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RESEARCH ARTICLE

Oral Vitamin K Prophylaxis in Newborns: A Survey of Clinician Opinions and Practices

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ABSTRACT

OBJECTIVES: The majority of newborns in the United States receive intramuscular (IM) vitamin K for prophylaxis against vitamin K deficiency bleeding (VKDB). Oral vitamin K is less effective than IM vitamin K in preventing VKDB but is widely used in Europe and by some in the United States when parents refuse IM vitamin K for their newborn. Our aim was to assess the practices, opinions, and knowledge of newborn clinicians regarding oral vitamin K prophylaxis when parents refuse IM vitamin K.

METHODS: We conducted an electronic survey of newborn clinicians from 3 academic medical centers in California, Iowa, and Connecticut. Descriptive statistics and χ^2 tests were performed.

RESULTS: Of 160 newborn clinicians at 3 sites, 110 (69%) completed the survey. Of respondents, 58 (53%) believed the incidence of IM vitamin K refusal is increasing and had prescribed or recommended oral vitamin K at least once. Regarding knowledge, 32 (28%) and 23 (20%) respondents did not know whether oral vitamin K decreases the risk of early- and late-onset VKDB, respectively. There were no significant differences in opinions, knowledge, or practices across institutions or practice settings (NICU, well-newborn nursery, or both) ($P > .05$).

CONCLUSIONS: Our study findings suggest that newborn clinicians may lack knowledge about the effectiveness of oral vitamin K in preventing VKDB. More information is needed about oral vitamin K regimens and outcomes of newborns who receive oral vitamin K.

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Drs Cheng and Kair conceptualized and designed the study, designed and distributed the survey, collected and analyzed data, and drafted the initial manuscript; Drs Loyal and Wood assisted with survey development and distributed the survey; and all authors reviewed and revised the manuscript, approved the final manuscript as submitted, and agree to be accountable for all aspects of the work.

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Vitamin K deficiency bleeding (VKDB) in newborns is a condition with potentially devastating sequelae including severe neurologic impairment and death. VKDB is categorized on the basis of the timing of onset: early (within the first 24 hours of life), classic (from day 1 to 7), and late (from week 2 to 12).[1] Estimates of the incidence of late-onset VKDB in the absence of prophylaxis range from 10.5 to 80 per 100 000 births.[2] A single intramuscular (IM) injection of vitamin K after birth has been shown to reduce late-onset VKDB by 98% and has been recommended by the American Academy of Pediatrics (AAP) since 1961.[2,3] Despite this, rates of parental refusal of vitamin K for their newborn are on the rise.[4–6] The rationale behind parental vitamin K refusal is multifactorial and can include mistrust of the medical establishment.[7] This same sentiment is a major driving force behind the refusal of routine childhood vaccinations with studies revealing that parents who refuse IM vitamin K are more likely to refuse routine vaccinations and other forms of newborn prophylaxis such as the hepatitis B vaccine and erythromycin ointment for their child.[8,9]

In the setting of increasing rates of IM vitamin K refusal in the United States, oral vitamin K has become an attractive alternative among parents. Oral vitamin K has been and continues to be used in other countries but has not been studied in the United States.[10–13] Although studies have indicated that biochemical indices of coagulation are similar between newborns who receive oral or IM formulations during the first week of life, these indices do not necessarily correlate with clinical signs of VKDB.[1] Comparisons of surveillance studies in countries where oral vitamin K is given versus countries where IM vitamin K is given demonstrate no significant difference in early-onset VKDB. However, there are more cases of late-onset VKDB in countries where oral vitamin K is routinely given.[10,14,15] The study of oral vitamin K is further complicated by the use of disparate oral formulations and regimens in different countries.[10–14,16–18] There is also no Food and Drug Administration (FDA)–approved formulation of oral vitamin K in the United States. All of these factors make it difficult for US clinicians to learn about oral vitamin K and potentially extrapolate its use in other countries to their own practice. As rates of IM vitamin K refusal rise, it is important to know how US clinicians are prescribing oral vitamin K prophylaxis and examine their understanding of its efficacy in preventing the different forms of VKDB.

Because of increasing numbers of parents refusing IM vitamin K for their newborn, we hypothesized that oral vitamin K prophylaxis is being prescribed as an alternative to IM vitamin K by newborn clinicians in the United States. We surveyed newborn clinicians regarding their oral vitamin K prescribing practices when a parent refused IM vitamin K and knowledge of the effectiveness of oral vitamin K in preventing early-onset and late-onset VKDB. For secondary outcomes, we reported differences in the frequency of oral vitamin K prescribing by newborn clinicians in the well-newborn nursery and NICU settings.

METHODS

Sample and Setting

We surveyed newborn clinicians at 3 academic centers in the United States (California, Connecticut, and Iowa). These centers were chosen as a convenience sample on the basis of previous research collaboration within the Better Outcomes through Research for Newborns network.[7] All 3 sites were tertiary-care academic centers with a well-newborn nursery and a level IV NICU. At the California site, there are ~1550 live births per year with a vitamin K refusal rate of ~1.3%.[9] At the Connecticut site, there are ~4000 live births per year with a vitamin K refusal rate of ~0.2%.[9] At the Iowa site, there are ~2400 live births per year with a vitamin K refusal rate of ~0.8%.[9] Inclusion criteria for survey respondents were clinicians who cared for newborns in the newborn nursery and/or the NICU. This included physicians, nurse practitioners, advanced practice registered nurses, and physician assistants.

Data Collection

We designed an electronic survey using Qualtrics, a secure online survey software (Qualtrics, Provo, UT). The survey included questions on demographics, opinions, practices, and knowledge of respondents regarding oral vitamin K (survey available in Supplemental Information). Survey questions were developed after a review of the literature and expert opinion. Because there were no previous surveys that we could find investigating this subject matter, our questions were developed and revised on the basis of our newborn clinical and research experience. Questions on practices were aimed at discerning clinicians' personal experience with prescribing or recommending oral vitamin K as well as their comfort with potentially performing a procedure with bleeding risk (ie, circumcision) in the setting of different levels of prophylaxis. Questions on knowledge were developed on the basis of systematic reviews on the efficacy of oral vitamin K in vitro as well as comparisons of rates of early-onset and late-onset VKDB among countries that have been using oral vitamin K for decades.[1,2,10] We did not have a psychometrician on our team, and no cognitive interviews or pilot testing was performed. Respondents were recruited from each site by the site principal investigator. The survey was distributed via the institutional e-mail platform at each individual site to clinicians who cared for newborns in the well-newborn nursery or NICU. Potential respondents received a link to the electronic survey and up to 3 e-mail reminders. Survey data were collected over a 6-month period from August 2018 to January 2019.

Data Analysis

Statistical analyses, including descriptive statistics and χ^2 tests, were performed on survey responses using SPSS 23.0 (IBM SPSS Statistics, IBM Corporation). Institutional review board approval was obtained at each of the 3 study sites.

RESULTS

Of 160 eligible respondents, we received responses from 110 (response rate of 69%). Characteristics of respondents are shown in Table 1. Of 110 respondents, 81% were physicians and 19% were advanced practice clinicians (nurse practitioners, advanced practice registered nurses, or physician assistants). For physicians, the number of

TABLE 1 Characteristics of Survey Respondents ($N = 110$)

Characteristic	*n* (%)
Specialty	
Neonatology	58 (53)
General pediatrics	21 (19)
Pediatric hospital medicine	16 (15)
Family medicine	14 (13)
Hematology and/or oncology[a]	1 (1)
Clinician type	
Physician	89 (81)
Advanced practice clinician[b]	21 (19)
Practice location[c]	
NICU	67 (61)
Academic newborn nursery	65 (59)
Community newborn nursery	14 (13)
Outpatient pediatric clinic	4 (4)
Sex	
Female	84 (76)
Male	26 (24)
Circumcisions performed as part of clinical responsibilities	
No	81 (74)
Yes	25 (23)
Did not respond	4 (4)

[a] Provided nursery coverage outside of primary clinical responsibilities.
[b] Nurse practitioners, advanced practice registered nurses, and physician assistants.
[c] Respondents could select >1 location.

years since completion of medical school ranged from 3 to 45 years with a mean of 15 years. Many clinicians (32%) worked in multiple practice locations. They self-identified as working in the NICU (61%), academic well-newborn nursery (59%), community hospital newborn nursery (13%), and outpatient clinic (4%).

Clinician practices regarding oral vitamin K prophylaxis are shown in Table 2. Of respondents, 53% believed that the incidence of IM vitamin K refusal was increasing, and 54% had prescribed and/or recommended oral vitamin K prophylaxis for VKDB. The predominant oral formulation prescribed and/or recommended was liquid. Two respondents reported using the parenteral intravenous formulation compounded to be given orally. The dosing regimen used varied, with 3 doses being the most common (2–4 mg after the first feeding, then 2 mg at 2–4 and 6–8 weeks) followed by weekly dosing (2–4 mg after the first feeding, then 2 mg within the first week and weekly while breastfeeding). Of the 3 clinicians who had prescribed a single dose, 2 prescribed the first dose and asked families to follow-up with their primary care provider and 1 attempted but was unable to convince the family to give additional doses. Daily dosing (2 mg after the first feeding, then 2 mg within the first week followed by 25 μg daily for 13 weeks) was used by only 1 clinician.

When asked why clinicians chose to prescribe oral vitamin K, the most common reasons given were that it is better than no prophylaxis and parental preference. The most common reasons given for not prescribing oral vitamin K were concerns for efficacy, poor compliance, and lack of encounters with parents who have refused IM vitamin K. The results regarding knowledge of oral vitamin K's effectiveness against VKDB are shown in Fig 1.

Of respondents, 77 (74%) knew that oral vitamin K is not as effective as IM vitamin K at preventing late-onset VKDB. Most respondents (87%) did not know that oral vitamin K has been shown to normalize biochemical indices of coagulation. Of respondents, 60% either did not know or did not believe that oral vitamin K decreases the risk of early-onset VKDB.

We also asked about practices regarding circumcision. Of respondents, 25 (23%) performed circumcisions as part of their clinical responsibilities. These included 9 family medicine practitioners (36%), 8 general pediatricians (32%), 5 pediatric hospitalists (20%), and 3 neonatologists (12%). Among the physicians who performed circumcisions, 1 (4%) reported ever having performed a circumcision on an infant who had only received oral and no IM vitamin K, but 7 (28%) reported that they would do so. Furthermore, 4 (16%) reported that they would perform a circumcision on an infant who had received neither oral nor IM vitamin K. These respondents were all family medicine practitioners at 2 different centers.

We performed χ^2 analysis to determine if there were statistically significant differences in opinions, practices, or knowledge across institutions, specialties, and/or practice location(s) (NICU, well-newborn nursery and/or clinic, or both). We found no statistically significant differences ($P > .05$ for all comparisons).

TABLE 2 Respondents' Practices Regarding Oral Vitamin K Prophylaxis ($N = 110$)

Clinician Response	*n* (%)
Have you ever prescribed and/or recommended oral vitamin K? ($N = 110$)	
Yes, more than once	36 (33)
Yes, once	23 (21)
No	49 (45)
Did not respond	2 (2)
Do you have the parent sign a declination form if they have refused IM vitamin K but you have prescribed and/or recommended oral vitamin K? ($n = 58$)[a]	
Yes	43 (37)
No	15 (13)
Which oral vitamin K formulation was prescribed and/or recommended? ($n = 59$)[a]	
Liquid	45 (76)
Tablets to be crushed	8 (14)
Parenteral	2 (3)
Do not remember	4 (7)
How was dosing of oral vitamin K regimen prescribed and/or recommended? ($n = 57$)[a]	
Three doses over 8 wk	32 (54)
Weekly	7 (12)
Daily	1 (2)
One dose	3 (5)
Recommendation declined or parents used own regimen	3 (5)
Do not remember	13 (22)

[a] Respondents who had ever prescribed and/or recommended oral vitamin K.

DISCUSSION

In our study, we found that newborn clinicians are prescribing oral vitamin K in response to refusal of IM vitamin K by parents. Respondents who had not prescribed oral vitamin K had concerns about efficacy against VKDB and adherence of parents to the prescribed regimen. Because multiple-dose oral regimens are

TABLE 3 Respondents' Opinion and Knowledge Regarding Oral Vitamin K Prophylaxis, $N = 110$

Survey Question	*n* (%)
Do you feel that the national incidence of parents declining IM vitamin K is:	
Increasing	58 (53)
Staying the same	24 (22)
Decreasing	5 (5)
Unsure	19 (17)
Did not respond	4 (4)
Oral vitamin K has been shown to decrease risk of early-onset VKDB.	
True	41 (37)
False	31 (28)
I do not know	32 (29)
Did not respond	6 (5)
Oral vitamin K has been shown to normalize coagulation test results.	
True	14 (13)
False	31 (28)
I do not know	59 (54)
Did not respond	6 (5)
Oral vitamin K is as effective as IM vitamin K at preventing late-onset VKDB.	
True	4 (4)
False	77 (70)
I do not know	23 (21)
Did not respond	6 (5)

more effective than a single oral dose at preventing VKDB, adherence is essential but can be variable. One study in the United Kingdom indicated a decline in adherence with a 3-dose regimen to 88% at 1 week and 39% at 6 weeks.[19] In a New Zealand study, 97% adherence at 1 week and 94% adherence at 6 weeks was shown, with the caveat that one-fourth received the third dose later than recommended.[20] With increased frequency such as a weekly dosing regimen over 3 months, Hansen et al[17] showed a best-case adherence of 94% and a worse-case adherence of 86% in which adherence was defined as receiving at least 9 out of 12 doses. There have not been any US studies performed on the efficacy of and/or adherence to different oral vitamin K regimens. In our study, a wide variation of oral vitamin K dosing regimens was reported among our clinicians, which is reflective of the wide variation among countries on a global scale.[10]

Within the medical community, there have been concerns that in offering oral vitamin K as an alternative, clinicians may become complicit in VKDB.[21] Some clinicians argue that despite counseling families that oral vitamin K is not equivalent to the IM formulation; many parents may still opt for oral vitamin K when they may have been otherwise swayed to use IM if the oral option was not available. In addition, providing the option of oral vitamin K may create a conundrum should the community become aware of a precedent among certain clinicians. Parents might specifically seek out these clinicians to request oral vitamin K.

We did find that some clinicians are willing to perform circumcisions on infants who receive only oral and no IM vitamin K as well as a smaller number who are willing to perform circumcisions on infants who have not received oral or IM vitamin K. The clinicians in this group were all family medicine trained, and this finding warrants further investigation to better understand factors associated with and the rationale behind clinician's willingness to perform circumcisions in infants with inadequate vitamin K prophylaxis. Only 23% of our sample performed circumcisions, so it would be important to see if these results would be replicated with a larger sample of physicians who perform circumcisions. There have been few studies on postcircumcision bleeding in particular, but one revealed that IM vitamin K reduces the risk of postcircumcision bleeding by 82% compared with infants who received no prophylaxis.[22]

The absence of an FDA-approved oral liquid formulation means that only the 5 mg tablet or parenteral formulation is available for prescription. Using the tablet entails cutting and crushing to achieve the typical 2 or 4 mg dose, whereas the parenteral formulation requires additional logistic hurdles once the newborn patient is discharged from the hospital. Because oral liquid formulations are not FDA approved, actual concentrations of vitamin K in over-the-counter formulations may be variable with unclear efficacy or safety.[14,21]

We found that clinicians have similar opinions and practices regarding oral vitamin K across geographic and practice locations. Knowledge of oral vitamin K was lacking among some respondents. This could be due to fewer encounters with vitamin K refusal as well as the absence of literature on oral vitamin K in the United States. Lack of knowledge could also be impacted by the complexity and wide variation in dosing and formulation as previously discussed as well as overall lack of experience with oral vitamin K in the United States. Educational information regarding oral vitamin K should be disseminated among clinicians in the United States so that they can better counsel and advise patients' families. More studies on oral vitamin K are also needed to guide evidence-based practice.

The AAP continues to recommend IM vitamin K as the sole mode of prophylaxis against VKDB but does not present a firm statement on oral vitamin K prophylaxis.[23] Our study shows that not only are perceived rates of IM vitamin K refusal by parents of newborns rising among clinicians, but oral vitamin K is being prescribed with the belief that it is better than nothing. Given these changing times, the AAP should update their policy statement from 2003 to include guidance on oral vitamin K prophylaxis, education for clinicians and families, and a unified approach in discussions on vitamin K prophylaxis.

Our study has several limitations. Only tertiary academic medical centers were included. Although the clinicians who we surveyed worked in different practice settings, all were affiliated with an academic center and cared for newborns born in a medical institution. This may have skewed our findings and made them less applicable to a larger population because higher rates of vitamin K refusal have been associated with deliveries at birth centers and home births.[24] Furthermore, because the 3 institutions were chosen as a convenience sample by using a nonprobability sampling method, selection bias may have played a role. Another

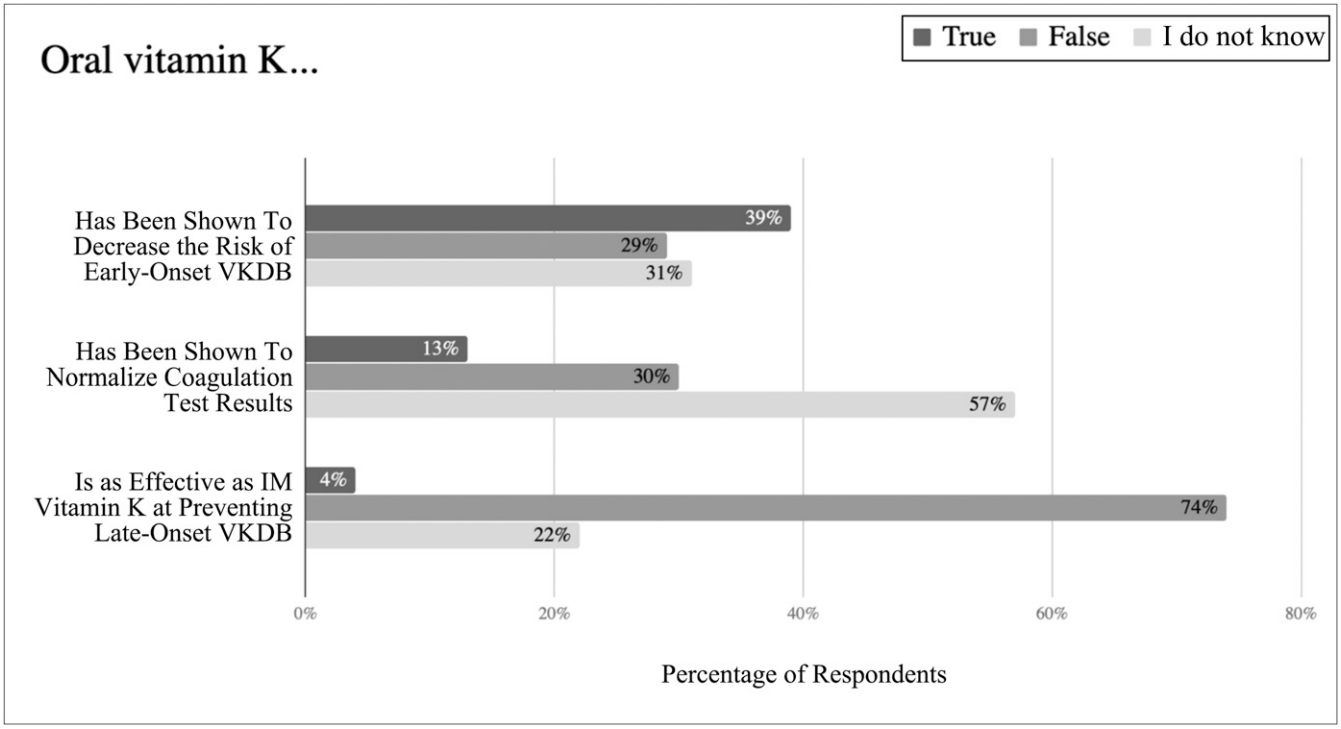

FIGURE 1 Clinical knowledge of oral vitamin K. Percentages are out of $n = 104$ with 6 nonresponses.

limitation is that midwives were excluded. Midwife-assisted deliveries are also associated with higher rates of parental vitamin K refusal.[24] Our small sample size and limited scope in survey sites may have captured different opinions and practices than had we expanded our survey population and practice locations.[24]

Because of resource constraints, we were unable to perform cognitive interviews or pilot testing in the development of our survey, which may impact the validity of our results. In addition, because our survey asked questions that prompted clinicians to remember their actions over the course of their career, there was likely an aspect of recall bias in our responses. When asking about liquid formulations of vitamin K, we did not specify whether it was a parenteral formulation that had been specially compounded and given orally or a specific formulation meant to be given orally. Because this has implications for both access (with parenteral formulations being more difficult to obtain outside of the hospital setting), cost, and efficacy, it would have been useful to know and will be important to specify in future studies.

CONCLUSIONS

More than half of clinicians surveyed from 3 academic medical centers across the United States prescribed oral vitamin K as prophylaxis against VKDB with wide variation in dosing and formulation. Evidence for oral vitamin K in the United States and knowledge of the available evidence among some newborn clinicians are lacking. It will be important to fill these gaps to provide the best and most informed care to patients. Crucial next steps include studying the efficacy and safety of oral vitamin K prophylaxis in the United States and the creation of concrete unified recommendations regarding its use.

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