



# Vitamin K Shots for Newborns: Questions and Answers

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Our doctors put together evidence-based answers for questions about preventative intramuscular (IM) Vitamin K injections for newborns.

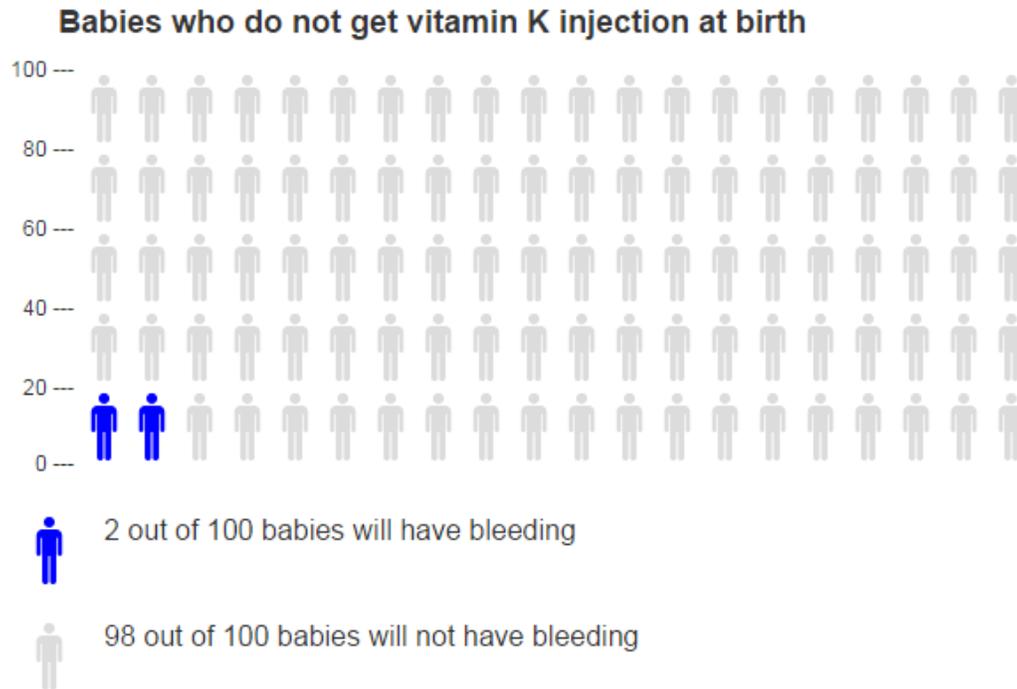
## **Question:**

How come I've never heard of any baby who has actually had vitamin K deficiency bleeding?

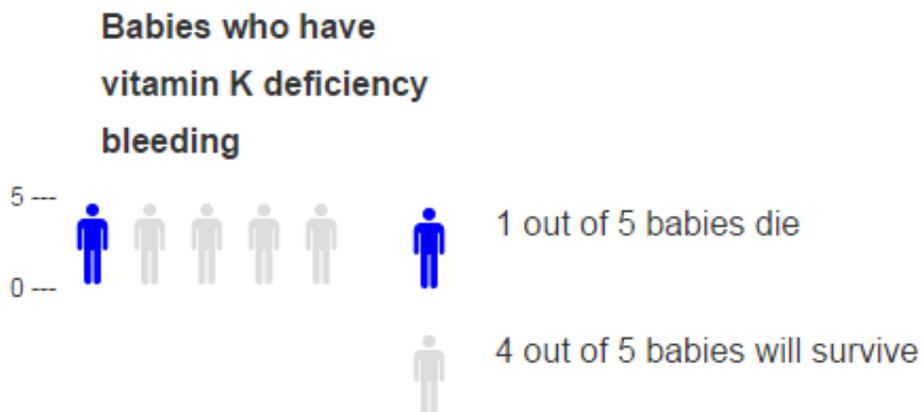
## **Answer:**

- That's because preventative IM Vitamin K work! Babies in the United States have been receiving IM vitamin K since the 1960s, and it has virtually **eliminated** vitamin K deficiency bleeding.
- 4 million babies are born in the United States each year. If we stopped giving IM vitamin K at birth, 12,000 to 80,000 babies per year would develop vitamin K deficiency bleeding, that's more than 200 infants per day.
- Babies in other parts of the world, where there is not universal access to IM vitamin K, **do** develop vitamin K deficiency bleeding, and many end up with permanent neurologic damage or dead.

- 2 out of every 100 babies who do not get a vitamin K injection at birth develop vitamin K deficiency bleeding



- 1 out of every 5 babies who develop vitamin K deficiency bleeding die.



We are starting to see an increase in vitamin K deficiency bleeding in the United States because more parents have been deciding not to give IM vitamin K prophylaxis to their babies.

For example, in 2013, the Centers for Disease Control and Prevention (CDC) reported on a cluster of 4 cases of vitamin K deficiency bleeding in Tennessee. 4 normal and healthy infants developed bleeding when their parents chose not to give vitamin K prophylaxis. 1 baby had gastrointestinal bleeding, and the other 3 had bleeding in the brain (diffuse intracranial hemorrhage).

**Question:**

I've heard that unless the baby has a difficult delivery, we don't need to give the vitamin K injection. Is that true?

**Answer:**

Most babies who develop vitamin K deficiency bleeding **do not** have any known birth trauma, injury, or illness. The bleeding starts suddenly, and may not be recognized until it is too late.

- Babies are at risk for vitamin K deficiency bleeding **until they are 6 months old**, not just at birth.
- There are a lot of things that can happen in a baby's first 6 months that can increase the risk of bleeding even more – such as falling over when learning to sit, or being in a minor car accident.

**Question:**

Does IM vitamin K increase the risk of cancer?

**Answer:**

There is extensive, strong evidence that **there is no connection** between vitamin K prophylaxis and any type of cancer in children or adults.

- There was a single researcher in Bristol, England, in the early 1990s who claimed to find an association between intramuscular vitamin K at birth and an increased risk of childhood leukemia.
- However, this claim has been **repeatedly and conclusively disproved** by many studies using huge amounts of data from multiple countries.
  - This is a fundamental tenet of science: when a study's findings cannot be replicated using high-quality study design and extensive data, the

initial findings are determined to be invalid and resulting from chance, bias, and/or confounding.

**Question:**

Are the ingredients in vitamin K “toxic”?

**Answer:**

No. These are the ingredients in the form of vitamin K currently used at the University of Michigan:

- Vitamin K1 (also called phytonadione)
- Polyoxyethylated fatty acid derivative – This is used in a small amount as a solvent and emulsifier, to dissolve the vitamin K into liquid form.
  - Some adults can have allergic reactions to this substance, but newborns cannot because their immune systems are not yet sensitized to possible allergens.
- Dextrose – this is simply sugar. This is what is used when a newborn has hypoglycemia (low blood sugar).
- Benzyl alcohol – A very small amount is used to prevent bacterial contamination in the shot. You would need to give approximately 100 times higher amounts of benzyl alcohol on a daily basis in order to cause any side effects.
- Hydrochloride – A small amount of hydrochloride may be used to adjust the pH of the solution. It is an acid, which means that it contains hydrogen ions that can adjust the pH of a substance.

The other forms of vitamin K that are available contain different inactive ingredients, but are equally safe.

**Question:**

Has the dose been studied? Is there any chance it may be excessive and dangerous?

**Answer:**

The current dose has been the standard since at least the 1950s in many parts of the world, including the United States.

Different doses were tried initially, and based on enormous amounts of data across numerous countries, the current standard dose of 1 mg IM vitamin K was determined to be both **safe and effective**.

**Question:**

Will my baby have a painful experience right after birth?

**Answer:**

Newborns experience significant physiologic stress during the delivery process; this is a normal and natural part of life. Compared to the stress of childbirth, a single brief injection is very minor. Most infants don't even notice.

There are wonderful ways to soothe your infant right after they receive their vitamin K. Many mothers choose to breastfeed their baby right afterwards, to hold them skin-to-skin, or to swaddle and hold them.

**Question:**

Is there an option to give my baby oral vitamin K instead?

**Answer:**

There are some countries in Europe that routinely administer oral vitamin K to all newborns instead of IM vitamin K. Multiple different doses and regimens have been used and studied, and the results show that oral vitamin K **is significantly less effective** than IM vitamin K, which virtually eliminates vitamin K deficiency bleeding.

- In the United States, the only licensed and FDA-approved oral form of vitamin K is a 5 milligram tablet, which would need to be divided, crushed, and reconstituted in liquid to give to a newborn. This is difficult, so some individuals have chosen to administer the intramuscular solution orally.

- The regimens used in Europe all involve multiple oral doses of vitamin K – an initial dose at birth, and subsequent doses daily, weekly, or monthly doses for many months.
- We recommend talking to your doctor individually about oral vitamin K.

### **The Bottom Line:**

Educated and caring parents are the best advocates for their children. There are many things in the world today that make it hard to feel confident that children are being raised in a safe and healthy environment, and being adequately protected from harmful exposures.

It has become popular to refuse certain preventive health measures such as preventative IM vitamin K injections because of fears about whether they might be harmful, “toxic,” “unnatural,” or unnecessary. For vitamin K, decades of well-designed research demonstrate clearly that this is not so.

By giving your baby intramuscular vitamin K at birth, you are protecting your baby from potentially catastrophic bleeding and death.

### **Where can I learn more?**

Access these evidence-based resources to learn more about IM Vitamin K

- **Evidence Based Birth® - Vitamin K** A website that discusses the risks and benefits of intramuscular vitamin K prophylaxis based on the available evidence. Access at: <http://evidencebasedbirth.com/evidence-for-the-vitamin-k-shot-in-newborns/>
- **The Centers for Disease Control and Prevention report** on a cluster of infants in Tennessee in 2013 who experienced vitamin K deficiency bleeding because they did not receive intramuscular vitamin K at birth:
  - “Notes from the Field: Late Vitamin K Deficiency Bleeding in Infants Whose Parents Declined Vitamin K Prophylaxis — Tennessee, 2013”: [http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6245a4.htm?s\\_cid=mm6245a4\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6245a4.htm?s_cid=mm6245a4_w)

- **Are Pediatricians Complicit in Vitamin K Deficiency Bleeding?** This academic article discusses many of the above topics, and references many of the most important studies that have been performed on vitamin K deficiency bleeding prevention in newborns:
  - Weddle M, Empey A, Crossen E, Green A, Green J, and Phillipi CA. “Are Pediatricians Complicit in Vitamin K Deficiency Bleeding?” Pediatrics 2015; 136(4): 753-757.
- **Vitamin K and Childhood Cancer.** This academic article examines all evidence disproving any association between vitamin K intramuscular prophylaxis and childhood cancer in great detail:
  - Fear NT et al. “Vitamin K and childhood cancer: a report from the United Kingdom Childhood Cancer Study.” Br J Cancer (2003);89:1228-1231.

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