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Parental Refusal of Vitamin K and Neonatal Preventive Services: A Need for Surveillance

Lauren H. Marcewicz[1,2,6], **Joshua Clayton**[1,3], **Matthew Maenner**[1,4], **Erika Odom**[2], **Ekwutosi Okoroh**[2], **Deborah Christensen**[4], **Alyson Goodman**[4], **Michael D. Warren**[3], **Julie Traylor**[3], **Angela Miller**[3], **Timothy Jones**[3], **John Dunn**[3], **William Schaffner**[3,5], and **Althea Grant**[2]

[1]Centers for Disease Control and Prevention, Epidemic Intelligence Service, Atlanta, GA, USA

[2]Centers for Disease Control and Prevention, Division of Blood Disorders, National Center on Birth Defects and Developmental Disabilities, Atlanta, GA, USA

[3]Tennessee Department of Health, Nashville, TN, USA

[4]Centers for Disease Control and Prevention, Division of Birth Defects and Developmental Disabilities, National Center on Birth Defects and Developmental Disabilities, Atlanta, GA, USA

[5]Vanderbilt University School of Medicine, Nashville, TN, USA

Abstract

Objectives—Vitamin K deficiency bleeding (VKDB) in infants is a coagulopathy preventable with a single dose of injectable vitamin K at birth. The Tennessee Department of Health (TDH) and Centers for Disease Control and Prevention (CDC) investigated vitamin K refusal among parents in 2013 after learning of four cases of VKDB associated with prophylaxis refusal.

Methods—Chart reviews were conducted at Nashville-area hospitals for 2011–2013 and Tennessee birthing centers for 2013 to identify parents who had refused injectable vitamin K for their infants. Contact information was obtained for parents, and they were surveyed regarding their reasons for refusing.

Results—At hospitals, 3.0% of infants did not receive injectable vitamin K due to parental refusal in 2013, a frequency higher than in 2011 and 2012. This percentage was much higher at birthing centers, where 31% of infants did not receive injectable vitamin K. The most common responses for refusal were a belief that the injection was unnecessary (53%) and a desire for a natural birthing process (36%). Refusal of other preventive services was common, with 66% of families refusing vitamin K, newborn eye care with erythromycin, and the neonatal dose of hepatitis B vaccine.

Conclusions for Practice—Refusal of injectable vitamin K was more common among families choosing to give birth at birthing centers than at hospitals, and was related to refusal of other preventive services in our study. Surveillance of vitamin K refusal rates could assist in further understanding this occurrence and tailoring effective strategies for mitigation.

[6]Present Address: Department of Veteran's Affairs, Atlanta VA Medical Center, Palliative and Supportive Care, 149 Ridley Lane, Decatur, GA 30030, USA

Keywords

Vitamin K; Vitamin K prophylaxis; Vitamin K deficiency bleeding; Vaccine hesitancy

Introduction

Vitamin K deficiency bleeding (VKDB) is a preventable coagulopathy (Zipursky 1999; Sutor et al. 1999; Winckel et al. 2009). Since 1961, the American Academy of Pediatrics has routinely recommended a vitamin K injection at birth as prophylaxis against VKDB (Vitamin 1961). VKDB can be severe, and may present as spontaneous intracranial or gastrointestinal hemorrhage (Zipursky 1999; Sutor et al. 1999; Winckel et al. 2009). Although there currently is no active surveillance of VKDB or prophylaxis administration in the United States (U.S.), U.S. and foreign medical literature seems to have noted an increase in both parental refusal of vitamin K prophylaxis and VKDB in the past few years (Schulte et al. 2014; Woods et al. 2013; Eventov-Friedman et al. 2013).

In late 2013, the Tennessee Department of Health (TDH) and Centers for Disease Control and Prevention (CDC) were notified of a cluster of late VKDB identified among 4 infants presenting to a children's hospital in Nashville, Tennessee. These 4 infants did not receive neonatal vitamin K prophylaxis, per parental choice (CDC 2013).

To estimate the frequency of and reasons for parental refusal of vitamin K at birth, TDH and CDC conducted chart reviews at Nashville-area hospitals and Tennessee birthing centers to estimate the number of infants born in these settings who did not receive vitamin K prophylaxis, and conducted a telephone survey of parents of infants identified as not receiving vitamin K from our chart review in order to identify parental reasons for refusal among this cohort.

Methods

Chart Review

We conducted chart reviews at the children's hospital where the cases were identified, five Nashville-area hospitals with labor and delivery units, and five birthing centers in Tennessee.

The children's hospital documented non-receipt of vitamin K by policy since 2011. Documentation procedures included providing parents with a handout with information about vitamin K prophylaxis and VKDB and having them sign a document indicating they had been informed of risks of refusing the injection. These documents were scanned into the infants' charts and the paper documentation was retained in a file by nursery staff. Utilizing this documentation, a list of all infants not receiving vitamin K between January and October 2013 was generated by the staff of the pediatrics department.

The other five area hospitals had no formalized or standardized means to document vitamin K non-receipt. A list of every live birth at these hospitals was obtained for January through October 2013 from the TDH's Office of Vital Records. The authors conducted chart reviews on a random sample of live births from each hospital to determine whether an infant had

received injectable vitamin K at birth. Any question of whether a chart review showed evidence of vitamin K refusal or not was discussed amongst the authors before making a decision. Sample size calculations were based on the ability to detect a 15% refusal rate from the number of live births during 2012 at each hospital (EpiInfo software, version 7.1.2.0; initial communication with the children's hospital suggested that near 12% of their live births were not receiving vitamin K due to parental refusal). The proportion of the sample refusing vitamin K was weighted based on the number of births at a given hospital (SAS, version 9.3). Non-receipt was inferred by either vitamin K administration not being recorded in the medication administration record of the infant's chart or documentation of parental refusal of vitamin K prophylaxis. Medication administration records were available for all charts reviewed.

In order to assess for trends, we applied this same sampling methodology to births at the six hospital-based labor and delivery units (including at the children's hospital) for 2011 and 2012.

At the time of our investigation, five free-standing birthing centers existed in Tennessee. Birthing centers are defined as homelike facilities that offer an alternative to hospital environments, according to the American Association of Birthing Centers (http://www.birthcenters.org/?page=bce_what_is_a_bc). Birthing centers were included in our examination of vitamin K refusal to account for births attended by non-physicians, such as midwives, in non-hospital settings. Since the number of births per year at each birthing center in Tennessee was low (under 100), we reviewed medical records for all live births occurring from January through October 2013 at all five free-standing birthing centers in Tennessee. We requested and received medical record information, including infant race, ethnicity, maternal age at delivery, insurance/payer source, whether vitamin K was administered and type (injection or oral) if administered, directly from birth centers. We did not review birthing center data for 2011 or 2012, as not all centers were open consecutively during these years.

Parent Survey

To better understand parental reasons for refusal of vitamin K prophylaxis, parents of infants who were identified as not receiving vitamin K in 2013 from our chart review were surveyed by telephone. These surveys were conducted by trained research assistants at TDH. We obtained parental contact information from hospitals and birthing centers and contacted parents up to three times to administer the phone survey. Parents provided verbal informed consent prior to being administered the survey.

Knowledge of the role of vitamin K prophylaxis was assessed by the question, “do you know of any risk of not giving vitamin K to your child?” Open-ended questions were used to capture a parent's reasons for choosing to refuse vitamin K prophylaxis and the sources that informed their decision. To understand the propensity for parents to refuse other routine preventive care measures, we also asked whether they refused the neonatal dose of the hepatitis B vaccine and/or erythromycin eye ointment.

In addition to the telephone survey, one author conducted interviews of the parents of 18 infants (4 affected by bleeding and 14 infants who did not receive prophylaxis but did not develop VKDB) as an additional part of our investigation not reported here. These interviews differed substantially from the telephone survey in that they involved gathering detailed maternal and infant medical histories, not relevant to the current report. One of these interviews was in-person at the infant's home, and the rest were via telephone. In addition to the histories, these interviews assessed knowledge of risks of refusal, reasons for doing so, and information sources. Two sets of these parents had elected to give their children injectable vitamin K prior to the interview; data from their interviews are not included here.

This work was reviewed by the Centers for Disease Control and Prevention and determined to be a response to a public health threat; it was therefore exempt from Institutional Review Board review.

Results

For January through October, 2013, 3.6% (111/3080) births at the children's hospital had documentation of parental refusal of vitamin K prophylaxis. From January through October 2013, 7661 live births occurred at the five other Nashville-area hospital-based labor and delivery units. Of 820 charts reviewed at these institutions, 19 [2.8%, 95% CL (1.3, 4.3)] infants had not received vitamin K prophylaxis. Only one had documentation of parental refusal in the form of an “against medical advice” form signed by the parents. Combined, 3.0% (95% CI 1.8, 4.2) of infants at six Nashville-area hospitals did not receive injectable vitamin K prophylaxis.

In 2011, 20 of 738 [2.8%, 95% CL (1.4, 4.3)] infants' chart's reviewed did not receive vitamin K; this number decreased slightly in 2012 to 2013 of 716 [2.3%, 95% CL (0.8, 3.8)].

The birthing centers had a higher refusal rate compared to the hospitals. We identified 91 of 294 (31%) infants born at birthing centers from January through October 2013 who did not receive injectable vitamin K.

Parents of 207 infants identified in chart reviews were eligible for the telephone survey. This included parents of 111 infants born at the children's hospital, 19 infants from other hospitals, and 91 infants born at birthing centers, and excludes the 14 families otherwise interviewed. Of these families, contact information was available for 164 (74%); all of these were contacted and 75 agreed to participate in the telephone survey (response rate 46%). Most of the families self-identified as white (93%) and were privately insured (62%). Of the 75 telephone survey participant families, 58 (77%) acknowledged opting out of vitamin K prophylaxis for their child. Families participating in the in-depth interviews (n = 16) all self-identified as white and were mostly insured by Medicaid (56%).

Of families who opted out of vitamin K, including families identified via telephone survey or interviewed (n = 74), 51 (69%) correctly identified bleeding as a risk of non-receipt of vitamin K prophylaxis. In addition to opting out of vitamin K prophylaxis, 69 (93%) opted out of the birth dose of hepatitis B vaccine, and 50 (68%) opted out of the application of

erythromycin eye ointment; 49 (66%) opted out of all three. Interviewed families were asked about whether their infants were vaccinated if over 2 months of age at time of interview. Only three of 15 infants (20%) who were over age 2 months were. Families could give multiple reasons for refusing vitamin K, but the most common reasons were a belief that it was not necessary (n = 39; 53%) and a desire for a natural birthing process (n = 27; 36%). Additional reasons included concern about preservatives or ingredients (n = 14, 19%), fear of adverse reactions (n = 10, 14%); wanting to avoid pain for their infant (n = 8, 11%); concern about the dosage being too high (n = 8, 11%); and concern that the injection might cause cancer (n = 6, 8%). One family noted that they did not want to overwhelm their infant's immune system with the prophylaxis (Table 1). Many families (n = 33; 45%) relied on the Internet as a main source of information. However, 38 (51%) families reported either consulting with or being influenced by a healthcare provider. The list of these providers was highly variable, and included not only obstetricians and pediatricians, but also chiropractors, doulas, and, in one case, a radio personality who gives medical advice.

Discussion

Results from our investigation confirm findings from a recent study of vitamin K refusal in Alberta, Canada, where vitamin K refusal was associated with births at home or in birthing centers as opposed to hospitals, and births attended by midwives as opposed to physicians (Sahni et al. 2014). In our study, almost one-third of infants born in birthing centers did not receive the vitamin K injection. This finding is also similar to that of a recent study in North Carolina, which found a higher rate of vitamin K refusal at birthing centers than hospitals (Hamrick et al. 2016). Variation in frequency of vitamin K refusal by delivery site may be due to inherent differences in the philosophies of parents who choose alternatives to delivering in hospitals, or may reflect the attitudes of providers at such facilities and the education they provide to parents. Midwives, for instance, favor “watchful waiting and non-intervention in normal processes,” (http://www.midwife.org/Our-Philosophy-of-Care) and may subscribe to a “normal until proven otherwise” (http://www.birthcenters.org/?page=bce_what_is_a_bc) view of birthing and newborn care. While this approach affirms the normalcy of the birthing process, it could also contribute to a view that some preventive services, such as vitamin K, are unnecessary.

Our rates of refusal are substantially higher than the rates of refusal found in both the Alberta and North Carolina studies. In our study, 31% of infants born at birthing centers in Tennessee did not receive vitamin K, compared with 10.7% of infants born at birthing centers in Alberta (Sahni et al. 2014), and 4.34 and 8.33% at two birthing centers in North Carolina (Hamrick et al. 2016). As in the other studies, rates of refusal for hospital births are low; however, in the Nashville area, rates of refusal are near 3%, which is nearly 10 times higher than the 0.2% refusal rate in Alberta (Sahni et al. 2014). Rates of refusal at hospitals in the North Carolina study varied, with most hospitals having a rate less than 1%; the highest rate of refusal was 3.15% and occurred at a community hospital with an established system of oral vitamin K administration (Hamrick et al. 2016). Reasons for the apparent regional variation in vitamin K refusal are unclear, but there may be hospital- or locality-specific explanations, such as counseling by a particular local provider, a well-developed alternative medicine network, or the availability of particular processes or medications.

Surveillance of vitamin K refusal at the institutional or state level, in the United States, could allow for clear identification of trends and geographical areas of concern, and investigations into reasons for such regional variation. Vitamin K prophylaxis effectively prevents VKDB (Zipursky 1999; Winckel et al. 2009; Kries and Hanawa 1993). A study in the United Kingdom estimated the risk of VKDB as 81 times higher in infants who did not receive injectable vitamin K prophylaxis compared with those who did (McNinch and Tripp 1991). In our study, parents who opted out of vitamin K prophylaxis generally understood that there was an associated risk of bleeding. However, it was unclear whether the majority understood that the duration of risk for infants extends to 6 months of age, that this bleeding could be severe and life-threatening, or that this risk is increased among children who are exclusively breastfed (Zipursky 1999; Sutor et al. 1999; Winckel et al. 2009). Indeed, in the North Carolina study, which was substantially smaller than ours (n = 54), while a majority of parents understood that there was a risk for bleeding, only a few understood that this could be life-threatening (Hamrick et al. 2016).

A large proportion of parents who opted out of vitamin K prophylaxis in our study also opted out of other important neonatal preventive services, such as hepatitis B vaccination and erythromycin eye ointment, findings also reported in the North Carolina study (Hamrick et al. 2016). In the Canadian study, vitamin K refusal was associated with later vaccine hesitancy (Sahni et al. 2014). Similarly, a recent study published in the American Journal of Public Health documented the association between refusal of topical fluoride and vaccine hesitancy (Chi 2014). Taken together, these results suggest that families who refuse one preventive service may be likely to refuse others. In the fluoride study, Chi suggests, using the model of the “common risk factor,” that the philosophical and behavioral underpinnings of refusal of one preventive service (e.g., vitamin K) are similar to those for refusal of other preventive services (Chi 2014; Sheiham and Watt 2000).

The most common reasons for refusing vitamin K in our study were either that it was unnecessary, unnatural or unsafe in injectable form. These match beliefs documented in studies of vaccine hesitancy, for example: those who are vaccine-hesitant are more likely to believe that vaccines are unnecessary and that the body can protect itself, and are more likely to have concerns about the safety of vaccines (Smith et al. 2011; Kennedy et al. 2005). The potential commonality of health beliefs among families who refuse various preventive strategies should be a clear cause for concern regarding the continued effectiveness of public health preventive strategies. Further work investigating not only the specific reasons that individuals refuse preventive services, but also how widespread these beliefs are is important for tailoring and scaling-up messaging that may address health beliefs.

Our study has a number of limitations. The difficulty in interpreting documentation of vitamin K refusal at hospitals other than the children's hospital, where a policy was in place, means that we may have artificially over-estimated refusal. However, refusal at the children's hospital was slightly higher than 3%, which is the most reliable hospital estimate. Our survey was a voluntary, retrospective survey; recall bias may have influenced answers. In addition to recall bias, it is interesting to note that only 77% of parents agreeing to participate in our survey acknowledged having refused vitamin K. Parents may have later received vitamin K from pediatricians, may have been intimidated by being contacted by the

Tennessee Department of Health, working in conjunction with CDC, or we may have incorrectly identified these families as having refused based on our decision to infer non-receipt without clear documentation in the medical record. Our study did not address additional risk factors for the development of VKDB that may have been present for infants who did not receive prophylaxis, such as exclusive breast feeding, nor did we address the role of oral vitamin K, which may represent important areas for future investigation.

Overall, our study highlights the limited information available regarding refusal of vitamin K prophylaxis. Processes for documenting vitamin K refusal are not standardized, either locally or regionally, compromising accurate assessment of the extent of vitamin K refusal. Although our study adds to the growing body of knowledge about why parents refuse vitamin K prophylaxis, we still have limited understanding about these health behaviors and whether they can be changed with additional education or intervention. Surveillance could assist in assessing the occurrence of refusal and any changes in the occurrence over time. This information could be utilized by diverse stakeholders, including local departments of health and clinicians, and could inform the development of communication strategies for the possible occurrence of VKDB in areas where prophylaxis refusal is on the increase. National surveillance of human papillomavirus vaccination coverage, for example, has allowed for the identification of trends in coverage from year to year, the identification of potential areas for intervention, and the development of effective communication strategies regarding the importance of vaccination (CDC 2014).

A possible way to institute local surveillance and increase informational awareness regarding vitamin K refusal risks is to adopt use of a standard form when parents refuse vitamin K, such as that in use at the children's hospital in our study. This form could serve as an acknowledgement from the family that they have been informed of the risks, similar to institutional and state “against medical advice” forms, and could be used to capture data regarding the frequency of refusal.

Neonatal intramuscular vitamin K is an important preventive service offered to newborns in the United States for the prevention of potentially devastating bleeding (Zipursky 1999; Vitamin 1961). Refusal of vitamin K led to the development of bleeding in four children in the Nashville area in 2013, prompting our public health investigation. In Nashville, rates of vitamin K refusal were low, but were substantially higher among infants born at birthing centers. Refusal of vitamin K in Nashville was associated with refusal of other important preventive services, including neonatal vaccination. These findings suggest the need for surveillance of vitamin K refusal rates, an important public health strategy that could lead to effective strategies for mitigating this alarming trend.

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Significance

Vitamin K deficiency bleeding (VKDB) is a preventable coagulopathy, but some parents refuse this service, and this has resulted in cases of (VKDB). This study examines how common refusal is in the Nashville area, where a cluster of VKDB cases was identified in 2013, and suggests that surveillance of refusal may assist in further understanding and addressing this issue.

Table 1

Interview and telephone survey results of families who refused injectable vitamin K prophylaxis for their child

	n (%)
Families of children not receiving prophylaxis	74 (100)
Participating in telephone survey	58 (78)
Participating in interview	16 (22)
Correctly identified bleeding as risk of refusal of vitamin K	51 (69)
Refusal of additional preventive services	
Erythromycin eye ointment	50 (68)
Neonatal hepatitis B vaccine	69 (93)
Refused vitamin K injection, erythromycin eye ointment and neonatal hepatitis B vaccine	49 (66)
Reasons for refusal of vitamin K injection (more than one could be given per family)	
Not necessary	39 (53)
Desired natural birthing process	27 (36)
Concern about preservatives/ingredients	14 (19)
Adverse reactions	10 (14)
Avoid pain for infant	8 (11)
Concern about dose being too high	8 (11)
Concern that injection causes cancer	6 (8)
Did not want to overwhelm infant immune system	1 (1)