or thrombosis, abnormal bone marrow function
	N	↑	↑	Hemorrhagic disease of the newborn (vitamin K deficiency)
	N	N	↑	Hemophilia
	N	N	N	Bleeding due to trauma or anatomic abnormalities, qualitative platelet abnormalities

↑ Increased; ↓ Decrease; APTT Activated partial thromboplastin time; DIC Disseminated, intravascular coagulation; INR International normalized ratio; N Normal

McMillan D, Wu J. Approach to the bleeding newborn. Paediatr Child Health. 1998 Nov;3(6):399-401

VKDB- Implications in ED and beyond

We only know a fraction of morbidity and mortality associated with Vitamin K refusal

- Some infants may not present with sequelae for months to years

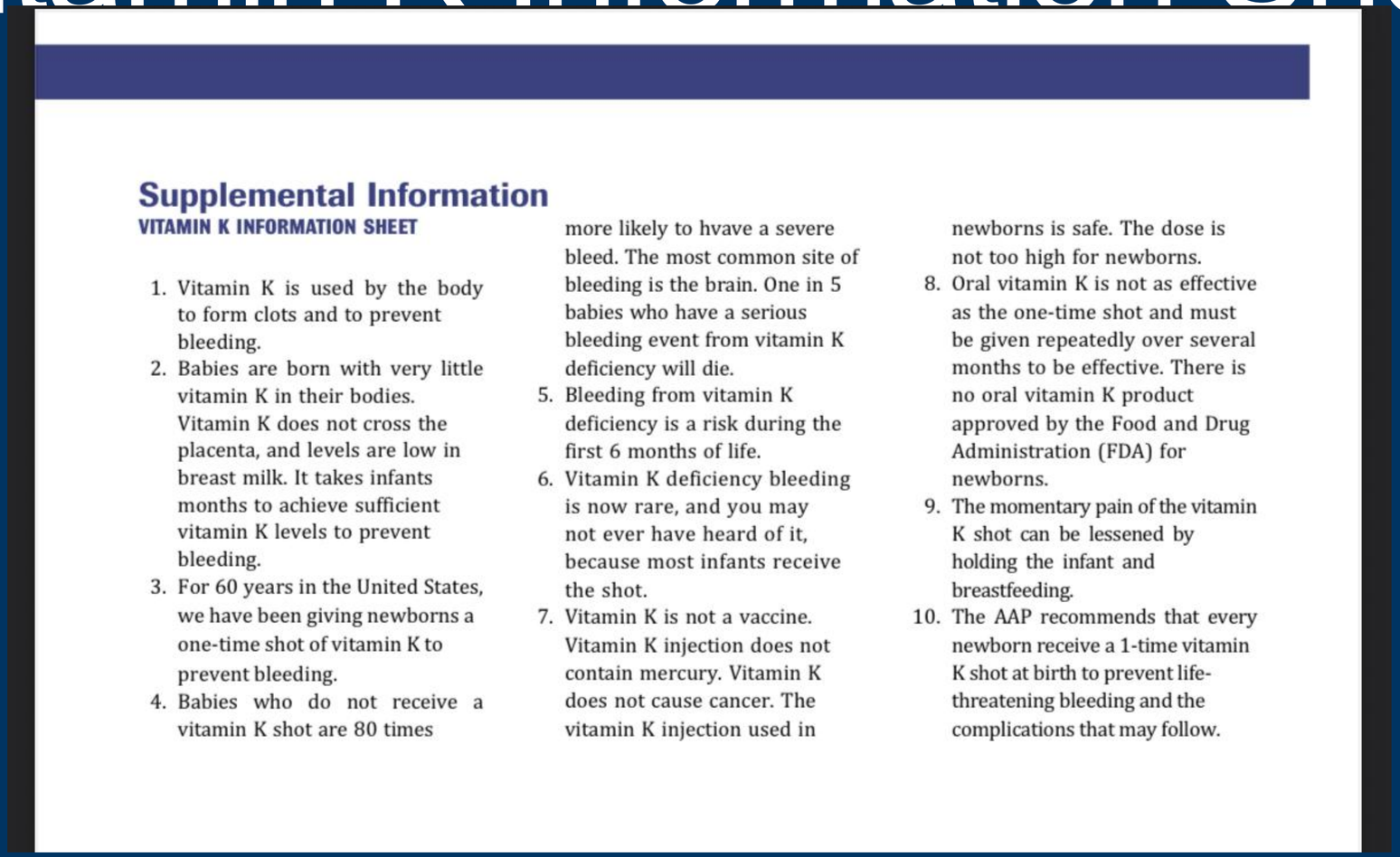
  - Not meeting developmental milestones
  - Learning difficulties in school
  - Seizure disorder develops

Could etiology be micro-hemorrhagic strokes due to VKDB?

Increasing Acceptance- Strategies

- Goal to help parents understand importance of Vitamin K, know basic function
- Assess parents level of understanding, addressing benefits/risks in understandable way based on their level of understanding
- Open-ended questions and listen carefully to responses
- If refuse IM and OK with oral, must be aware of late VKDB risk
- Strongly consider Vitamin K refusal form for parents to sign after discussion
- Strongly recommend no circumcision if IM Vitamin K has not been given

AAP’s Vitamin K Information Sheet



Supplemental Information

VITAMIN K INFORMATION SHEET

1. Vitamin K is used by the body to form clots and to prevent bleeding.
2. Babies are born with very little vitamin K in their bodies. Vitamin K does not cross the placenta, and levels are low in breast milk. It takes infants months to achieve sufficient vitamin K levels to prevent bleeding.
3. For 60 years in the United States, we have been giving newborns a one-time shot of vitamin K to prevent bleeding.
4. Babies who do not receive a vitamin K shot are 80 times more likely to hvave a severe bleed. The most common site of bleeding is the brain. One in 5 babies who have a serious bleeding event from vitamin K deficiency will die.
5. Bleeding from vitamin K deficiency is a risk during the first 6 months of life.
6. Vitamin K deficiency bleeding is now rare, and you may not ever have heard of it, because most infants receive the shot.
7. Vitamin K is not a vaccine. Vitamin K injection does not contain mercury. Vitamin K does not cause cancer. The vitamin K injection used in newborns is safe. The dose is not too high for newborns.
8. Oral vitamin K is not as effective as the one-time shot and must be given repeatedly over several months to be effective. There is no oral vitamin K product approved by the Food and Drug Administration (FDA) for newborns.
9. The momentary pain of the vitamin K shot can be lessened by holding the infant and breastfeeding.
10. The AAP recommends that every newborn receive a 1-time vitamin K shot at birth to prevent life-threatening bleeding and the complications that may follow.

Hand, Ivan et al. Vitamin K and the Newborn Infant, *Pediatrics* (2022) 149 (3)

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