UC Davis UC Davis Previously Published Works

Title

Refusal of Vitamin K by Parents of Newborns: A Qualitative Study

Permalink

https://escholarship.org/uc/item/0w75q3c3

Journal

Academic Pediatrics, 19(7)

ISSN

1876-2859

Authors

Loyal, Jaspreet Weiss, Theresa R Cheng, Jessica H <u>et al.</u>

Publication Date

2019-09-01

DOI

10.1016/j.acap.2019.04.003

Peer reviewed



HHS Public Access

Author manuscript *Acad Pediatr.* Author manuscript; available in PMC 2020 September 01.

Published in final edited form as:

Acad Pediatr. 2019; 19(7): 793-800. doi:10.1016/j.acap.2019.04.003.

Refusal of Vitamin K by Parents of Newborns: A Qualitative Study.

Jaspreet Loyal, MD, MS¹, Theresa R. Weiss, MPH¹, Jessica H. Cheng, MD², Laura R. Kair, MD², Eve Colson, MD, MHPE³

¹Department of Pediatrics, Yale University, New Haven, Connecticut,

²Department of Pediatrics, University of California Davis, Sacramento, California,

³Department of Pediatrics, Washington University School of Medicine, St. Louis, Missouri

Abstract

Background and Objective: Despite American Academy of Pediatrics recommendations, some parents refuse IM vitamin K as prophylaxis against vitamin K deficiency bleeding (VKDB) for their newborn. The purpose of our study was to describe attitudes and perceptions of parents who choose to defer IM vitamin K for their newborn.

Methods: Using qualitative methodology, we conducted in-depth semi-structured interviews with parents of newborns in 3 hospitals in Connecticut and California. We used the grounded theory approach and the constant comparative method until saturation was reached.

Results: Nineteen participants (17 mothers and 2 fathers) of 17 newborns were interviewed: 14 newborns did not receive IM vitamin K due to refusal by parent and for 3 newborns IM vitamin K administration was delayed due to initial hesitation by the parent. Four major themes emerged: (1) *Risk to Benefit Ratio*: parents who refused IM vitamin K perceived risk to their newborn from preservatives for example; (2) '*Natural' Approaches*: leading to seeking oral vitamin K or increasing mother's own prenatal dietary vitamin K intake; (3) *Placement of trust and mistrust*: mistrust of the medical and pharmaceutical community with overlapping concerns about vaccines and trust of self, likeminded allopathic and non-allopathic healthcare providers, the social circle, the internet and social media; (4) *Informed by Experiences*: including hospital experiences with prior pregnancies and communication with health care providers.

Discussion: Parents' perception of risk, preference for alternative options, trust and communication with health care providers are pivotal factors when making decisions about IM vitamin K.

Keywords

Vitamin K refusal; newborns; parent perspectives

Conflict of Interest: The authors have no potential conflicts of interest to disclose.

Address correspondence to: Jaspreet Loyal, Department of Pediatrics, Yale University, 333 Cedar Street New Haven CT 06445, Jaspreet.Loyal@yale.edu.

Financial disclosure: The authors have no financial relationships relevant to this article to disclose.

Introduction

The American Academy of Pediatrics (AAP) recommends intramuscular (IM) injection of vitamin K at birth to eliminate Vitamin K Deficiency Bleeding in Newborns (VKDB).¹ In recent years, reports of parents refusing the vitamin K injection for their newborns in the United States (U.S)^{2–4} and other countries have increased.^{5–6}

Why parents refuse IM vitamin K for their newborns in the U.S. is not well understood. Reported concerns from parents include the dose of IM vitamin K as too high, potential harm from the injection. and belief that it is unnecessary.^{2–7} Investigators in a qualitative study exploring vitamin K refusal in New Zealand found that parents' concern for their child's welfare, external social factors, including health professionals, and parents' belief system influenced their decision-making.⁸

There is little qualitative data on parent perspectives and decision-making regarding IM vitamin K refusal in the U.S. We followed the methodologic approach used in previous research which has subsequently informed ongoing research related to behaviors and attitudes of parents.⁹ Through qualitative research, investigators identified attitudes and perceived social norms that have been verified using quantitative methods and have informed interventions nationwide.^{10–12} The purpose of our study was to explore attitudes and perceptions of parents who are hesitant or refuse IM vitamin K for their newborn using qualitative methodology as the initial step to better define what appears to be a growing concern for families.

Methods

Study Design and Sample:

We conducted a qualitative study using data from semi-structured interviews with Englishspeaking parents of newborns who refused IM vitamin K for their newborn. Interviews were ether face-to-face during the post-partum stay or via telephone following hospital discharge.

Purposeful sampling was used to recruit parents from the post-partum unit of 2 well newborn units in New Haven, CT. For context, there are approximately 5500 annual deliveries (~60% White, ~20% Hispanic, ~15% African American, and ~5% are Asian or Other race). In 2015, there was a 0.5% IM vitamin K refusal rate within the health system.¹³ In the CT hospitals, IM vitamin K is administered on the Labor and Birth unit by nursing staff shortly after the birth. Labor and Birth staff verbally explain the rationale for the injection to the parent. Parents who decline IM vitamin K are asked to sign a refusal form. Oral vitamin K as an alternative to IM vitamin K is not offered routinely. Parents who refused IM vitamin K were referred to the study's principal investigator by the post-partum nurses or pediatric clinicians.

To aid with triangulation, purposeful sampling was subsequently used to recruit parents from the post-partum unit of a well newborn unit in Sacramento, CA. The hospital has approximately 1550 annual deliveries (~50% White, ~25% Hispanic, ~15% Asian or Pacific Islander, ~7% African-American and ~3% Other race). IM vitamin K is administered by

nurses on the Labor and Delivery unit immediately following birth and nursing and physician teams both verbally explain the rationale for the injection to the parent. Parents who decline IM vitamin K are asked to sign a refusal form. Oral vitamin K as an alternative to IM vitamin K is offered by most but not all providers. Parents who refused IM vitamin K were referred to the study's site principal investigator by the pediatric clinicians.

Verbal consent was obtained from each participant in a private room with only the participant prior to the interview. If both parents were present in the room, they were interviewed together but were addressed individually to obtain consent. Demographic data collected included age, race/ethnicity, years of education, and health insurance (Table 1). Enrollment continued until saturation, when no new concepts emerged.

Data Collection:

Data collection was performed in a constant comparative manner, with each new interview informing the investigator's understanding and line of inquiry for the next. An initial interview guide was created based on current literature and our previous work examining healthcare provider perception of vitamin K refusals.¹⁴ The interview guide (Table 2) was revised in an iterative process as new information emerged from the data.

All interviews were audiotaped and transcribed verbatim by an independent transcription service (ASP.MD Inc., Cambridge, MA and Home Row, Inc., Henderson, NV). No identifying information was collected on participants and audio files were stored on an encrypted computer by the study PI and site PI. Approval from the Yale University Human Investigation Committee and the University of California Davis Institutional Review Board was obtained prior to beginning the project.

Data Analysis:

Data from the transcripts were analyzed using coding techniques common to qualitative research using grounded theory methodology.^{15–17} Data analysis was conducted in an iterative process, with data collection and analysis continuing concurrently until no new themes emerged ('saturation'). $^{15-17}$ In the first part of the analysis, an initial code list was created by the first author based on the first read-through of transcripts. Codes (participant's words, phrases, or authors' concept words) served as labels for important participant data. Authors JL, EC and TW coded every transcript independently. Transcripts were then compared and discussed as a group, to share reflections and to abstract commonalities in the codes each author had assigned. The initial code list was iteratively revised using the constant comparative method as new data were collected. In the second part of the analysis, codes were clustered into cohesive categories. To reduce redundancy among the categories and to ensure the category linkages were firmly established, all researchers came to agreement in the coding schema, which was then reviewed for data that expressed the main ideas or themes. Disagreements were resolved through working with two or more researchers (peer debriefing).¹⁸ In the third part of the analysis, data were reviewed for evidence of relationships among themes.

Trustworthiness in the data was established through 1) ongoing debriefing sessions by the authors to discuss reflections, insights and incoming data; 2) coding development over 6

months, allowing adequate comparison with the literature and enabling prolonged engagement with the data to recognize biases or distortions¹⁹ and 3) member checking during interviews to ensure correct interpretation of what was being shared, and by discussing tentative themes and interpretations with a subset of research participants. Data was organized in Microsoft Excel 2016.

Results:

Sample

We conducted 15 interviews in Connecticut (13 were exclusively with the mother and 2 interviews included both mother and father) and 4 interviews in California (exclusively with mothers) for a total of 19 participants (Table 1). Parents of 3 infants who initially refused IM vitamin K agreed to the injection; one participant was concerned about aluminum in the injection, but changed her mind after gathering information from the internet and speaking with her pediatrician. The second hesitant mother wanted to be more 'natural', but agreed to the injection because of obstetrician requirements pre-circumcision. The third hesitant parent agreed to IM vitamin K after counseling from the pediatrician regarding the risk of intracranial bleeding from late VKDB in the absence of prophylaxis. All participants deferred the hepatitis B vaccine for their newborn in the hospital and expressed hesitancy about childhood vaccines. One parent explained that *"We're not parents who think that vaccines give kids autism….But I'm not one of those people who believes that I should blindly listen to the CDC guidelines."* All participants stated that they put a lot of thought into their decision to not give their newborn IM vitamin K and felt overwhelmed with having to filter through copious sources of information.

Knowledge About IM vitamin K and Indication for Injection

All 19 participants were aware that IM vitamin K is administered to newborns shortly after delivery to prevent bleeding. One participant who refused IM vitamin K said, "...*if they get cut they can bleed more because vitamin K is important for clotting. And the other part of it is the possible hemorrhage...which is serious.*" Participants reported that their knowledge about vitamin K came from experience with previous children, having a medical background, discussion with prenatal or pediatric clinicians, or gathering information prior to delivery.

Themes

Four main themes emerged on decision-making about vitamin K. Themes, subthemes and exemplars are listed in Table 3.

1. Risk to Benefit Ratio—Participants who refused IM vitamin K stated the risk of the injection outweighed the benefit. Specific concerns included the effect of the product's alcohol on the newborn liver, the synthetic nature of polysorbate 80 and propylene glycol, and perceived neurotoxic effects of aluminum. Participants who refused IM vitamin K sometimes referred to vitamin K as the "vitamin K vaccine". In trying to distinguish between concerns about vaccines and IM vitamin K, we found 3 major overlapping concerns: a fear of preservatives, doubt as to whether IM vitamin K and vaccines are

necessary, and a perceived potential threat of harm from these injections, whether from pain or a perceived high dose.

Additional concerns included pain from the injection, timing of the vitamin K injection being too early in life and concern that the dose is too high. Participants reported that their decision to forgo IM vitamin K was influenced by a perception of low risk for VKDB. Participants considered their newborns to be at low risk for VKDB if there was an uncomplicated vaginal delivery, the newborn was not having a circumcision, on the advice of a likeminded prenatal or pediatric health care provider or because they were planning to administer oral vitamin K to the newborn.

2. 'Natural' Approaches—Participants who refused IM vitamin K had a shared interest in wanting to stay 'natural', leading some to seek oral vitamin K as an alternative. Some participants increased their own dietary vitamin K intake during pregnancy by eating vitamin K rich foods (kale, spinach, cantaloupe, Brussels sprouts, and alfalfa), took vitamin K supplements or consumed organ meats. A few believed that vitamin K would cross the placenta or be transferred to their newborn through breast milk.

Some participants questioned the need to give *all* newborns IM vitamin K. Another participant said she believed vitamin K deficiency in newborns at birth is 'natural' and hence normal. One participant's desire to use a 'natural' approach was supported by her religious beliefs.

3. Placement of Trust and Mistrust—Participants expressed mistrust of some health care providers and pharmaceutical companies. One participant suggested that healthcare providers were not being truthful about the contents of IM vitamin K, and were potentially benefiting from adverse effects of preservatives. Six participants perceived a lack of transparency from the medical community about the contents of IM vitamin K, including the preservative-free version. Statements from three participants implied a financial motivation on the part of pharmaceutical companies.

Almost all participants reported trust in their prenatal and/or pediatric healthcare provider when making the decision about IM vitamin K. One participant who refused felt supported by a like-minded pediatrician. Participants sought information from their midwives, non-allopathic health care professionals or chose to do their own research. Participants' partner, social circle of family, friends, and other parents were considered trusted resources of advice. For example, one participant began to question whether to allow IM vitamin K after talking with parents during a prenatal hypnobirthing class (https://us.hypnobirthing.com/).

When seeking information about vitamin K, some participants used the internet and social media. Information from the internet often supplemented information obtained from a health care professional and the social circle. Participants who had access to medical libraries reported seeking the scientific literature through PubMed, UpToDate® or specific journals. Other websites considered reliable by participants include the Centers for Disease Control and Prevention, WebMD, Google and nutrition sites. Some participants chose to review the

IM vitamin K package insert in detail. Social media was reported by some participants as increasing their curiosity about IM vitamin K, prompting additional inquiry.

4. Informed by Experiences—Some participants stated that in previous pregnancies there had been no discussion or explanation of IM vitamin K, which affected their current decision to forgo it, following the most recent pregnancy. Participants with a positive perception of communication with their health care provider noted the provider's willingness to include the parent in decision making by answering questions and engaging in open dialogue with respect and professionalism, even when parent and provider may not agree, as opposed to a provider who becomes defensive and paternalistic.

Participants who planned to refuse IM vitamin K after the current pregnancy had varying experiences in the hospital. For two participants, having a birth plan in place prior to delivery resulted in a positive experience, and both participants did not feel judged as previously feared. Some participants were aware that the hospital does not provide oral vitamin K and brought their own. These participants noted that hospital staff appeared unsure about how to proceed in the absence of a hospital guideline, and this created some confusion. One participant who refused IM vitamin K chose to not mention her birth plan until after the delivery. Participants reported mixed experiences when asked to sign the hospital's refusal form. One participant stated that signing the form allowed her to not have to explain herself and feel judged.

Discussion

Decision-making about IM vitamin K was influenced by parent's perception of risk, a desire to be 'natural', trust in self, health care providers, the social circle, internet/social media, and open communication with health care professionals. Our findings were those reported in the qualitative study in New Zealand.⁷ Parents in our study also reported being influenced by social media and previous post-partum experiences in the hospital setting where they perceived not being involved in the decision-making process or with health care professionals not willing to hear and address their concerns.

The perceived risk of harm from preservatives in the injection influenced decision making. Despite concerns, studies have found no evidence that aluminum in vaccines caused any serious or long-lasting adverse events.²⁰ There is no evidence to suggest that the small amount of benzoyl alcohol in the vitamin K injection when used as recommended has adverse effects.²¹ Polysorbate 80 is an ingredient in the preservative-free IM vitamin K. Polysorbate 80 (P80) is a nonionic detergent used to solubilize proteins and is widely used in oral and injectable medications. There are limited studies about P80 but no adverse effects have been reported in infants who received vaccines with P80.²²

A desire for 'natural' approaches for their newborn led some parents to choose oral vitamin K as an alternative. Oral vitamin K for the prevention of VKDB is less effective than IM vitamin K. In newborns, oral vitamin K for the prevention of VKDB is not approved by the U.S. Food and Drug Administration²³ but is widely used in Europe.^{24,25} Some participants increased their own dietary intake of vitamin K during pregnancy to indirectly increase the

fetus' vitamin K level at birth. Very small quantities of vitamin K cross the placenta from mother to fetus and vitamin K content in human milk is low.²⁶ Evidence about the effects of increasing vitamin K intake during pregnancy is limited.²⁷ In the absence of current evidence-based recommendations regarding amounts and frequency of prenatal and postpartum dietary supplementation with vitamin K, the exact benefit of these practices alone in the absence of IM vitamin K to the newborn is unclear.

Many participants expressed trust in their own and their child's health care provider. The importance of trust when parents are making decisions about vaccines for themselves or their newborn has been previously reported.^{28–30} In a study about information sources of future mothers, investigators found that health professionals are the main source of encouraging information about infant immunization, and, conversely, that receipt of information against immunization was associated with delayed infant immunization.³¹ There is some inconsistency among health care professionals regarding the importance of IM vitamin K. In a 2014 survey of medical staff and midwives in New Zealand, investigators found that all medical staff felt that newborns should receive vitamin K but only 55% of midwives agreed.³² Some participants shared their mistrust of information provided by healthcare providers and pharmaceutical companies. These findings were also noted in the qualitative study about vitamin K refusal in New Zealand⁷; similar concerns have been reported in studies about vaccine hesitancy.³⁰ Parents who refuse vitamin K are more likely to delay or refuse vaccines^{5,33} and this overlap between vaccines and IM vitamin K is important for clinicians counseling parents to recognize and provide guidance with thorough antenatal education.

Participants sought to become more informed health care consumers by seeking information from the internet or social media. In some instances, information shared on social media sparked a curiosity to further explore claims made about the harmful effects of IM vitamin K and alternative sources of prophylaxis. Although studies about the influence of social media on decision making about IM vitamin K is lacking, similar research on vaccine hesitancy implies that social media is a notable influence on parents.³⁴ Many participants shared examples of reputable internet sources suggesting that parents recognize the importance of seeking legitimate sources online. Critical appraisal of peer-reviewed journal articles requires some skill; even though more parents potentially have access to databases such as PubMed, there may be an opportunity for clinicians to guide parents on how to review and interpret the findings. In a study by Miller at al., investigators found various educational resources with inconsistent information about vitamin K prophylaxis and recommended standardizing information to facilitate easier review of content as well as translation to other languages.³³

Finally, our study demonstrates a continued shift in the doctor-patient relationship away from parents simply accepting the universal standard of care without question. Parents are informed health care consumers asking well-researched questions and want to be part of the decision-making process from the beginning. This suggests that clinicians need to begin having conversations and address concerns about IM vitamin K during the pregnancy and guide parents through their research process. The importance of the physician's simultaneous role as educator while respecting the opinions and autonomy of parents was

reported by Weddle et al³⁶ and our study findings confirm parents' preference for physicians performing this dual role.

This study was limited by the sample size and homogeneity of participant characteristics. In our experience, parents who refuse vitamin K can be hesitant to talk about their reasons for refusal which was a challenge during recruitment. We did not collect the exact number of families we approached who refused to participate but estimate that 50% of parents we approached did not want to be interviewed, many due to convenience and many were hesitant to discuss their reasons for vitamin K refusal. We do not know if those who did not agree to be interviewed differed in their attitudes and perspectives from those who were interviewed.

Our sample is a homogenous group of mostly White, educated parents with private insurance who delivered in a hospital. The reported epidemiology of parents who refuse or are hesitant about vaccines is similar³⁷ but this is not the only population refusing vitamin K and we may have missed additional perspectives had our sample been more diverse. We attempted to address this by recruiting from an additional site for triangulation. In our previous work studying factors associated with refusal of IM vitamin K, we found that Non-Hispanic white race/ethnicity was significantly associated with IM vitamin K refusal.³⁸ In a study by Hamrick et al, of parents intending to refuse IM vitamin K prophylaxis at birth, most respondents were white and college graduates.³

Two interviews were conducted with both mother and father present, as preferred by the parents, and we may have missed information if one participant was not completely open about his/her perspective. Women who give birth outside a hospital or have a midwife provider are more likely to refuse IM vitamin K than women giving birth in a hospital environment⁵ and our sample was limited to women delivering in a hospital. We included English speaking parents only which potentially excluded other cultural contexts. Only three participants in our study were initially hesitant to the administration of IM vitamin K to their newborn and we did not separately explore their perceptions in this study. Regarding sample size, the number of participants needed to reach saturation in a qualitative study depends on a number of elements including data quality, nature of the topic, among other factors.³⁹ Considering these factors, we felt that our findings, while not generalizable, adequately described the context of parental refusal of IM vitamin K in our setting. Despite the limitations, our findings can inform the creation of a quantitative survey that would include a more diverse group of parents from a variety of backgrounds and geography.

In conclusion, we have provided additional insight into decision making about vitamin K by parents in the U.S. A next step would be to utilize these findings to develop a survey of U.S. parents to quantify the prevalence of themes and subthemes found in our study in a larger population. An additional next step would be to explore decision-making among parents with initial hesitation to vitamin K prophylaxis and the impact of open communication with clinicians. Information from these studies could also be considered when developing educational interventions to change behavior.

Acknowledgments

Funding source: Dr. Kair's effort was supported by the National Center for Advancing Translational Sciences, National Institutes of Health, through grant number (UL1 TR001860). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

References

- American Academy of Pediatrics Committee on Fetus and Newborn. Controversies concerning vitamin K and the newborn. Pediatrics. 2003;112:191–192. [PubMed: 12837888]
- Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report. Notes from the field: late vitamin K deficiency bleeding in infants whose parents declined vitamin K prophylaxis—Tennessee 2013. MMWR. 2013;62:901–902. [PubMed: 24226627]
- Hamrick HJ, Gable EK, Freeman EH, et al. Reasons for refusal of newborn vitamin K prophylaxis: implications for management and education. Hospital Pediatrics. 2016;6:15–21. [PubMed: 26711469]
- Kassis KL, Wada KJ and Milton A. Another disease re-emerges due to parental shot refusal: case report of a fussy infant with blood in stool. The Journal of Emergency Medicine. 2015;49(1):e15– 17. [PubMed: 25841290]
- Sahni V, Lai FY, MacDonald SE. Neonatal Vitamin K refusal and nonimmunization. Pediatrics. 2014;134:497–503. [PubMed: 25136042]
- Burke M, Bernhardt H, Reith DM, et al. Perinatal influences on the uptake of newborn vitamin K prophylaxis – a retrospective cohort study. Australian and New Zealand Journal of Public Health. 2015;39(6):573–576. [PubMed: 26123282]
- Majid A, Blackwell M, Broadbent RS et al. Newborn Vitamin K Prophylaxis: A Historical Perspective to Understand Modern Barriers to Uptake. Hospital Pediatrics. 2019;9(1):55–60. [PubMed: 30593456]
- Miller H, Kerruish N, Broadbent RS, et al. Why do parents decline newborn intramuscular vitamin K prophylaxis? J.Med. Ethics 2016;42:643–648. [PubMed: 27501788]
- Colson ER, McCabe LK, Fox K, et al. Barriers to following the back-to-sleep recommendations: Insights from focus groups with inner-city caregivers. Ambulatory Pediatrics. 2005;5:349–354. [PubMed: 16302836]
- Colson ER, Levenson S, Rybin D, et al. Barriers to following the supine sleep recommendation among mothers at four WIC centers. Pediatrics. 2006;118:e243–50. [PubMed: 16882769]
- 11. Von Kohorn I, Corwin MJ, Rybin DV, et al. Influence of prior advice and beliefs of mothers on infant sleep position. Archives of Pediatric and Adolescent Medicine. 2010;164:363–369.
- Moon RY, Hauck FR, Colson ER. Safe infant sleep interventions: What is the evidence for successful behavior change? Current Pediatric Reviews. 2016;12:1–9.
- Schlissel E, Kim Connie, Shapiro ED, Loyal J. Refusal of Vitamin K by parents of Newborns in a large health system in Connecticut. Poster Presentation, Pediatric Academic Societies Meeting, Baltimore 2015.
- Loyal J, Taylor JA, Phillipi CA, et al. Refusal of Vitamin K by Parents of Newborns: A Survey of the Better Outcomes Through Research for Newborns Network. Acad Pediatr. 2017;17;368–373. [PubMed: 28277269]
- 15. Charmaz K Constructing grounded theory: a practical guide through qualitative analysis. Thousand Oaks: Sage; 2006.
- Glaser BG, Strauss AL. The Discovery of Grounded Theory: Strategies for Qualitative Research. New Brunswick: Aldine Transaction; 2008.
- 17. Strauss A, Corbin K. Basics of qualitative research. Thousand Oaks: Sage Publications;1998.
- Hanson JL, Balmer DF and Giardino AP. Qualitative Research Methods for Medical Educators. Academic Pediatrics. 2011;11:375–386. [PubMed: 21783450]
- 19. Erlandson DA, Harris EL, Skipper BL & Allen SD (1993). Doing naturalistic inquiry: A guide to methods. Newbury Park, CA: Sage Publications

- Jefferson T, Rudin M, Pietrantonj C. Adverse events after immunization with aluminum-containing DTP vaccines: systematic review of the evidence. Lancet Infect Dis. 2004;4:84–90. [PubMed: 14871632]
- Vitamin K1 injection. Phytonadione Injectable Emulsion, USP [package insert]. Lake Forest, IL 60045: Hospira; 2004.
- 22. Gadzinowski J, Tansey SP, Wysocki J, et al. Safety and Immunogenicity of a 13-valent Pneumococcal conjugate vaccine manufactured with and without polysorbate 80 given to healthy infants at 2, 3, 4 and 12 months of age. Pediatr Infect Dis J. 2015;34:180–185. [PubMed: 25126854]
- 23. US Food and Drug Administration. Drugs@FDA: FDA approved drug products. http:// www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. Accessed 3.29.17.
- Laubscher B, Banziger O, Schubiger G, Swiss Paediatric Unit (SPSU). Prevention of vitamin K deficiency bleeding with three oral mixed micellar phylloquinone doses: results of a 6-year (2005– 2011) surveillance in Switzerland. Eur J Pediatr. 2013;172(3):357–60. [PubMed: 23192459]
- Hansen KN, Minousis M, Ebbesen F. Weekly oral vitamin K prophylaxis in Denmark. Acta Paediatr. 2003;92(7):802–5. [PubMed: 12892158]
- 26. Greer FR. Vitamin K the basics-What's new? Early Human Development. 2010;86:S43-47.
- 27. Greer FR, Marshall SP, Foley AL, Suttie JW. Improving the vitamin K status of breastfeeding infants with maternal vitamin K supplements. Pediatrics. 1991;99(1):88–92.
- Benin AL, Wisler-Scher DJ, Colson E, et al. Qualitative analysis of mothers' decision –making about vaccines for infants: the importance of trust. Pediatrics. 2006;117(5):1532–41. [PubMed: 16651306]
- 29. 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]
- 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]
- Veerasingam P, Grant CC, Chelimo C, et al. Vaccine Education During Pregnancy and Timeliness of Infant Immunization. Pediatrics. 2017;140(3):e20163727 [PubMed: 28821625]
- Gosai S, Broadbent RS, Barker DP, Jackson PM and Wheeler BJ (2014), Medical and midwifery attitudes towards vitamin K prophylaxis in New Zealand neonates. J Paediatr Child Health, 50: 536–539. doi:10.1111/jpc.12490 [PubMed: 24528494]
- 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(9):889–94. [PubMed: 25873083]
- 34. Tangherlini TR, Roychowdhury V, Glenn B, et al. "Mommy Blogs" and the Vaccination Exemption Narrative: Results From A Machine-Learning Approach for Story Aggregation on Parenting Social Media Sites. JMIR Public Health and Surveillance. 2016;2(2):e66:1–15.
- 35. Miller H, Wheeler B and Kerruish N. Newborn vitamin K prophylaxis: an analysis of information resources for parents and professionals. NZMJ. 2016;129(1446): 44–52.
- Weddle M, Empey A, Crossen E, et al. Are pediatricians complicit in vitamin K deficiency bleeding? Pediatrics. 2015;136(4):753–7. [PubMed: 26371205]
- Yang YT, Delamater PL, Leslie TF, Mello MM. Sociodemographic predictors of vaccination exemptions on the basis of personal belief in California. American Journal of Public Health. 2016;106(1):172–177. [PubMed: 26562114]
- Loyal J, Taylor J, Phillipi CA et al. Factors associated with refusal of intramuscular vitamin K in normal newborns. Pediatrics. 2018;142(2):e20173743. [PubMed: 30030367]
- 39. Morse JM. Determining Sample Size. Qualitative Health Research. 2000;10(1):3-5.

Author Manuscript

What's New

Using qualitative methodology, we explored perspectives of a sample of US parents regarding IM vitamin K refusal. Parents' perception of risk, wanting alternative options, trust and communication with health care providers were pivotal when making decisions about vitamin K.

Table 1:

Participant Characteristics (N=19)

	N (%)
Participant	
Mother	17 (89%)
Father	2 (11%)
Age (years)	
35	13 (68%)
> 35	6 (32%)
Race/Ethnicity	
White, non-Hispanic	16 (84%)
African-American	3 (16%)
Highest Education Level	
Graduate school	7 (37%)
College	10 (52%)
High school	2 (11%)
Mother's Insurance Type	1
Private	16 (94%)
Public	1 (6%)
Mother's First Child ¹	
Yes	9 (53%)
No	8 (47%)
Infant Gender ¹	
Male	8 (47%)
Female	9 (53%)

¹N=17 newborns

Author Manuscript

Table 2:

Final Iteration of Interview Guide

General Questions	Probing Questions
Tell me about your process during pregnancy when you were making the decision about the vitamin K injection for your baby?	What were your conversations with your obstetrician, midwife or pediatrician about the vitamin K injection during your pregnancy?
	Who or what resources did you use and trust when making a decision about vitamin K during your pregnancy
What is your understanding about vitamin K and why we give the vitamin K injection to newborns?	How did you come to that information?
What were your thoughts about the vitamin K injection?	Do you have a plan to provide your baby with vitamin K in another way?
	Is there anything that would have changed your mind about the vitamin K injection?
	Did your other children get the vitamin K injection? What changed this time?
Some mothers feel that increasing their own vitamin K intake would be sufficient for the baby. What are your thoughts on this? $*$	How did you supplement your own diet?
What are your plans regarding vaccines for your new baby?*	How is vitamin K different from vaccines?
Tell me about your experience in the hospital after the delivery regarding the vitamin K injection?	Who spoke to you about the injection and what was that experience like?
	How do you feel hospital staff responded when you elected to not give the injection to your baby?
What advice do you have for us as a hospital as parents come in with concerns about the vitamin K injection?	

*Plans to supplement the prenatal diet with vitamin K and concerns about vaccines in relation to IM vitamin K emerged spontaneously in early interviews and were added to the Interview Guide for later interviews.

Table 3:

Decision making about IM Vitamin K administration: Themes and Subthemes

Theme	Subtheme	Examples
RISK OUTWEIGHS BENEFIT	Additives	"She [the nurse] brought in the actual vial and my husband said that it has 100mcg of aluminum, and I'm not sure if I want to give our minute old baby aluminum"
		"I'm not okay with the things that are in them [IM vitamin K] that are being injected into our bodies"
	Timing of injection	"they are so young and there is so much going in at once and it's scary"; "if you give a baby a shot within this many hours of life, they're going to have this much more of a chance of having anxiety later in life."
	Dose	"get the oral rather than having something injected at that concentration this young . I think that's the biggest thing"
	Pain	"not to have, you know, a newborn baby get stabbedright away."
	Perceived low risk for VKDB	"if there was forceps birth or my kid had a big hematoma or circumcision that would've changed my opinion."
	Vitamin K is similar to vaccines	"I don't like unnecessary vaccines like chicken pox and flu and vitamin K goes in that realm."
'NATURAL' APPROACHES	Oral vitamin K option	"when I had learnedthat there was a more homeopathic natural alternative, it immediately kind of sparked my interest"
		"If they would've came out after he was born and said "Oh he definitely needs it" that would be a different story. They were like "Oh, do you want it? Do you not want it?"
	Religious beliefs	"I believe in a Creator who is so wise and created us so wonderfully. Why would he make us in such a way that we lack something that important?"
	Prenatal dietary supplementation	"my pediatrician recommended alfalfa supplements and then just boosting my diet with like greens and like natural forms of vitamin K"
PLACEMENT OF TRUST AND MISTRUST	Self	"When you are making the decision from a public health perspective it might make sense, but as a parent it doesn't. You have your one baby that you are worried about."
		"I had enough confidence in my own ability to figure it out with the information that was available to me from peer reviewed studies and logic."
	Healthcare providers	"I hate to say it but [I am] not taking MDs for what they say 100%but that's the truth."
		"For all we know, it could be mercurythey're trying to, at a low amount, give you metal in your bloodstream and raise the cancer rates so maybe they hit you another way."
		"My pediatrician was very supportive. 'If you want to do this, ok, fine, I'll support you. If you don't want to do this, I'll support you, too'"
		"Why is this country pushing so much for that vitamin K shot when there hasn't been a willingness to explore another route?Is it financially motivated?"
	Pharmaceutical companies	"I would say [I trust] my friends who are like, more like-minded"
	Social circle	"I have a lot of antivax friendstheir kids have had vaccine reactions"
		"I just Google search things on Facebook there's like 'Crunchy Mom' groups that I belong to and I always follow threads when they talk about things that are pertinent."
	Internet and social media	"I do my own research, I usually go on PubMedI like review articles[they] give you the direct sources if needed"
INFORMED BY EXPERIENCES	Experience with previous pregnancies	"With my first child, they had given it to her and I didn't even know. My husband told me that they took her, that they had given it to her and they didn't say anything, and when he did ask they said, 'It was just a vitamin.'"
	Shared decision making with clinician	"I just appreciate it when a doctor is willing to hear me out because to meit means that they are in control and they don't feel threatened and I can most certainly be waved in certain things if I see that willingness on the doctor's part."
		"She [pediatrician] wasn't saying "I'm the doctor, you do what I saywhen a doctor does that, Ishut off."

Theme	Subtheme	Examples
	Experience in the hospital	"my husband let them know we didn't want that [injection]the nurses weren't too happy about that. They gave my husband a bit of a hard time."
		"We weren't comfortable signing it [refusal form] because it looked like we were signing that we were okay with our baby bleeding to death which we weren't, that's not what we want and we had the oral drops to try to help."
		"I want her to have the most calm and peaceful experiencein the first few days of life"