HHS Public Access

Author manuscript

Acad Pediatr. Author manuscript; available in PMC 2018 May 01.

Published in final edited form as:

Acad Pediatr. 2017 ; 17(4): 368–373. doi:10.1016/j.acap.2016.10.012.

Refusal of Vitamin K by Parents of Newborns: A Survey of the Better Outcomes Through Research for Newborns Network

Jaspreet Loyal, MD, MS, **James A. Taylor, MD**, **Carrie A. Phillipi, MD, PhD**, **Neera K. Goyal, MD**, **Niramol Dhepyasuwan, MEd**, **Eugene D. Shapiro, MD**, and **Eve Colson, MD, MHPE**

Department of Pediatrics, Yale University (Drs Loyal, Shapiro, and Colson), New Haven, Conn; Department of Pediatrics, University of Washington (Dr Taylor), Seattle; Department of Pediatrics, Oregon Health & Science University (Dr Phillipi), Portland; Department of Pediatrics, Cincinnati Children's Hospital Medical Center (Dr Goyal), Cincinnati, Ohio; and Academic Pediatric Association (Ms Dhepyasuwan), McClean, Va

Abstract

Objective—To survey newborn clinicians in the United States regarding the frequency of intramuscular (IM) vitamin K refusal by a parent, reasons for refusal, and approaches of clinicians to refusals.

Methods—An electronic survey was administered to the clinician site representative (nursery director or designee knowledgeable about site-specific nursery policies) at all newborn nurseries in the Better Outcomes through Research for Newborns (BORN) network of newborn nurseries.

Results—Of 92 BORN sites, 85 (92%) respondents completed the survey. Frequency of IM vitamin K refusal during the past 5 years was reported as increased by 52% of respondents, unchanged by 42%, and 6% did not know. Reported frequencies of refusal of IM vitamin K was weekly (9%), a few times a month (31%), once a month (13%), once every 3 to 4 months (20%), once or twice a year (26%), or never (1%). The overall distribution of the reported frequencies of refusal differed among regions in the United States (higher in the West and the South; $P < .05$). Reported reasons for refusal by parents included perceptions of parents that the injection was unnecessary, lack of knowledge about vitamin K deficiency bleeding, and concern about preservatives. Approaches to refusal included attempts to educate parents, enlisting support from community clinicians, a state mandate, and prescription of oral vitamin K.

Conclusions—Respondents from a national sample of newborn nursery clinicians reported an increase in refusal of IM vitamin K in the past 5 years with regional variation. Approaches to refusals need further investigation to determine effectiveness.

Keywords

BORN network; vitamin K refusal

Address correspondence to Jaspreet Loyal, MD, MS, Department of Pediatrics, Yale University, 333 Cedar St, New Haven CT 06445 (Jaspreet.Loyal@yale.edu).

The authors have no conflicts of interest to disclose.

Newborns are born with low reserves of vitamin K, putting them at risk for vitamin K deficiency bleeding of the newborn (VKDB).[1,2] Estimates of the incidence of late VKDB in the absence of prophylaxis range from 10.5 to 80 per 100,000 births.[3] A one-time, prophylactic intramuscular (IM) injection of vitamin K at birth, recommended by the American Academy of Pediatrics (AAP) since 1961, had virtually eliminated this serious disease of newborns.[1] Recently, there have been increasing numbers of reports of parents refusing the vitamin K injection for their newborns in the United States[4–9] and an increase in the number of reports of infants with VKDB.[4,8]

The reasons for parents' refusal of IM vitamin K for their newborns are not well understood but there have been reports of concerns from parents about the dose of IM vitamin K, potential harm from the injection, and belief that the injection is unnecessary.[4,5,7,8] In large-scale surveillance studies on vitamin K refusal in New Zealand and Canada, the authors reported refusals rates of 1.7% and 0.5%, respectively.[6,10] There is a paucity of data on vitamin K refusal rates in the United States; the only reports are from single centers. There have been no large-scale, multisite studies in the United States about the scope of the problem of vitamin K refusal, approaches to refusal from the newborn clinician perspective, or regional variation in this phenomenon. The purpose of our study was to survey a sample of clinicians of newborns in the United States about the frequency of IM vitamin K refusal, reasons for vitamin K refusal by parents, and strategies to respond to refusals.

Methods

Sample

This study was conducted through the Better Outcomes through Research for Newborns (BORN) network, which includes newborn clinicians from 92 newborn nurseries in 34 states in the United States; approximately 330,000 newborns are cared for in these nurseries annually (approximately 8.25% of 4 million live births in the United States). At each participating nursery there is a BORN representative. This individual is either the nursery director or another nursery clinician who is knowledgeable about nursery policies at his/her institution and clinical practice at the site. BORN is a core activity of the Academic Pediatric Association.

Design

In February 2015, we sent a 10-item electronic survey about administration of vitamin K to each BORN site representative. The survey was developed on the basis of published reports on the topic[1,2,4–6,8] and expert opinion. The survey included questions about perceived frequency of refusal of IM vitamin K: possible responses included "a few times a month," "1 to 2 times a year," "once every 3 to 4 months," "once per month," "once a week," "more than once per week," or "never." The BORN representative was asked about her/his perception regarding change in frequency of parental refusal of IM vitamin K over the past 5 years. Respondents were also asked about cases of VKDB in their community, their agreement with the current AAP policy regarding IM vitamin K prophylaxis for all newborns, institutional practices for signed refusal forms, and whether oral vitamin K was offered as an alternative for parents who refused IM vitamin K. Representatives from sites

that offered oral regimens were asked to describe the oral regimens offered. Respondents were also asked about their perceptions of reasons for refusal given by parents, approaches to refusals, and specific strategies used to mitigate refusals. A list of possible reasons for refusal were provided in addition to a free-text option. Respondents were allowed to select multiple answers for some of the questions. The survey was administered electronically (Yale Qualtrics) with up to 5 e-mail reminders. For each site, we had data from the BORN network about number of annual deliveries, payer mix, and estimation of the percentage of infants who are breastfed during the nursery stay. The project was approved by the Yale Human Investigation Committee.

Analyses

We report descriptive statistics of clinician perceived frequency of IM vitamin K refusal, reasons for IM vitamin K refusal, and clinician approaches to refusal. To assess whether there is regional variation in parental refusal of vitamin K for their newborns, we categorized BORN nurseries into 4 geographical regions (Midwest, Northeast, South, and Western United States), dichotomized the reported frequency of vitamin K refusal into “frequent” (once per month or more) and “infrequent” (4 times a year or fewer), and used the χ^2 test to assess the statistical significant of differences in reported frequency of IM vitamin K refusal between regions.

Results

Representatives from 85 of the 92 BORN sites (92%) responded to the survey. Characteristics of responding sites are shown in Table 1. Sites in all regions of the country were represented. Responses to the survey are shown in Table 2. Of respondents, 52% reported an increase in refusal of IM vitamin K in the previous 5 years. Regional differences in clinician-reported frequency of IM vitamin K refusal are shown in Table 3. The overall distribution of the reported frequencies of refusal differed among regions in the United States; there was a significantly greater proportion of nurseries in the Western United States at which the rate of perceived vitamin K refusal was classified as “frequent” than in other regions (76% vs 45%; $P = .014$). In comparing refusal rates between BORN sites in the South versus Midwest and Northeast (excluding the West), although refusals were classified as “frequent” in 62% of sites in the South vs 38% in the Northeast and Midwest, the difference was not statistically significant ($P = .06$). There were no statistically significant differences in reported rates of vitamin K refusal and the number of annual deliveries, the percentage of patients receiving public insurance, or the percentage of patients who were breastfed.

Reasons for Refusal

Reported reasons for refusal of IM vitamin K are shown in Table 2. These included lack of understanding the indication for the injection, belief that the injection is unnecessary, concern about pain from the injection, and concern about harm to the baby from preservative in the formulation. Only 3 responses used free text in addition to the options provided in the survey which noted that some parents refused vitamin K: 1) for religious reasons, 2) because

of mistrust of the medical establishment, and 3) because of belief that mother's vitamin K intake was sufficient.

Approach to Refusals

Reported approaches to refusals and perceived effectiveness of the approaches are shown in Table 2. Most respondents used education and/or educational handouts to respond to concerns from parents. Additional responses included prescribing oral vitamin K, reviewing the AAP policy statement regarding vitamin K with parents, and enlisting the support of either the private pediatric clinician or the midwife.

The approaches to refusal reported to be effective by most respondents were use of an educational intervention followed by requiring IM vitamin K for the infant to undergo certain procedures (eg, circumcision or frenotomy). Four of 6 respondents from New York state reported that their unique state health mandate regarding IM vitamin K was a successful strategy to curb refusals in their respective nurseries. The law in New York states that "it shall be the duty of the attending physician, licensed midwife, registered professional nurse, or other licensed medical professional attending the newborn to assure administration of a single IM dose of 0.5 to 1.0 mg of vitamin K1".[11] Parents who do not comply with the requirement might be reported to Child Protective Services. Some respondents explained that they address specific concerns by reviewing the package insert with parents, by sharing anecdotes about cases of VKDB, by negotiating with parents to agree to an early discharge if they accept IM vitamin K, or by revisiting the issue with parents after the first day in the hospital.

Twenty-seven respondents reported offering oral vitamin K as a last resort. Of these 27 respondents, 10 (from all 4 geographic regions) reported that they had an institutional process in place to administer vitamin Korally and described the oral regimens used. The oral regimens included either a 3-dose series or a multiple-dose regimen administered at varying times starting at birth. Vitamin K administered orally was either a parenteral formulation that was given orally, an oral suspension, or crushed tablets. Three respondents commented on the importance of not offering an alternative to the injection in the absence of evidence-based guidelines in the United States and the risk of endorsing an ineffective practice that might encourage refusal of the injection.

Discussion

VKDB has been virtually eliminated in the United States by routine administration of IM vitamin K to newborns. However, because refusal of IM vitamin K prophylaxis by parents is increasing, there is a risk of re-emergence of VKDB. To our knowledge, this is the first-large scale survey about refusal of IM vitamin K by parents of newborns in the United States. The results suggest that many clinicians throughout the United States are facing vitamin K refusal by parents with increasing frequency, although there might be some regional variation. There clearly is a need for large-scale, population-based surveillance about the frequency of the problem in the United States.

Refusal of IM vitamin K by parents of newborns has significant implications for public health. The regional variation in IM vitamin K refusal in our study has some similarities with regional variations in vaccine coverage in the United States.[12] Studies have shown that parents who refuse IM vitamin for their newborn are also more likely to refuse other standard practices such as administration of hepatitis B vaccine and ocular prophylaxis for gonococcal ophthalmia in the newborn nursery[5,6]; they are also more likely subsequently to delay or to refuse routine immunizations.[13]

Clinicians reported strategies to address refusal mostly through educating parents and by addressing specific concerns. Three major reported reasons for vitamin K refusal in our survey were that parents believed that the injection was unnecessary, that parents did not understand why the injection was needed, and that they feared the infant might be harmed by the injection. Newborn clinicians are well positioned to positively engage and educate parents to accept routine, evidence-based practices beginning in infancy, but prenatal providers also play a role in this decision-making process. Future research might also focus on obstetric/midwife provider perspectives on newborn vitamin K and immunization administration. Because the relationship between the parent and pediatric clinician often begins in the newborn nursery, discussions about standard of care in the newborn nursery are critical. Studies about vaccine hesitancy and refusal highlight the importance of parents' trust in the provider when making decisions about vaccines for themselves or their child.[14–16] The desire by parents to forgo IM vitamin K to be more 'natural' and factors underlying the concern about pain from the injection and harm from the preservative in IM vitamin K need to be better understood using qualitative studies of parents and their health beliefs.

Some of the educational tools being used included handouts and/or signed refusal forms, but, most of the clinicians use education specifically targeting parent concerns directly, because these might not be adequately addressed in currently available educational tools. For instance, a handout created by the Centers for Disease Control and Prevention for clinicians to educate parents does not address concerns about either preservative in the injection or pain from the injection.[17] New York State's use of a state mandate might result in fewer refusals and has implications for policy in other states.

We found that clinicians at approximately one-third of the nursery sites offered oral vitamin K as an alternative to a minority of the parents who refused. There is disagreement among clinicians about whether oral regimens should be offered at all because these might further encourage refusal of IM prophylaxis. Moreover, there is no licensed form of oral vitamin K for use in infants in the United States.[18] In a recent published discussion about the ethics of using oral vitamin K, the authors concluded that clinicians should not offer or support the use of available oral vitamin K preparations in the absence of evidence of effectiveness.[19] However, oral vitamin K preparations are widely used in Europe.[20] There is a need for research to provide evidence to guide policies.

Limitations

There are several limitations to our study. Estimates of the frequency of vitamin K refusal were provided by 1 representative from each participating BORN site and are not a direct

measure of actual refusal rates. We chose the Medical Director of each nursery site as a survey respondent with the expectation that this person would have the most accurate knowledge of the frequency of vitamin K refusal at their hospital, but the accuracy of the reports of the respondents in the absence of actual tracking of this information is a limitation. Recall also could be biased by other factors, such as reports in the press or discussions with colleagues. Actual rates of refusal might be higher or lower than reported. Although there was representation from across the country, BORN sites are generally academic centers, which might have different rates of refusal of vitamin K refusal compared with private community hospitals or birthing centers associated with midwives. Data on payer mix, number of deliveries, and breastfeeding rates are estimates provided by the BORN site representative at the time they enrolled in the BORN network. Finally, reasons for vitamin K refusal were not obtained directly from parents.

Future Directions

Results of this exploratory study show that refusal of vitamin K by parents is a widespread problem according to responses of newborn clinicians from throughout the country and underlines the need for further research on this problem. Large-scale surveillance studies similar to those from New Zealand[10] and Canada[6] are needed in the United States to better quantify the problem. More in-depth, qualitative studies of parents who refuse IM vitamin K are needed to better understand attitudes and beliefs. There are scant data about use of an oral vitamin K regimen to protect infants against VKDB in the United States. Additional information is needed before a consensus on use of oral vitamin K can be reached. Future efforts might focus on better monitoring of the frequency of refusals at individual hospitals and on a national level, and evaluation of the effects of policies such as state mandates to reduce refusal of IM vitamin K. Finally, our study serves as a call to action for pediatricians to find better ways to help reticent parents overcome their reluctance to have vitamin K administered to their newborns.

Acknowledgments

The authors thank members of the BORN network for participating in the survey.

Financial disclosure: Administrative support was provided by the Academic Pediatric Association. This publication was made possible, in part, by Clinical and Translational Science Award grant number UL1 TR000142 from the National Center for Advancing Translational Science at the National Institutes of Health (NIH), and NIH roadmap for Medical Research. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the NIH.

References

1. American Academy of Pediatrics Committee on Fetus and Newborn. Controversies concerning vitamin K and the newborn. Pediatrics. 2003; 112:191–192. [PubMed: 12837888]
2. Pichler E, Pichler L. The neonatal coagulation system and the vitamin K deficiency bleeding – a mini review. Wien Med Wochenschr. 2008; 158:385–395. [PubMed: 18677590]
3. Sankar MJ, Chandrasekaran A, Kumar P, et al. Vitamin K prophylaxis for prevention of vitamin K deficiency bleeding: a systematic review. J Perinatol. 2016; 36:s29–s34. [PubMed: 27109090]
4. Centers for Disease Control and Prevention. Notes from the field: late vitamin K deficiency bleeding in infants whose parents declined vitamin K prophylaxis—Tennessee 2013. MMWR Morb Mortal Wkly Rep. 2013; 62:901–902. [PubMed: 24226627]

5. Abrams S, Savelli SL. Be prepared to address parents' concerns about vitamin K injection. AAP News. 2014; 35:1.
6. Sahni V, Lai FY, MacDonald SE. Neonatal Vitamin K refusal and non-immunization. Pediatrics. 2014; 134:497–503. [PubMed: 25136042]
7. Hamrick HJ, Gable EK, Freeman EH, et al. Reasons for refusal of newborn vitamin K prophylaxis: implications for management and education. Hosp Pediatr. 2016; 6:15–21. [PubMed: 26711469]
8. Kassis KL, Wada KJ, Milton A. Another disease re-emerges due to parental shot refusal: case report of a fussy infant with blood in stool. J Emerg Med. 2015; 49:e15–e17. [PubMed: 25841290]
9. Eventov-Friedman S, Vinograd O, Ben-Haim M, et al. Parents' knowledge and perceptions regarding vitamin K prophylaxis in newborns. J Pediatr Hematol Oncol. 2013; 35:409–413. [PubMed: 23242324]
10. Burke M, Bernhardt H, Reith DM, et al. Perinatal influences on the uptake of newborn vitamin K prophylaxis – a retrospective cohort study. Aust N Z J Public Health. 2015; 39:573–576. [PubMed: 26123282]
11. New York State Department of Health. Administration of vitamin K to newborn infants. Available at: https://www.health.ny.gov/regulations/recently_adopted/docs/2014-06-10_administration_of_vitamin_k_to_newborn_infants.pdfAccessed April 18, 2016
12. Centers for Disease Control and Prevention. National, state and selected local area vaccination coverage among children aged 19–35 months – United States, 2014. MMWR Morb Mortal Wkly Rep. 2015; 33:889–896.
13. Bernhardt H, Barker D, Reith DM, et al. Declining newborn intramuscular vitamin K prophylaxis predicts subsequent immunization refusal: a retrospective cohort study. J Paediatr Child Health. 2015; 51:889–894. [PubMed: 25873083]
14. Meharry PM, Colson ER, Grizas AP, et al. Reasons why women accept or reject the trivalent inactivated influenza vaccine (TIV) during pregnancy. Matern Child Health J. 2013; 17:156–164. [PubMed: 22367067]
15. Benin AL, Wisler-Scher DJ, Colson E, Shapiro ED, Holmboe ES. Qualitative analysis of mothers' decision-making about vaccines for infants: the importance of trust. Pediatrics. 2006; 117:1532–1541. [PubMed: 16651306]
16. Wu AC, Wisler-Scher DJ, Griswold K, et al. Postpartum mothers' attitudes, knowledge, and trust regarding vaccination. Matern Child Health J. 2008; 12:766–773. [PubMed: 17987370]
17. Centers for Disease Control and Prevention. [Accessed March 1, 2016] Protect your baby from bleeds – talk to your healthcare provider about vitamin K. Available at: www.cdc.gov/ncbddd/blooddisorders/documents/vitamin-k.pdf
18. US FOOD AND DRUG ADMINISTRATION. [Accessed March 29, 2016] Drugs@FDA. FDA approved drug products. Available at: www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm
19. Weddle M, Empey A, Crossen E, et al. Are pediatricians complicit in vitamin K deficiency bleeding? Pediatrics. 2015; 136:753–757. [PubMed: 26371205]
20. Ipema HJ. Use of oral vitamin K for prevention of late vitamin K deficiency bleeding in neonates when injectable vitamin K is not available. Ann Pharmacother. 2012; 46:879–883. [PubMed: 22619475]

What's New

By report, intramuscular vitamin K refusal has increased in recent years with regional variation. Response to refusals by clinicians of newborns is mostly with education and less common responses are a state mandate and oral vitamin K prescription.

Table 1

Characteristics of BORN Sites That Responded to Survey* (N = 85)

Characteristic	n (%)
Region†	
Northeast	22 (26)
Midwest	21 (25)
South	21 (25)
West	21 (25)
Number of annual deliveries	
≤2500	38 (45)
2501–4999	31 (37)
≥5000	15 (18)
Unknown	1 (1)
Percentage of publicly insured patients	
<50%	37 (44)
≥50%	34 (40)
Unknown	14 (17)
Percentage of infants breastfed during nursery stay	
<50%	6 (7)
50–74%	27 (32)
≥75%	45 (53)
Unknown	7 (8)

BORN indicates Better Outcomes through Research for Newborns.

*Data were from BORN site enrollment surveys and on the basis of estimates by the site representatives.

†Northeast: Massachusetts, New Jersey, Vermont, New York, New Hampshire, Pennsylvania, Connecticut, Rhode Island; Midwest: Illinois, Michigan, Montana, Ohio, Iowa, Minnesota, Kentucky, Kansas; South: South Carolina, Florida, North Carolina, Tennessee, Virginia, Alabama, Mississippi, Texas, Louisiana, West Virginia; West: Arizona, California, Oregon, Washington, Utah, Colorado.

Table 2

Vitamin K Refusal Survey Responses

Survey Question	n (%)
1. Has there been an increase in IM vitamin K refusal in the past 5 years?	
Yes	44 (52)
No	36 (42)
Don't know	5 (6)
2. How often does a parent refuse IM vitamin K in your nursery?	
A few times a month	26 (31)
Once or twice a year	22 (26)
Once every 3–4 months	17 (20)
Once per month	11 (13)
More than once per week	4 (5)
Once per week	4 (5)
Never	1 (1)
3. Are you aware of VKDB cases in your community in the last year?	
No	71 (84)
Yes	14 (17)
4. Do you support the AAP policy regarding vitamin K?	
Yes	84 (99)
No	1 (1)
5. In the event of a refusal, does your hospital require parents sign a vitamin K refusal form?	
Yes	56 (66)
No	29 (34)
6. Is there an institutional process to assist nursery providers to provide oral vitamin K?	
No	73 (86)
Yes	12 (14)
7. What are the reasons for IM vitamin K refusal in your newborn nursery? *	
Parental perception that IM vitamin K is unnecessary	59 (69)
Lack of knowledge regarding the role of IM vitamin K in preventing VKDB	59 (69)
Concern about preservative in the IM injection	45 (53)
Concern about damaging effects of pain from injection	43 (51)
Concern about the association of IM vitamin K with leukemia	27 (32)
Perception that vitamin K is a vaccine	26 (31)
Parental perception that dose of IM vitamin K is too high	10 (12)
8. What is your approach to parents refusing IM vitamin K? *	
Education and addressing specific concerns	79 (93)
Provide an educational handout	39 (46)
Offer oral vitamin K	27 (32)
Provide the AAP policy statement	19 (22)
Enlist the help of the private community provider	11 (13)
9. In the case of a refusal, how often are you able to help a parent overcome their hesitation and allow administration of IM vitamin K?	

Survey Question	n (%)
Sometimes	75 (88)
All the time	7 (8)
Never	3 (4)
10. What approaches have been successful in overcoming refusals from parents? *	
Individual education	72 (85)
Requirement before procedure	27 (32)
Educational handout	21 (25)
Endorsement of private community provider	15 (18)
In-availability of oral regimen	11 (13)
Physical examination findings of bruising, subconjunctival hemorrhage, cephalohematoma	10 (12)
Total	85 (100)

IM indicates intramuscular; VKDB, vitamin K deficiency bleeding of the newborn; and AAP, American Academy of Pediatrics. Questions in this table represent actual survey questions.

* Percentages do not add up to 100 because respondents had the option to select multiple responses.

Table 3

Regional Differences in Reported IM Vitamin K Refusal

Region*	Frequent	Infrequent	Total
Midwest	9 (43)	12 (57)	21 (100)
Northeast	7 (32)	15 (68)	22 (100)
South	13 (62)	8 (38)	21 (100)
West	16 (76)	5 (24)	21 (100)
Total	45	40	85 (100)

IM indicates intramuscular.

Data are presented as n (%), “Frequent” defined as reported frequency of IM vitamin K refusal occurring once per month or more; “Infrequent” defined as reported frequency once every 3 to 4 months or less.

*Chi-squared analysis for overall distribution of reported frequencies of refusal differed among regions $\chi^2(3) = 10.03$, $P = .02$.