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An Evidence-Based Ethical Approach to Parental Refusal of Screening Tests: The Case of Asymptomatic Neonatal Hypoglycemia

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Since the advent of the phenylketonuria screen for newborns in the 1960s, there has been an explosion of new tests for the early detection of numerous genetic, cardiac, and metabolic diseases. The intent is to discover and treat these illnesses before symptoms develop and to prevent possible irreparable harm. Screenings are typically conducted with parental assent rather than explicit consent. However, parental refusal on the grounds of personal and religious beliefs are becoming increasingly more common.¹ Experts in both the legal and bioethical fields have argued that even in the case of seemingly harmless, noninvasive tests, such as the critical congenital heart disease screening, it is sometimes ethically permissible for parents to refuse on behalf of their children.^{2,3} The American Academy of Pediatrics (AAP) Committee on Bioethics maintains that state intervention against a parental decision should only be sought in the rare cases where “the decision of a parent places a child at substantial risk of serious harm.”⁴ Most of the target diseases for these screenings are rare, and therefore the burden of “likely” preventing harm would infrequently be met. Yet, what if the target pathology were more common and impacted nearly one-half of all infants at risk? Would the ethical obligation to honor parental wishes still outweigh the risk to the newborn? This question underpins the complicated issue of parental refusals of asymptomatic neonatal hypoglycemia screening and, more broadly, the question of when a physician’s ethical obligation to advocate for the best interests of a newborn supersedes the duty to honor parental wishes.

Hypoglycemia in the first 48 hours of life is estimated to occur in 6%-19% of all newborn infants.⁵ For those infants identified as at risk based on their size (large or small) for gestational age, their status as an infant of a mother with diabetes or as a preterm infant, this statistic rises to at least 50%.⁶ Screening for neonatal hypoglycemia is typically done in the first 1-2 days of life, via heel stick blood sampling every few hours. If positive, it can lead to recommendations such as early lactation support, hand expression and pumping, administration of dextrose gel, and ultimately formula supplementation. If hypoglycemia is deemed severe or persistent, treatment with intravenous dextrose and admission to the neonatal intensive care unit becomes more likely. Refusal of such screening protocols has become a more frequent occurrence in our center, although there are no current national or regional data on its prevalence. In our experience, families have cited numerous reasons for declining, including

concerns related to the painful heel stick, increased separation between mother and baby, the screening’s potential impact on breastfeeding, resulting pressure to use formula, and the perception of over-medicalizing birth and newborn care. Most of these cases can be resolved with individual discussion and parent education about the test, but a few have resulted in continued conflict, leading ultimately to ethics committee consults and degradation of a therapeutic relationship.

Neonatal hypoglycemia has been implicated in poor neurodevelopmental outcomes, specifically pertaining to cognitive skills later in life, but the thresholds for this effect are poorly understood and difficult to study.⁷ Matters become more complicated still, in that the standard of care, and even the simple definition of neonatal hypoglycemia, are neither clearly defined nor agreed upon. It would seem that, before answering whether a parental refusal of hypoglycemia screening in an asymptomatic newborn should be honored, the scientific foundations upon which that screening rests must be interrogated. Our willingness to deviate from an accepted or standard practice should be inversely proportional to the strength of the science supporting that standard.

Neonatal Hypoglycemia: Definitions, Incidence, and Impact

Neonates are physiologically predisposed to experience low plasma glucose levels, while also having a greater glucose demand compared with fetal requirements, and less efficient compensatory mechanisms to make up the difference.^{8,9} In fact, reports have observed that anywhere from 10% to 19% of all well, asymptomatic newborns will have at least 1 episode of low blood glucose in their first days of life, with that incidence increasing to around 50% for those infants deemed at risk.^{5,6,10} Harris et al examined 67 healthy, term newborns without any known risk factors for neonatal hypoglycemia and attempted to characterize the physiologic transition from fetal to neonatal glucose metabolism.⁶ By measuring continuous interstitial glucose levels, along with

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the traditional intermittent glucose checks, investigators found that glucose concentrations increased over the first 18 hours of life, stabilized, and then increased to adult concentrations by day 4. They also found that, on continuous monitoring, 73% of these asymptomatic infants had at least 1 episode of hypoglycemia, defined as 47 mg/dL or less, with a median of 5.5 hours of the first 4 days (96 hours) of life spent in that hypoglycemic range.¹¹ Without any signs of pathology and with such high incidence, it is difficult to discern the precise point at which hypoglycemia crosses from physiologic to pathologic.

The frequently cited 47 mg/dL cutoff, originated by Lucas et al, one of the earliest systematic studies of adverse neurodevelopmental outcomes in infants with hypoglycemia.¹² They found that lower developmental scores at 18 months were independently correlated with glucose values of 47 mg/dL or less during the newborn period, and therefore defined hypoglycemia at or below this limit. The authors also found that prolonged exposure to hypoglycemia was associated with worse outcomes, noting that 5 or more separate days of low glucose levels conferred a 3.5 times higher adjusted risk of developmental delay and cerebral palsy compared with normoglycemic infants. Although the results are striking, and the definition ever persistent, this study was not designed for broad applicability, because the primary study population was exclusively preterm infants and interventions for hypoglycemic events were not standardized.

The current literature is split on whether this threshold of 47 mg/dL portends a quantifiable risk for future neurologic impairment (Table).^{5,13-19} Many published studies do not control for other factors known to impact neurodevelopmental outcomes, such as maternal education or socioeconomic status (denoted by asterisk in the Table), making these results difficult to interpret. In 1 US study, where universal glucose screening was performed on all newborns born in 1 state, a single episode of hypoglycemia (<45 mg/dL) significantly increased the risk of future failure of 4th-grade literacy and mathematics proficiency examinations.⁵ Another large trial from New Zealand, designed to determine the safety and efficacy of glucose gel,

found no association between hypoglycemic episodes and negative neurodevelopmental outcomes at 2 years of age, irrespective of gel treatment.¹⁴ Similarly, another large prospective cohort from New Zealand also detected no association between hypoglycemia and poor neurologic outcomes at 2 years of age.¹³ However, when this same cohort was evaluated at 4.5 years of age, a dose-dependent risk of poor executive function and visual motor impairment was detected, with both severity of nadirs and frequency of episodes augmenting the risk.¹⁷ Furthermore, interventions to maintain euglycemia did not negate this effect, and more than 21% of hypoglycemic episodes found on masked continuous monitoring were not picked up by traditional intermittent screening. A secondary analysis of this cohort also found that infants who were noted to have large swings in glucose levels during the first 12 hours of life, often from rapid intravenous dextrose infusions, had higher rates of impairment noted at 2.5 years, though this effect was not seen at 4 years of age.¹⁷ Although there is certainly evidence to suggest that hypoglycemia can negatively impact neurodevelopment, the threshold between transitional physiology and pathology remains unclear. The current data cannot provide clear definitions of how low is too low, nor can it show reproducibly negative impacts across a child's lifetime.

Screening for Neonatal Hypoglycemia: Measurements, Inaccuracies, and Alternatives

Diagnosing an infant with hypoglycemia is nearly always dependent on measurements of glucose levels from a blood sample. Clinical signs of hypoglycemia are nonspecific, varied, and often completely absent. In the prospective study of at risk newborns by Harris et al, 79% of infants with hypoglycemia presented with no clinically identifiable signs.⁶ Grave and serious presentations, including hypoglycemic encephalopathy and seizures are possible, yet seem to be exceedingly rare, except in cases of genetic and metabolic disorders.²⁰

Without clear clinical signs of impending danger, clinicians are left to rely on intermittent measurements of glucose levels to diagnose hypoglycemia, yet these measurements can be imprecise and temperamental. The gold standard glucose oxidase test is cumbersome and time consuming, and more accessible point of care glucometers are subject to changes in peripheral perfusion, hematocrit, and altitude. Guidance by the US Food and Drug Administration for over-the-counter glucometers recommends accuracy to only ± 15 mg/dL when concentrations fall below 100 mg/dL.²¹ Likewise, the intermittent nature of the checks is bound to miss some transient episodes, with 1 study reporting that traditional screening protocols missed around 25% of all hypoglycemic events.¹⁷

Moreover, there is no consensus regarding the threshold for intervention. The Pediatric Endocrine Society recommends a cutoff for treatment at mean or expected normal

Table. Summary of current literature regarding the impact of neonatal hypoglycemia

Studies	Year	Sample size, characteristics	Age at follow-up	Negative outcome associated with hypoglycemia?
Lucas ¹²	1988	433, <1850 g	18 months	Yes
McKinlay ¹³	2015	404, 35 wk, at risk	2 years	No
Harris ¹⁴	2016	184, 35 wk, at risk	2 years	No
*Brand ¹⁵	2005	75, term, LGA	4 years	No
Kerstjens ¹⁶	2012	832, 32-35 wk	4 years	Yes
McKinlay ¹⁷	2017	477, 35 wk, at risk	4.5 years	Yes
Kaiser ⁵	2015	1943, all newborns	10 years	Yes
*Tin ¹⁸	2012	543, <32 wk	15 years	No

Inconsistent age of follow-up evaluation and criteria for screening have yielded mixed and conflicting results.^{5,12-18}

*A study in which socioeconomic status and/or maternal education was not controlled.

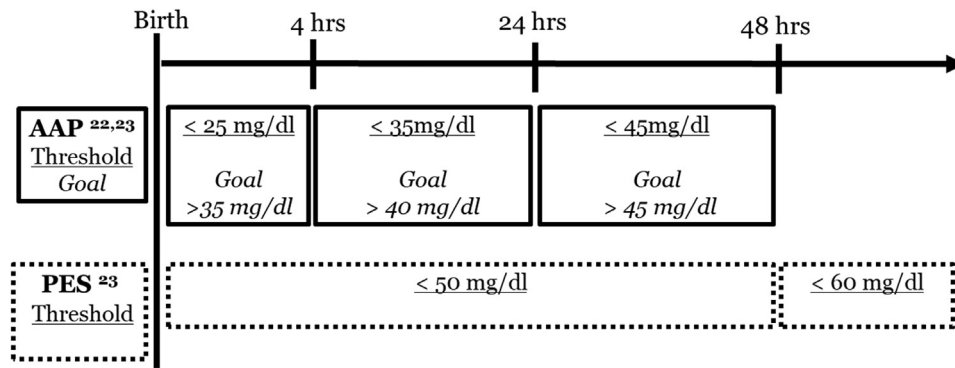


Figure. Definitions of neonatal hypoglycemia. A summary of the AAP and Pediatric Endocrine Society (PES) guidelines for defining neonatal hypoglycemia and thresholds for treatment.²²⁻²⁴

glucose values, whereas the AAP recommends the cutoff at the lower 95th percentile, among other different clinical recommendations (**Figure**).²² The AAP guidelines, written in 2011 and then reaffirmed in 2015, recommend the target for intervention be set at less than 25 mg/dL in the first 4 hours with subsequent targets increasing to 35 mg/dL and 40 mg/dL in the first 24 and 48 hours, respectively.²³ The guidelines from the Pediatric Endocrine Society were published in 2015 in response to criticisms that the AAP guidelines were lax and missed neonates with critical inborn errors of metabolism.²⁴ They propose using a target glucose of greater than 50 mg/dL for the entire first 48 hours of life and recommend longer testing duration. With standards of care differing between professional societies, it is no surprise that 2 infants presenting with the same clinical picture may be treated entirely differently, depending on the birth hospitals' protocols.

The screening itself is not entirely without risk. Multiple heel sticks in the first days of life may lead to bruising and pain-related stress that may impact future pain response and neurodevelopmental outcomes.²⁵ One study that specifically looked at pain responses in infants of mothers with diabetes found that exposure to frequent heel lances was associated with the development of hyperalgesia, with a more intense pain response after initial hypoglycemia screening.²⁶ Point-of-care glucose measurements are inherently inaccurate. Test strip devices are often designed with the adult diabetic populations in mind, translating to better precision at higher glucose readings, but greater margins of error at lower levels targeted in the neonatal population. False-positive results lead to more testing, which in turn may lead to increased mother-baby separation, familial anxiety, and decreased rates of sustained breastfeeding.²⁷ Alternatives to invasive screening may include more frequent clinical assessment for symptoms, consultation of lactation specialists, or prophylactic administration of supplemental formula or oral glucose gel. However, these more proactive and preventative options, without associated blood sam-

pling, likely carry a higher risk of failing to diagnose an episode of hypoglycemia.

The Risks: Likelihood and Degrees of Harm

When weighing the duty to honor parental wishes against the threatened risks to a newborn, clinicians must account for both the likelihood of the risk and the severity of possible harm. In the case of asymptomatic neonatal hypoglycemia, trends in available data and physiologic reasoning would suggest the potential for significant consequences. Few would debate that deficiencies of metabolic substrate in a developing brain could lead to irreparable neuronal injury. There have been several small case series which reported abnormal and characteristic magnetic resonance imaging findings in infants who had neonatal hypoglycemia. However, in all the cases described, infants presented with convulsions and were secondarily found to have low glucose levels.^{28,29} Although hypoglycemia seems to be a common problem for the newborn, reports of these most severe presentations appear to be rare, with fewer than 50 cases described, most of which are associated with rare inborn errors of metabolism.^{20,28,29} In the asymptomatic infant, the literature seems to be split on hypoglycemia's impact on future functioning, with the most pessimistic reports predicting sensory processing and executive function deficits.

The potential harm of hypoglycemia seems to be real, possibly with significant consequences, yet there are also harms associated with the screening. There is no way to calculate the potential harm of disenfranchising a parent in the care of their child. Short-term harm to the therapeutic relationship is likely, but the distrust sown in the newborn period could also lead to a future reluctance surrounding medical recommendations. In extreme cases, parental distrust can lead to a complete rejection of all future medical care and ultimately lead to more harm to the child. The screening itself is an imperfect test, with a high likelihood for a positive result, debated thresholds for pathology and

intervention, and an incomplete understanding of what reliably predicts deleterious harm. Although these harms may be less significant in severity when compared with future neurologic functioning, they are arguably more likely to occur. Likewise, no study to date has demonstrated efficacy of our current interventions for preventing future neurologic impairment related to hypoglycemia. Clinical trials designed to delineate precise thresholds and risks would not be ethically permissible, because they would require denying treatment to some infants and exposing others to undue risk. In the case of the asymptomatic infant at risk for hypoglycemia, the data will always be imperfect and, as a result, clinicians must choose a course of action based on the best available evidence and the individual circumstances.

Recommendations in the Setting of Parental Refusals

The risk of hypoglycemia-related neurologic injury is both real and significant, but the likelihood of this harm is not known. There are also risks of harm related to screening that are unquantifiable, although presumably less significant. Contemporary guidelines for screening the asymptomatic infant are based on the best available evidence and should be recommended to all those at risk. When met with parental hesitance, clinicians should respond with an exploration of the refusal, and information tailored to educate parents about potential harms and benefits. However, when parents continue to refuse, the clinician will need to determine whether to accept or override that refusal.

For parental refusal of any medical recommendation, including the case of screening for asymptomatic neonatal hypoglycemia, there are 2 thresholds of the assessed risk/benefit balance that which must be considered. The first threshold is reached when the available information regarding the test or intervention under consideration indicates that the anticipated benefits outweigh risks. When this threshold is reached, the test should be recommended to parents, and generally be part of standard care. Similarly, if risks outweigh benefits, it should not be part of standard care, and the physician should recommend against it. In either case, the right of parental authority is such that informed parents may choose to reject the recommendation, and the clinician should honor that refusal.³⁰ However, a second, more stringent threshold may be reached, when the anticipated benefits vastly outweigh the risks, and it is strongly in the child's best interest to undergo the test or intervention in question. This second threshold may apply, for example, when the anticipated harm of forgoing the test includes severe consequences. In considering whether the recommended test reaches this second, higher threshold, the clinician should assess both the likelihood and the severity of the harm anticipated in forgoing the test, and the data and/or physiologic reasoning supporting that assessment. When this second threshold has been reached, a screening test or intervention should no longer be considered merely advisable or recommended, but rather ethically oblig-

atory.³¹ At this second, higher threshold, the parental right to decide for their child should be outweighed by the child's right to protection from harm, and the clinician's obligation to provide that protection.⁴

Given what is known and what remains to be elucidated, hypoglycemia screening in most high-risk asymptomatic term newborns is here suggested to be advisable, consistent with professional guidelines, but the evidence does not meet the ethical threshold to supersede parental refusal. Thus, informed parental refusal should be respected. Permissible approaches may include less frequent or even no invasive glucose testing. In such cases, more frequent clinical monitoring, lactation consultations, and careful observation for the potential development of clinical signs may be appropriate.

Conclusions

We recommend following professional guidelines for glucose screening. What should be done when parents decline those recommendations? We suggest that the clinician's response to refusal should be based on 3 factors: the strength of evidence behind those recommendations, the prognosis with and without the recommended screening, and an understanding of relevant rights and obligations. Parents have a right to determine what will be done to, and for, their newborn. Pediatric clinicians have an obligation to educate parents, and to generally honor informed parental judgment. But there is also the obligation to protect newborns from some rare bad parental decisions, particularly when parental refusal would likely lead to significant harm to the child. With these 3 factors in mind, a risk/benefit ratio may be estimated and measured against 2 fundamental thresholds, for recommendation and requirement.

Based on the information available, it is here suggested that the threshold for recommendation has been reached, but the threshold for requirement has not. That is, there is not sufficient justification to mandate hypoglycemia screening in asymptomatic term newborns over informed parental objection. Like other newborn screenings such as the metabolic screen, hypoglycemia screening in the at risk asymptomatic newborn may be conducted with parental assent given that there is sufficient evidence to suggest benefit. When parents refuse, clinicians should prioritize efforts to educate them about the potential dangers of hypoglycemia. However, if the parents' position is unchanged, their refusal should ultimately be accepted. As more data emerge, this same analysis could well lead to the opposite conclusion. It is also recognized that others might look at the currently available information and reach the opposite conclusion now. The analysis, in any case, now or in the future, should be predicated upon the 3 factors described in this article and tested against the 2 thresholds for practice. Moreover, periodic consideration of all medical recommendations for screening procedures (eg, screening for hyperbilirubinemia, critical congenital heart disease, metabolic disorders, coronavirus disease-19 infection, etc) should be

undertaken with this same model in mind, seeking evidence and physiologic reasoning upon which to base recommendations, and upon which to justify overriding parental refusal. ■

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