

## REVIEW ARTICLE

# Relationship Between Vitamin K Refusal and Refusal of Other Newborn Interventions

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## KEYWORDS

Newborn

Parental refusal

Vaccine hesitancy

Vitamin K refusal

## ABSTRACT

Infants are born with low levels of vitamin K, placing them at risk for vitamin K deficiency bleeding (VKDB). To prevent this, the American Academy of Pediatrics recommends intramuscular (IM) vitamin K for all newborns. However, parental refusal of this and other standard newborn interventions is increasing. While vitamin K refusal has been studied individually, this review explores its association with broader refusals of newborn medical care. A literature search using keywords including newborn, parental refusal, vaccine hesitancy, and vitamin K refusal was conducted across PubMed, Scopus, and PsycINFO databases, covering publications from 2000 to 2025. Fifteen studies were included that examined IM vitamin K refusal and its relationship to other intervention refusals at birth. Findings reveal that parents who refuse vitamin K are significantly more likely to decline other preventative interventions such as hepatitis B vaccine and erythromycin eye ointment. These refusals increase the risk of preventable conditions, including hepatitis B transmission, neonatal conjunctivitis, and VKDB. Trends are more prominent among non-Hispanic white families and those giving birth outside of hospital settings. Often-mentioned reasons for refusal include misinformation, distrust in the medical system, and a preference for “natural” approaches. Continued increases in newborn intervention refusal may contribute to lower vaccination rates and greater public health burdens. This review draws a strong association between refusal of IM vitamin K and refusal of other newborn interventions, emphasizing a need for targeted education and trust-building between families and healthcare providers.

## INTRODUCTION

After Minnesota clinicians noticed an increase in refusal of prophylactic vitamin K in infants, a study was performed on a cohort of Minnesota hospital-born infants, showing that incidence of vitamin K refusal had increased between 2015 and 2019.<sup>1</sup> Vitamin K, a crucial assistant to vitamin K-dependent clotting factors, is present in newborns, however, in low levels, which is why the American Academy of Pediatrics (AAP) has been recommending the prophylactic use of additional vitamin K since 1961 to prevent vitamin K deficiency bleeding (VKDB).<sup>2</sup> AAP

recommends a vitamin K dose intramuscularly (IM) within 6 hours of birth, with newborns weighing >1500 g receiving 1 mg and newborns weighing ≤1500 g receiving 0.3 mg/kg to 0.5 mg/kg.<sup>3</sup> Refusal of vitamin K alone is not an isolated event, as a study from *Maternal and Child Health Journal* showed that of all parents who refused vitamin K prophylaxis in Nashville-area hospitals, 66% also refused erythromycin eyedrops and neonatal hepatitis B vaccine.<sup>4</sup> While refusal rates, causes, and consequences of vitamin K prophylaxis have been thoroughly studied, the predictive relationship with broader newborn medical intervention refusals has not been deeply reviewed. This literature review aims to explore the relationship between refusal of vitamin K prophylaxis and broader newborn medical intervention, along with beliefs, motivations, and implications that exist within this trend.

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## METHODS

### Search Strategy

A systematic literature search was conducted in PubMed, Scopus, and PsycINFO covering the period January 1, 2000, to April 30, 2025. Full search terms with Boolean operators included: (“vitamin K” OR “vitamin K prophylaxis” OR “IM vitamin K”) AND (“parental refusal” OR “vaccine hesitancy” OR “decline” OR “refusal:”) AND (“newborn” OR “infant”) AND (“hepatitis B vaccine” OR “erythromycin” OR “newborn interventions”).

The search returned 412 articles in PubMed, 298 in Scopus, and 126 in PsycINFO (total = 836). After removing 214 duplicates, 622 unique articles remained for screening.

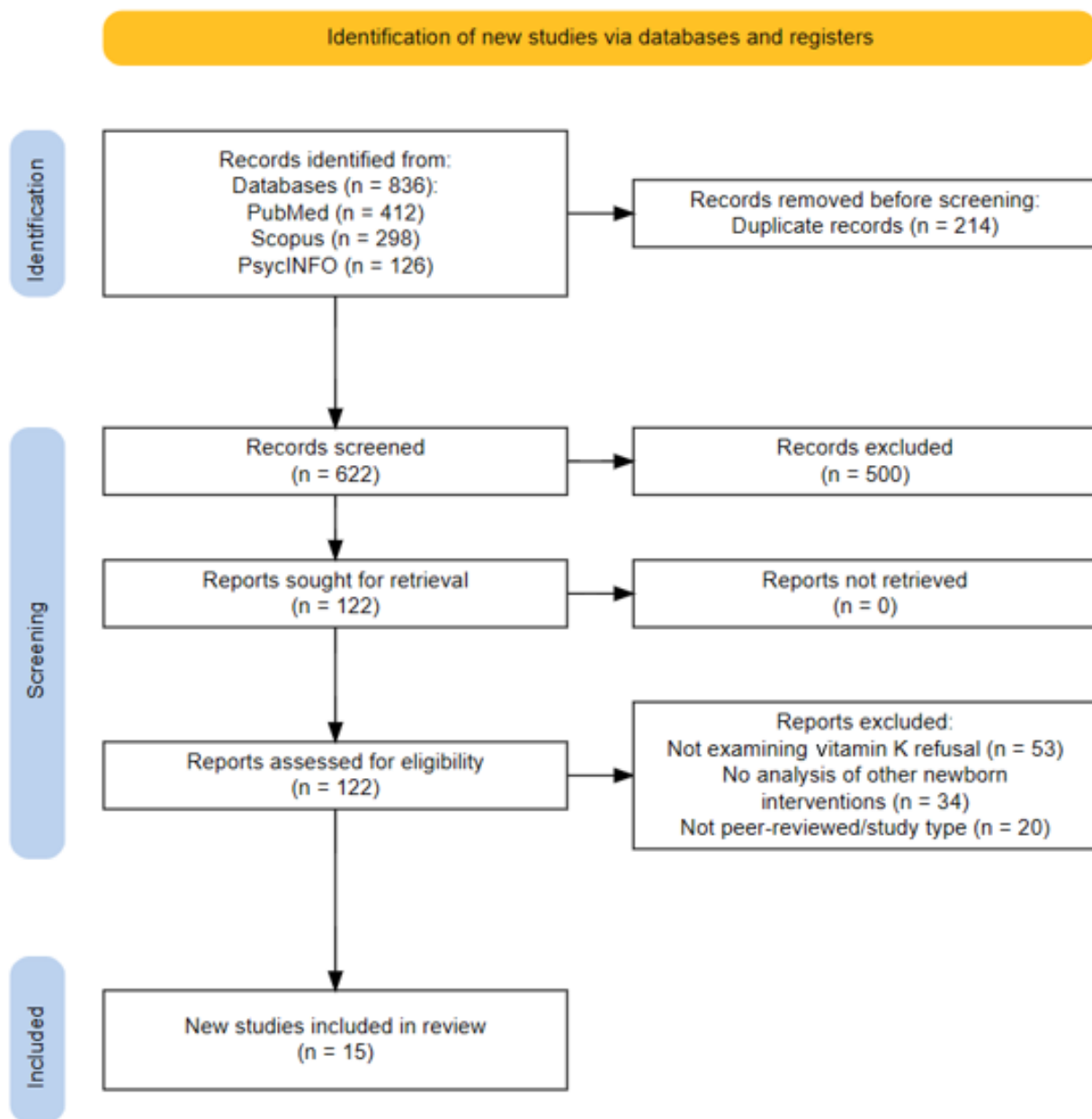
### Screening and Study Selection

Two independent reviewers screened titles and abstracts for relevance. Disagreements regarding inclusion were resolved through consensus; a third reviewer was available but not required. After a full-text review, 15 studies met all inclusion criteria. Reasons for exclusion included:

- Not examining vitamin K refusal (n = 376)
- No assessment of other newborn interventions (n = 144)
- Non-peer-reviewed or review articles (n = 87)

The PRISMA flowchart (shown in Figure 1) details the selection process.

FIGURE 1: PRISMA flowchart.



**TABLE 1:** Study quality based on Newcastle-Ottawa Scale or CASP.

Author(s)	Design	Newcastle-Ottawa (Quantitative)	CASP (Qualitative)	Strengths	Weaknesses
Sahni et al. (2014)	Retrospective cohort	8	NA: quantitative study	Large sample; population-based	Retrospective design
Vereen et al. (2022)	Cohort study (military)	7	NA: quantitative study	Unique population	Limited generalizability
Bernhardt et al. (2015)	Retrospective cohort	7	NA: quantitative study	Clear association w/ immunization rates	Small sample size
Loyal et al. (2018)	Survey study	6	NA: quantitative study	Multicenter data	Self-reported bias
Loyal et al. (2019)	Qualitative interviews	NA: qualitative study	High	Rich parental perspectives	Single-center, small cohort
Hamrick et al. (2016)	Survey study	7	NA: quantitative study	Diverse population sample	Response bias possible
Danziger et al. (2020)	Review of refusal trends	6	NA: quantitative study	Longitudinal trend analysis	Limited to hospital births
Aragona et al. (2021)	Retrospective chart review	6	NA: quantitative study	Documentation trends	Missing demographic data
Marcewicz et al. (2017)	Retrospective cohort	7	NA: quantitative study	Birth-setting comparisons	Retrospective nature
George et al. (2025)	Retrospective cohort	8	NA: quantitative study	Population-based data	Missing variables on refusals
George et al. (2025)	Retrospective cohort	8	NA: quantitative study	Large database	Some missing refusal reasons
Loyal et al. (2017)	Survey study	6	NA: quantitative study	Multicenter network	Self-reporting issues
Loyal et al. (2018b)	Qualitative focus groups	NA: qualitative Study	Moderate	Parent attitudes explored in depth	Small single-center
Hamrick et al. (2015)	Survey study	6	NA: quantitative study	Early refusal data	Limited longitudinal follow-up
Blauvelt et al. (2025)	Retrospective cohort (hospital births)	7	NA: quantitative study	Contemporary data; linked refusal of vitamin K, hepatitis B vaccine, and erythromycin to missed nirsevimab	Refusal rate not isolated for vitamin K; limited to one health system

## Inclusion and Exclusion Criteria

Studies were included if they:

1. Investigated parental refusal of IM vitamin K in newborns
2. Explored associations with refusal of other newborn interventions
3. Were original research articles in peer-reviewed journals

Studies were excluded if they:

- Focused solely on vitamin K administration without refusal data
- Lacked analysis of other newborn interventions
- Were nonoriginal studies (eg, reviews, editorials)

## Data Extraction

From each study, the following information was extracted:

- Author(s), year, country, and study design
- Population demographics and sample size
- IM vitamin K refusal rates
- Associations with refusal of other newborn interventions
- Key findings and conclusions

## QUALITY ASSESSMENT

Study quality was evaluated using the Newcastle-Ottawa Scale for quantitative studies and the Critical Appraisal Skills Programme (CASP) checklist for qualitative studies (see Table 1).

### Strengths and Weaknesses of Included Studies

Overall, included studies were of moderate to high quality based on the Newcastle-Ottawa Scale for quantitative research and the CASP checklist for qualitative research. Strengths included adequate sample sizes, population-based or multicenter designs, and strong statistical or qualitative methods, improving generalizability and insights. However, most studies were observational, limiting causal inference. Some qualitative studies had small single-center samples, reducing external validity. Several relied on self-reported parental attitudes, posing response bias risk. Heterogeneity in settings and definitions challenged direct comparison.

**TABLE 2:** Study characteristics of included primary research articles.

Author(s)	Year	Setting	Sample Size	Refusal Rate (%)	Associated Refusals
George et al.	2025	Minnesota, USA (hospital births)	2015–2019 birth cohort (102,451)	1.30%	More likely to refuse hepatitis B vaccine and eye ointment
Schulte et al.	2014	USA (multistate, case series of VKDB)	7 infants with vitamin K deficiency, 5 with VKDB	100%	Parents who refused vitamin K often also delayed/refused vaccines
Marcewicz et al.	2017	US – Nashville hospitals and Tennessee birthing centers	>3.8 million births	3% in hospitals, 31% in birthing centers	Associated with hepatitis B vaccine refusal and erythromycin
Sahni et al.	2014	Alberta, Canada (population-based)	~282,000 infants	0.3% refused IM vitamin K	Strongly associated with nonimmunization at 2 years
Vereen et al.	2022	US Military Health System	7140 infants	0.07%	Refusal linked with later under-immunization
Bernhardt et al.	2015	New Zealand (retrospective cohort)	3575 babies	3%	Vitamin K refusal predicted later vaccine refusal
Loyal et al.	2018	US hospitals (multisite)	102,878 infants	0.60%	Associated with refusal of erythromycin eye ointment and hepatitis B vaccine
Hamrick et al.	2016	US, 5 community hospitals, 1 academic medical center, 2 birthing centers (Southeast states)	45 parents interviewed	89%	Associated with refusal of erythromycin eye ointment and hepatitis B vaccine
Loyal et al.	2019	Qualitative interviews, US	17 newborns	82% refused; 18% delayed	Not Applicable
Loyal et al.	2017	BORN Network survey (US hospitals)	85 hospitals	Rates varied; refusal up 52% by region	Associated with refusal of other prophylaxis (hepatitis B vaccine + erythromycin)
Loyal and Aragona	2021	US (hospital electronic medical records [EMR] data)	67,750 infants	0.40%	Co-refusal of hepatitis B vaccine and erythromycin
Ye et al.	2024	US academic hospital, New Jersey	2038 infants	0.88%	28% refused all prophylaxis; explored parent decision-making
Blauvelt et al.	2025	US health system (hospital births)	~6000 infants	Not specified for vitamin K alone; refusal linked to missed prophylaxis bundle	Infants who missed vitamin K, hepatitis B vaccine, and erythromycin were also far less likely to receive nirsevimab (0% uptake when vitamin K refused)

**TABLE 3:** Reported reasons for parental refusal of IM vitamin K.

Category	Example From Studies	Frequency/Studies Reporting
Safety concerns	Fear of preservatives; “too much dose for a newborn”; risk of leukemia (myth); pain; potential side effects	Reported in Hamrick et al. 2016; Loyal et al. 2019; George et al. 2025; Marcewicz et al. 2017; Loyal et al. 2017
Preference for “natural” approach	Belief that baby should stay “pure” and avoid “unnecessary chemicals”; preference for oral vitamin K	Hamrick et al. 2016; Loyal et al. 2019; Loyal et al. 2017; Bernhardt et al. 2015; Marcewicz et al. 2017; Ye et al. 2024
Distrust of medical system	Mistrust of pharmaceutical companies, vaccines, or government mandates; preference for advice from social circle or internet	Hamrick et al. 2016; Sahni et al. 2014; Bernhardt et al. 2015; Marcewicz et al. 2017; Loyal et al. 2019; Ye et al. 2024
Lack of knowledge	Belief that vitamin K is unnecessary or unaware of interventions	Loyal et al. 2017; Bernhardt et al. 2015; Ye et al. 2024
Misunderstanding vitamin K as a vaccine	Parents confused vitamin K injection with hepatitis B vaccine; vaccine hesitancy	Hamrick et al. 2016; Marcewicz et al. 2017; Loyal et al. 2018; Loyal et al. 2017; Ye et al. 2024
Sociodemographic/ Other	Religious objections; prior negative medical experiences; desire for “delayed” interventions	Hamrick et al. 2016; Loyal et al. 2019

## RESULTS

Review of several studies shows a strong link between parents who decline IM vitamin K for their newborns and a broader pattern of hesitancy toward routine childhood vaccinations and other early preventive care (Table 2). This connection raises public health concerns, as it may lead to lower immunization rates and increased vulnerability to preventable illnesses.

In a population-based study, Sahni et al. discovered that parents who declined IM vitamin K for their newborns were significantly more likely to have unvaccinated children.<sup>5</sup> This finding was supported by research conducted by Vereen et al., which focused on military families, and revealed that refusing vitamin K at birth often predicted incomplete immunization by the time the child reached 15 months.<sup>6</sup> Bernhardt et al. reported similar findings, noting that infants whose parents declined vitamin K were more likely to be unvaccinated by 6 months.<sup>7</sup> Together, these findings establish vitamin K refusal as an early marker of ongoing vaccine hesitancy (settings, sample sizes, and associated outcomes summarized in Table 2).

Research also demonstrates co-refusal of interventions within birth hospitalization. Loyal et al. observed that

parents declining IM vitamin K frequently refused hepatitis B vaccine birth dose and erythromycin eye ointment.<sup>8</sup> Hamrick et al. reinforced this, finding that 90% of parents who refused vitamin K also declined hepatitis B vaccine, and 77% declined erythromycin, often citing online information about preservatives, dosage, and side effects.<sup>9</sup> Loyal and Aragona (2021) used EMR data to show consistent trends in refusal of vitamin K alongside hepatitis B vaccination and erythromycin eye ointment, demonstrating how these refusals often occur together across hospital settings.<sup>10</sup> Recent evidence adds to these findings. Blauvelt et al. (2025) observed that infants who did not receive standard newborn prophylaxis, such as vitamin K, erythromycin, and hepatitis B vaccine, were much less likely to receive nirsevimab for respiratory syncytial virus (RSV) prophylaxis before discharge. Uptake was 0% among those whose families refused vitamin K.<sup>11</sup> This highlights how refusal of one prophylaxis often predicts cascading refusal of others, even beyond the immediate newborn period (see “Associated Refusals” column in Table 2).

Qualitative studies provide insight into parental motivations (Table 3). Loyal et al. (2019) described parents favoring “natural” methods expressing concerns about preservatives and distrusting conventional medical care.<sup>12</sup> Similar themes of safety fears, perceived lack of necessity, and medical mistrust were echoed across multiple surveys and interviews.<sup>13</sup> These studies underscore how refusal decisions are shaped by broader belief systems, not just isolated concerns about vitamin K.

Further studies by Marcewicz et al. and George et al. found that vitamin K refusal was more common in out-of-hospital births and among families who also declined other preventive services. George et al. also found that in Minnesota, refusal rates were higher among white non-Hispanic families and those who had midwife-assisted births.<sup>1,4</sup>

However, findings also reveal variation across populations and settings. Marcewicz et al. and George et al. reported higher refusal rates among out-of-hospital births, midwife-attended deliveries, and white non-Hispanic families.<sup>1,4</sup> Danziger et al. (2020) described refusal as occurring along a spectrum, where most parents declined only one intervention and very few rejected all.<sup>14</sup> In contrast, Ye et al. (2024), using a large hospital-based database, found that 28% of families who refused IM vitamin K also declined every form of newborn prophylaxis.<sup>15</sup> These estimates are not contradictory; they reflect different populations and care contexts. Danziger et al. examined in-hospital largely urban cohorts, whereas Ye et al. analyzed a broader dataset that captured settings in which refusal tends to be categorical. This interpretation aligns with settings and populations detailed in Table 2. Taken together, these studies suggest that while many refusals are selective, a

significant minority of families, particularly those outside hospital systems, decline all newborn interventions.

In summary, early refusal of IM vitamin K is rarely an isolated decision. It often signals broader parental hesitancy toward preventive care, with patterns varying across populations but consistently carrying implications for both newborn and long-term child health.

## DISCUSSION

The reviewed research highlights a consistent association between parental refusal of vitamin K and other newborn interventions, including hepatitis B vaccine and erythromycin eye ointment (Table 2). This pattern suggests that refusal of vitamin K is rarely an isolated health decision but rather part of a broader hesitancy toward conventional newborn care. For many families, these choices reflect deeply held values and beliefs, including a preference for more natural approaches to newborn care and concerns about additives or unexplained ingredients in medical interventions, alongside broader mistrust of healthcare systems and providers (Table 3).

Qualitative studies provide insight into these motivations. For example, in Loyal et al. (2019), one parent explained, “She [the nurse] brought in the actual vial and my husband said that it has 100 mcg of aluminum, and I’m not sure if I want to give our minute-old baby aluminum.”<sup>11</sup> This testimonial illustrates how worries about ingredients or preservatives can shape parental decisions.

Refusal of newborn medical interventions poses serious public health challenges. When refusals cluster within certain communities or demographic groups, they create pockets of under-immunized populations who are highly susceptible to preventable illnesses such as VKDB, perinatal hepatitis B, and vaccine-preventable diseases. These clusters compromise herd immunity, increasing the likelihood of localized outbreaks that can spread beyond the initial community, especially impacting immunocompromised individuals and infants too young for routine immunizations. A consistent pattern of multiple newborn intervention refusals shown in this review reflects a broader form of medical hesitancy that can potentially lead to refusal or delay of important routine childhood vaccines.

Importantly, these findings highlight the need to understand parents as partners rather than categorize them as compliant or noncompliant. Many families refusing interventions are motivated by a desire to protect their child, shaped by prior experiences, personal values, and information sources they trust. Recognizing this perspective helps shift conversations from persuasion toward collaboration.

Clinicians can help bridge this gap by initiating conversations early in prenatal care, listening actively to parental concerns, and inviting parents to share the reasoning behind their choices. Practical strategies include using open-ended questions to explore beliefs, clarifying misinformation without judgment, and offering clear evidence-based information in a way that respects parental autonomy. Public health campaigns can further support this effort by providing accessible information and engaging directly with the same online spaces where many parents first encounter vaccine- and vitamin-related content.

Ultimately, early trust-building between parents and providers is essential. By approaching these conversations with empathy, transparency, and respect for parental values, clinicians can prevent cascading refusals, support informed decision-making, and strengthen the physician-patient relationship in ways that benefit both families and communities.

## CONCLUSION

This review demonstrates that refusal of IM vitamin K frequently occurs alongside refusal of other newborn prophylaxis, particularly hepatitis B vaccine and erythromycin eye ointment (Table 2). Motivations for refusal are complex and include concerns about preservatives such as aluminum, fears of potential side effects, preferences for “natural” alternatives, misunderstandings that vitamin K is a vaccine, and mistrust of the medical system (Table 3). These perspectives show that refusals are often rooted in a genuine desire to protect the child rather than in simple noncompliance. Although refusal rates remain low in most hospital-based populations, they rise substantially in out-of-hospital births and in settings with midwife-attended deliveries, reflecting differences across populations and care environments. For clinicians, the value of these findings lies not in the observation that refusals cluster, which is already apparent in practice, but in understanding the specific reasons parents provide. This knowledge can support more effective conversations in which providers clarify misconceptions, respect parental values, and build trust to prevent cascading refusals that place newborns and communities at greater risk.

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