Clinical Review

The Legal Limits of Parental Autonomy: Do Parents Have the Right to Refuse Intramuscular Vitamin K for Their Newborn?

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Abstract

Description

The American Academy of Pediatrics recommends that all newborns receive an intramuscular (IM) dose of vitamin K within 6 hours of delivery for the prevention of vitamin K deficiency bleeding (VKDB). There has been an increase in the number of parents who have refused the IM vitamin K dose for their infant based on its possible link to leukemia, preservatives that may lead to adverse reactions, and wanting to avoid pain for the infant. When newborns do not receive IM vitamin K, the most serious feared potential complication is intracranial hemorrhage with potential neurologic sequela including seizures, developmental delay, and death. Recent studies support the contention that parents are making the choice to refuse IM vitamin K without sufficient knowledge of the potential consequences. Parental decisions typically align with the best interest of the child; however, when parental decisions veer from the child's best interest, the limit of parental autonomy is tested. The precedent set by previous cases in which parental autonomy was challenged suggests parents should not be able to refuse IM vitamin K because the therapy has nearly no burden and forgoing this therapy has the potential for substantial harm. It has been argued that as long as the degree of intrusion is modest (a single IM injection) and the benefit substantial (prevention of possible death), states are granted the power to mandate the use of such an intervention. Mandated IM vitamin K for all newborns, regardless of parental approval, would rescind some parental autonomy but improve overall beneficence, nonmaleficence, and justice in the care of newborns.

Keywords

vitamin K deficiency/prevention and control; vitamin K deficiency bleeding; infant nutrition diseases; hemorrhagic disease of the newborn; intracranial hemorrhages; treatment refusal; parental autonomy; government regulation; best interest; newborn; infant

Case Presentation

A mother of advanced maternal age at 42 weeks gestation was admitted to a labor and delivery ward in Georgia due to failure to progress in labor at a local birthing center. Upon admission, she refused induction of labor. Following the birth of her baby boy, she also refused many of the standards of care for newborns, including the initial dose of the hepatitis B vaccination series, erythromycin eye ointment, and the IM vitamin K injection. While refusal of routine pediatric vaccinations is a well-known and frequently discussed occurrence, refusal of a vitamin that is made naturally by the body, though at insufficient levels in newborns, is perplexing. Without the ability to follow up on this particular infant, it is not known if he experienced complications, including the relatively rare vitamin K deficiency bleeding (VKDB), formerly known as hemorrhagic disease of the newborn (HDN). Regardless, this case sets the stage for the discussion of an interesting ethical dilemma for parents, most of whom have no formal medical education, making decisions about routine recommendations that have been proven to optimize the health of newborns. Healthcare providers are challenged

to seek out where the legal limits of parental autonomy meet the physician's obligations of beneficence, nonmaleficence, and justice.

Introduction

Background for the Use of IM Vitamin K in Newborns

Vitamin K is an enzymatic cofactor required for the activation of a number of coagulation factors involved in the coagulation cascade, which contribute to the prevention of hemorrhage-associated morbidity and mortality.[1] The administration of a single IM dose of vitamin K within the first 6 hours of life is helpful in preventing VKDB.[2] Neonates are innately deficient in vitamin K secondary to very little vitamin K transferred through the placenta to fetuses in utero, limited liver storage of vitamin K, and low amounts of vitamin K in breast milk.[3] There are 3 types of VKDB: early-onset VKDB occurs within the first 24 hours of life, classic VKDB occurs between 24 hours and 1 week of life, and late-onset VKDB occurs between 2 weeks and up to 6 months of life.[1] Late-onset VKDB has the worst prognosis as more than 50% of newborns with late-onset VKDB present with intracranial hemorrhage and have a 20% risk of mortality.[3] Since 1961, the American Academy of Pediatrics has recommended that all newborns receive a single IM dose of 0.5-1 mg vitamin K for the prevention of VKDB.[2] Its use virtually eliminated VKDB in the United States (US) until recently, when rates of parental refusal increased, followed by an expected increase in the incidence of VKDB.[3,4]

Parents often ask the doctor or hospital staff if oral vitamin K is effective, as parents tend to prefer oral administration to IM injections. While a single dose of oral vitamin K given at birth has been shown to decrease the incidence of early-onset and classic VKDB, a single dose of oral vitamin K is ineffective at preventing late-onset VKDB because of its shorter duration of activity.[5] Additionally, for high-risk neonates, such as those with gestational age less than 33 weeks, difficult deliveries or asphyxia, biliary disease including biliary atresia and cholestasis, and in utero exposure to anticonvulsant medication have an even greater risk of oral vitamin K being ineffective in preventing VKDB.[6,7] There are several European studies in which continuous dosing of oral vitamin K over weeks to months was used as a prophylactic regimen.[6,7] In their review, Ipema et al. conclude there is no consensus in the literature regarding the best oral vitamin K regimen, and given the limited oral dosage forms available in the US, oral prophylaxis is an impractical strategy in this country.[8] Thus, a single IM injection of vitamin K within the first 6 hours of life remains the recommended prophylaxis against all types of VKDB in the US.

Background of Parental Refusal of Vitamin K

Several studies have assessed the rationale for parental refusal of vitamin K. Parental rationale for refusing IM vitamin K includes concerns about a possible link between vitamin K and childhood leukemia, the belief that vitamin K is unnecessary, concerns about preservatives that may lead to adverse reactions, and wanting to avoid pain for their infant.[4,9,10] There is a regional variation in refusal rates, with the Southeastern US having the highest likelihood of refusal.[3,4] Additionally, there is a correlation between the likelihood to refuse IM vitamin K and the type of medical facility in which the birth occurs. Within the hospital setting, most parents are willing to accept the recommended vitamin K injection, with refusal rates of up to 3.2%.[11] Parents choosing home births or birthing centers are much more likely to refuse the vitamin K injection, with refusal rates up to 14.5% and 31%, respectively.[11] Other common characteristics of parents who refuse IM vitamin K include mothers over 30 years of age, plans to exclusively breastfeed, refused epidural analgesia during delivery, higher levels of education, European heritage, and subsequent immunization refusal.[2,10,11] The case presented from Georgia supported several of these parental characteristics including transfer from a birthing center, maternal age over 30, and plans to exclusively breastfeed.

Consequences of Parental Refusal of IM Vitamin K

As mentioned previously, the most serious potential consequence of the refusal of the recommended prophylactic dose of IM vitamin K is VKDB, particularly intracranial hemorrhage with potential neurologic sequela.[3,4] The prevalence of VKDB was very low in the US from 1980 – 2013 because of the use of recom-

mended IM vitamin K; however, as refusal rates increased, cases of VKDB also increased.[3,4] In 2013, 4 cases of late-onset VKDB in Tennessee were associated with parental refusal of IM vitamin K, which brought national focus back to the disease.[3,4,9,10] There is a lack of systematic tracking of VKDB, making it difficult to fully assess the rate of occurrence outside of case reports and case series. With overwhelming evidence revealing the consequences of forgoing IM vitamin K, it is quite concerning that the incidence of parental refusal is increasing.[9] For example, Marcewicz et al. reported that 3% of infants did not receive injectable vitamin K due to parental refusal in 2013, a frequency higher than 2011 and 2012.[9] The likely explanation for higher refusal rates among parents is a lack of awareness of the consequences associated with forgoing vitamin K. As discussed by Hamrick et al., 83% of parents reported an awareness of the risks of not receiving vitamin K, but only 67% of parents reported an awareness of bleeding, 17% reported an awareness of intracranial bleeding, and 9% reported an awareness of the risk of death.[10] Thus, the data support the contention that parents are making the choice to decline IM vitamin K without sufficient knowledge of the consequences.

Ethical Considerations

Defining the Limits of Parental Autonomy

The Fourteenth Amendment to the US Constitution states there is a "...fundamental liberty interest of natural parents in the care, custody, and management of their child".[12,13] This constitutional right is based on the assumption that parents act in the best interest of their child, as parents act for their children out of love; however, parental autonomy is not without limits as the state can overturn a parent's decision, given evidence that the decision is not in the child's best interest.[12] Not only can courts overturn a decision that is not in a child's best interest, but they can also go further and order invasive treatment over parental objection.[12] Ruling against a parent's objection to treatment is generally reserved for situations in which there is a clear medical consensus about the proper treatment, the treatment has a high likelihood of success, the treatment is not too invasive or painful, and the child will certainly die without it.[12] The latter half of this statement suggests that parental autonomy should be revoked when a parent refuses a treatment that a child will certainly die without, or in other words, a treatment that is lifesaving. Because absolute outcomes are rarely known in medicine, the prerequisite of certainty of death is challenging to uphold, making the limits of parental autonomy difficult to define. However, in the first half of this statement, the ability of courts to overturn decisions that are not in the child's best interests is easier to define. That is, the medical community continually reviews evidence that supports the standard of care recommendations for children with their best interests in mind.

History of Parental Autonomy

The first well-documented case of a state arguing against parental autonomy is the case of Baby Doe.[14] In 1982, Baby Doe was an Indiana infant with Trisomy 21 and a tracheoesophageal fistula. The parents and physicians decided to withhold lifesaving corrective surgery for the fistula, as well as hydration and nutrition, as they reasoned that despite the interventions, the infant would have lasting cognitive impairments from Trisomy 21. In this case, the physicians and the parents were in agreement about the course of treatment. Officials at the hospital, unsure of the legal implications of such a decision, had the Indiana Juvenile Courts appoint a guardian for Baby Doe to determine whether or not to perform the surgery despite the agreement among the physicians and parents. The Indiana Juvenile Court ruled in favor of the parents' right to "an informed medical decision".[14] The case did not progress to the Indiana Supreme Court or the US Supreme Court. The infant died soon after the final decision to withhold surgery and other means of supportive care.

The public outcry from pro-life and disability rights groups led to national recognition of the Baby Doe case.[14] These groups argued that regardless of lasting cognitive disability, Baby Doe had the right to live.[14] The outcry was so strong, President Ronald Reagan weighed in and notified all public healthcare institutions that they could lose federal funding if they did not provide treatment to infants with disabilities.[14] The controversy surrounding Baby Doe ultimately led to the development of the

"Baby Doe Rules."[14] The Baby Doe Rules have been credited with both reducing some of the traditional powers of parents to make medical decisions for their children and identifying legally bound obligations for care.[14] Thus, the fight to limit parental autonomy, when it was believed to be in opposition to the best interests of the child, had begun. After years of legal discussion on the matter, the Child Abuse Amendment of 1984 was approved by the US Congress as revised Baby Doe Rules that stated, "withholding treatment is only permissible if 1) the newborn is irreversibly comatose, 2) treatment would only prolong death, or 3) treatment would be inhumane".[12,14] The enforcement of these rules was placed on hospital ethics committees, along with the involvement of state child protective services. The Baby Doe Rules set the precedent that parents have autonomy over the care of their children as long as they do not choose to withhold lifesaving intervention. Based on the language of the Baby Doe Rules, and the setting in which they were first created, physicians are also not permitted to withhold lifesaving intervention from children. When a parent or physician chooses to withhold care, the autonomy over the choice to proceed with the intervention ultimately lies with child services of the state, notified via obligated reporting from hospital ethics committees.

Applying Parental Autonomy to the Refusal of Vitamin K

A major difference between the case of Baby Doe and the practice of refusing IM vitamin K is that vitamin K is not considered a lifesaving therapy. However, the refusal of IM vitamin K does have the potential to cause death. If preventing death can be seen as saving life, the precedent set by the Baby Doe Rules, of parents not having irrefutable autonomy, suggests parents should not be able to refuse the prophylactic dose of IM vitamin K.

Not all lifesaving therapies are held to the same standard for overriding a parent's autonomy to refuse the therapy. Gerdes et al. presented an argument on differing thresholds for overriding parental autonomy to refuse care based on the underlying diagnosis and associated prognosis.[15] These authors discussed several therapies including blood transfusions, chemotherapy, cardiothoracic surgery, and neonatal intensive care interventions. Each therapy has a different mortality threshold for which physicians must weigh the factors required to override a parent's decision.[15] Important considerations for deciding which treatments warrant overriding parental autonomy include long-term neurocognitive outcomes, the burden of the therapy itself, and a physician's sense of agency, or ability to make a mistake inadvertently causing harm, in providing the therapy.[15] Extrapolations from these considerations can be made with regard to the use of prophylactic IM vitamin K. First, there are no known negative long-term neurocognitive outcomes caused by exposing a child to IM vitamin K, but there are potential long-term neurocognitive outcomes of forgoing IM vitamin K. Second, the burden of the therapy itself is limited to possible fever, pain, and swelling associated with the injection. While pain to the infant is not negligible, one could argue pain associated with injections is a less significant burden than the disease the injection is designed to prevent, as can also be argued with routine childhood vaccinations. Finally, a physician's sense of agency in administering the therapy must be considered. This consideration is more applicable for therapies such as surgery in which the physician's agency can greatly affect a patient's outcome. A physician's sense of agency in administering IM vitamin K is not a significant concern as vitamin K is generally administered by nursing staff and the administration itself has little potential for mistakes that affect the overall outcome. Taken together, the threshold for a physician overriding a parent's autonomy to refuse vitamin K is very low. Forgoing IM vitamin K has the potential for substantial harm, including long-term neurocognitive impairment. The therapy itself has nearly no burden to the patient and is not reliant on physician agency. Therefore, physicians should have the authority to override a parent's refusal of IM vitamin K.

The argument in support of physicians having the authority to override parental autonomy is not universal to all medical decisions. Joseph Goldstein, a longtime law professor at Yale University who was known for his work in family law, said parents should only need to make the decision to oppose physician

recommendations if there is no general agreement among the medical community that the outcome of treatment is clearly preferred to the outcome of no treatment.[12] If a lack of agreement among the medical community is the only reason a parent needs to make the decision to refuse treatment, that is certainly not the case with vitamin K. The effectiveness of the use of prophylactic IM vitamin K is well-accepted among the pediatric physician community and has been for over 50 years.[2] Additionally, as mentioned previously, there are well-documented consequences associated with the refusal of its use. Thus, in the case of prophylactic IM vitamin K, which has general agreement among the medical community supporting its proven ability to prevent morbidity and mortality, parents have no need for refusing the therapy.

With evidence strongly supporting the use of IM vitamin K, there is an opportunity to consider the use of governmental intervention to mandate IM vitamin K use for all newborns, regardless of parental preference. Nevertheless, as of 2020, New York was the only state with a government mandate requiring the IM dose of vitamin K be administered to all newborns.[16] While government mandates revoke some parental autonomy, the best interests of the child are at their core. For example, the use of seatbelts and car seats is mandated by the government, revoking the autonomy to travel without these devices, but providing a well-accepted safety benefit for children. As was concluded in the review by Shah et al., it is believed that as long as the degree of intrusion is modest (a single IM injection) and the benefit substantial (prevention of possible death), states are granted power to mandate the use of such an intervention.[17] Thus, although VKDB is a rare disease[2,4], the consequences are severe enough to warrant the advocation for mandated prophylactic strategies.

Physician and Parental Beneficence

Physicians, nearly unanimously, want to do what is best for their patients, and parents, nearly unanimously, want to do what is best for their children. Therefore, physician and parent decisions should align when it comes to acting in the best interest of the pediatric patient. Despite this expected alignment, there is discordance between the physician's recommendation of prophylactic IM vitamin K and the willingness of some parents to accept their recommendation. If physicians and parents have different ideas about what is best for the child, it can be difficult to determine which course is in the child's best interest. Legally, courts do not have the right to rule on the best decision for a child; rather, they have the obligation to rule when a parent is not acting in the child's best interest.[12] Instead of parents having the burden to prove that their decision is in their child's best interest, it has been determined that the state bears the burden of proving that the parent's choice is wrong.[12] As cases of VKDB continue to increase, particularly when parents refuse IM vitamin K administration, there will be growing evidence for courts to use to decide that a parent's refusal of IM vitamin K is not in their child's best interest.

Physician and Parental Nonmaleficence

A physician's oath to do no harm should align closely with the innate motivations of parents to do no harm. While the parents who opt for refusal of IM vitamin K believe they are preventing harm to their child, including pain at the injection site and potential adverse effects from the injection, physicians are certain they are preventing harm as IM vitamin K has been proven to effectively prevent morbidity and mortality caused by VKDB. At present, it is common for states to require parents to sign documentation indicating informed refusal when they opt out of the IM vitamin K dose. A case study of a 3-week-old infant presenting with an intracranial hemorrhage after parental refusal of IM vitamin K at birth revealed that the parents signed informed refusal documentation.[18] Despite listening to the hospital staff's description of the benefits of IM vitamin K and accepting the potential harm by signing the form, the mother later commented, "I thought not giving vitamin K was reasonable as it was just a vitamin. I wish I had been more informed about the risks of forgoing vitamin K".[18] This parent's words help to emphasize the point that physicians are trained in the standards of care, while parents are often making important medical decisions without adequate medical knowledge. Even when provided with evidence and counseling on the benefits of the recommended IM vita-

min K, a small number of parents choose to accept the possible consequences. There are many potential reasons why a parent would sign informed refusal documents and later say they wish they had been better informed. For instance, the informed refusal document could have been signed without thorough reading or comprehension, the medical provider could have given inadequate information during counseling which allowed the parent to think their decision was reasonable, or there could have been extensive use of medical jargon that only further worsened the disconnect between the parent and physician, among other potential reasons. Regardless of the specific circumstances, these parents want to do no harm by avoiding an injection, but because they do not fully understand the evidence-based use of IM vitamin K, they are exposing their child to substantial potential harm. Thus, the physician and the state, both of whom can objectively assess the evidence in favor of IM vitamin K should render the decision for its administration at birth.

Justice

The principle of justice involves the equitable distribution of healthcare resources. As mentioned previously, those with higher levels of education, which generally correlates with higher socioeconomic status, are more likely to refuse the use of IM vitamin K.[10] There are several reasons why a higher rate of refusals occurs in this population, including the growing spread of medical misinformation on the internet.[10] Other factors that are linked to an increased likelihood of refusing IM vitamin K are also associated with higher socioeconomic status and include older age or the ability to participate in home births and birthing centers[10], some of which have large out-of-pocket costs.

As might be expected, there are a number of countries that have difficulty providing prophylactic IM vitamin K to newborns. One study evaluating VKDB in Malaysia revealed 42 cases of the disease within a 2-year study period. A significant proportion (81%) of these cases were associated with births where IM vitamin K was not available to be administered.[18] Thus, it is unfortunate to observe the increased incidence of a preventable disease occurring in the US where there are adequate resources to prevent the disease. Thankfully, the access to IM vitamin K is not a barrier to its use in the US, and a government mandate for its administration to all newborns would ensure its equitable distribution regardless of a parent's decision.

Directions for Future Study

Directions for future study include systematically tracking cases of VKDB in the state of Georgia, including follow-up on cases of IM vitamin K refusal similar to the case presented above. Additionally, there is evidence to suggest that there is little vitamin K education coming from obstetric providers[10], providing an opportunity for an extension of further education on newborn standards of care through our obstetric colleagues. This additional education would be particularly helpful coming from midwives in birthing centers as the patient population in birthing centers has a disproportionately high refusal rate for IM vitamin K. Furthermore, it can be argued that personal narratives of VKDB cases may be more effective evidence to parents than traditional statistics.[17] Thus, providing a comprehensive handout with parents' descriptions of their experiences with VKDB following their refusal of IM vitamin K may be another effective strategy to help reduce IM vitamin K refusal.

As reported above, New York is the only state with a mandate for the use of IM vitamin K at the time of birth, and as expected, their incidence of IM vitamin K refusal and resultant VKDB is substantially lower than states in which its use is not mandated.[3,16] Specifically, the rate of IM vitamin K refusal in New York is 0.4% compared to 2.3% in Tennessee, with no recent case reports of VKDB in New York.[3] Thus, an effective and legally binding approach to minimizing parental refusal of IM vitamin K and maximizing newborn well-being would be a government mandate requiring its use at the time of birth. The mandated use of IM vitamin K will reduce parental autonomy, but improve overall beneficence, nonmaleficence, and justice in the care of newborns.

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Conflicts of Interest

The author declares that she has no conflicts of interest.

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