

Potential Psychosocial Risks of Sequencing Newborns

Leslie Ann Frankel, PhD,^a Stacey Pereira, PhD,^b Amy L. McGuire, JD, PhD^b

abstract Various stakeholders have issued recommendations regarding the use of genomics in pediatrics. These guidelines are driven in part by concerns about psychosocial risks of disclosing predictive genomic information during childhood. As genomic sequencing becomes more commonly used in pediatric settings, it is important to systematically study the psychosocial impact of genomic sequencing of newborns, including the impact on family dynamics. Through review of the psychological and genetic counseling literature, we identify the following 3 domains of family dynamics that have potential to be impacted by the return of genomic results during the newborn period: perceived child vulnerability, parent-child bonding, and self and partner blame. In this article, we outline the complexity of studying these psychosocial outcomes and our plan to examine them in the BabySeq Project, a randomized controlled trial in both healthy and sick infants, in which the return of genomic information will be compared with standard of care.



^aDepartment of Psychological, Health, and Learning Sciences, The University of Houston, Houston, Texas; and ^bCenter for Medical Ethics and Health Policy, Baylor College of Medicine, Houston, Texas

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Address correspondence to Amy L. McGuire, JD, PhD, Center for Medical Ethics and Health Policy, Baylor College of Medicine, One Baylor Plaza, Suite 310D, Houston, TX 77030. E-mail: amcguire@bcm.edu

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Technological advances have allowed for more cost-effective rapid genomic sequencing to be carried out in clinical settings.^{1,2} As a result, increasing numbers of individuals will have their genomes sequenced as part of their clinical care. Genomic sequencing has the potential to be useful in the clinical care of patients, allowing clinicians to diagnose disease, identify disease risk, and alter drug treatment on the basis of pharmacogenomic information.³ Enthusiasm for the clinical utility of genomic sequencing, however, has been tempered by concerns about the potential psychosocial harms of disclosing genomic information to individuals.

Concern about the risks of returning genomic information is complicated for any patient but is especially complex in the context of pediatric medicine.⁴ Concerns about the use of genomics in pediatrics are reflected in guidelines and recommendations regarding the return of pediatric genomic sequencing results. The American Academy of Pediatrics (AAP),⁵ the American Society of Human Genetics (ASHG),⁶ and other stakeholders⁷ have issued policy statements discouraging the return of information related to adult-onset conditions during childhood. Some also caution that genetic testing in children should be limited to analysis of single genes or targeted sets of genes associated with specific illnesses that are suspected in children as opposed to sequencing the entire genome.⁶ The AAP further cautions against carrier testing in children when the results are not expected to have health benefits during the childhood period.⁵ Both the British Society for Human Genetics (BSHG) and ASHG argue against testing healthy children and caution clinicians to wait until children reach the age of majority to decide for themselves whether they want genetic testing.^{6,7} In their report, the BSHG emphasizes

that young children are not able to make decisions about what personal information they want discovered, leading to the possibility that parents will make choices that their children will disagree with when they develop the autonomy to decide for themselves.⁷

These guidelines emphasize respect for the child's developing autonomy and prioritize the child's "right to an open future."⁸ They also assume, however, that there is some risk of harm associated with obtaining predictive genomic information that children ought to be protected from. For example, the BSHG, among others, advise that clinicians only return results related to the reason for testing, arguing that returning results to asymptomatic children who have not yet shown symptoms makes these children "patients in waiting," which could cause psychosocial harm.^{7,9-11}

All of these guidelines and recommendations reflect careful analysis of the relevant ethical considerations, including the potential risks and benefits of testing, but because they are largely based on hypothetical concerns, rather than empirical evidence of actual harm, they should be interpreted cautiously.

IS THERE EMPIRICAL EVIDENCE OF PSYCHOSOCIAL HARM?

Empirical studies of the psychosocial impact of disclosing genomic information have mostly focused on anxiety and distress as the primary outcomes. In one such study, Bloss et al¹² explored the psychosocial impact of receiving disease risk information via direct-to-consumer genomic assessments and found no measureable changes in psychological health among the selected consumers. Likewise, the Risk Evaluation and Education for Alzheimer's Disease (REVEAL) study found that returning Alzheimer

Disease risk information to adults with a family history of the disease did not significantly impact anxiety, depression, or test-related distress over time, or in comparison with individuals who were not genotyped.¹³

Although these studies have not found any serious or sustained psychological symptoms in response to receiving genetic disease risk information, they have all focused on adults' experiences of receiving their own results. Studies of parents' experiences of receiving results from expanded newborn screening suggest that the psychological experience of receiving genetic information about one's child may be very different from the experience of receiving information about oneself. For example, parents report psychological stress in response to receiving false-positive information from newborn screening, and they tend to misinterpret false-positive results.¹⁴⁻¹⁶ Although such studies are informative, they provide only a one-dimensional perspective that focuses on the parent's own psychological response and fails to account for how complex the psychosocial impact of genomic sequencing of newborns may be.

FAMILY SYSTEMS THEORY

According to Family Systems Theory, an event that impacts one individual in a family will impact the entire system.¹⁷ It is important, therefore, to investigate how returning genomic information about a newborn impacts the entire family system. The psychological risks of returning genomic information at the individual level are important and should continue to be studied, but research investigating the broader psychosocial impact of returning results in pediatric populations needs to consider the impact not only on individuals but also on family relationships.

The Genome Sequence-Based Screening for Childhood Risk and Newborn Illness Project, referred to as BabySeq, is a randomized controlled trial investigating the benefits and potential harms of providing genomic sequencing to families of newborns and their physicians. Genomic sequencing may be especially useful in pediatric populations in whom rare and poorly understood conditions often present and for whom single-gene and panel testing may not be sufficient. The project is enrolling newborns and their parents from the Well-Baby Nursery at Brigham and Women's Hospital in Boston, Massachusetts, and from the NICU at Boston Children's Hospital. The study is also enrolling the health care providers who are taking care of these infants. Newborns within each cohort are randomly assigned to receive standard newborn screening (NBS) only or NBS plus genomic sequencing. Approximately 6 weeks after enrollment, all parents return for a disclosure visit, during which they are informed of their randomization status and study results. Those randomly assigned to the genomic sequencing arm will receive genomic results related to childhood-onset conditions, carrier status, and pharmacogenomics. Parents complete longitudinal surveys over the first year of their newborn's life at 4 time points: (1) at enrollment, which is within 8 weeks of the infant's birth; (2) immediately after the disclosure of results; (3) 3 months postdisclosure; and (4) 10 months postdisclosure. Parents' surveys assess psychological response, attitudes toward and perceived utility of NBS and genomic sequencing, and impact on family dynamics. Looking to psychology and genetic counseling literature, we have identified 3 important domains of family dynamics that have the potential to be impacted by the return of genomic results during the newborn period: perceived child

vulnerability, parent-child bonding, and self and partner blame.

Perceived Child Vulnerability

This concept refers to a parent's belief that his or her child is medically vulnerable, whether that child truly has a medical condition. This perception is often the result of the parents' medical experiences with their child: parents whose children have been ill are more at risk of perceiving their child to be vulnerable.^{18,19} Notably, perceived child vulnerability can continue to impact how parents think about and treat their children even after their child is no longer ill,²⁰ potentially influencing how parents view their infants beyond infancy and into childhood.²¹ As a result, parent perceptions of child vulnerability are associated with worse developmental outcomes for children regardless of their actual medical vulnerability.²²

Genomic sequencing has the potential to impact and even distort parents' perception of their child.³ Distorted perceptions could influence the interactions between parents and their children throughout the childhood years and even beyond. Although it won't be clear how this plays out with genomic sequencing in newborns until systematic studies are conducted, we can draw on previous studies of parent perceptions of child vulnerability²²⁻²⁵ and studies of genetic testing and self-perception in adults to inform our research.²⁶ These studies show that parents' perception of their infant as being highly medically vulnerable is sometimes related to developmental delays in infancy²² and behavioral problems in childhood.²⁵ Parents' perception of their child as medically vulnerable has also been related to social issues in children, such as anxiety in social situations.²³

Studies of parental responses to traditional and expanded newborn screening results also give clues

as to how parents might deal with information from genomic testing. Waisbren et al¹⁵ compared mothers whose children received false-positive results in expanded newborn screenings with mothers whose children did not receive positive results. They found that mothers of children who received false-positive results experienced higher parenting stress. In addition, although these mothers did not report worrying more about the health of their child, there was a trend toward these children being hospitalized more (21% of false-positive group versus 10% of normal-results group, $P = .06$).¹⁵

In the BabySeq Project, we are assessing parent perceptions of their child's vulnerability. Although we expect parents of children in the NICU to perceive their children as more medically vulnerable than parents of children in the Well-Baby Nursery, we are exploring whether the return of genomic information has an additional and independent impact on parent perceptions of their child's vulnerability.

Parent-Child Bonding

The parent-child bond begins before a child is even born.²⁷ Parent-child bonding in the first months of life is important because it sets the stage for the enduring emotional relationship between the infant and caregiver that lasts a lifetime.^{28,29}

In the context of expanded newborn screening, Waisbren et al¹⁵ found that mothers who received false-positive results on expanded newborn screenings reported higher levels of parent-child dysfunction compared with parents whose children received normal results. As part of the BabySeq Project, we are exploring whether the return of genomic information impacts parent-child bonding. Measuring parent-child bonding presents a particular challenge because it has the potential to be influenced by increases in

parent anxiety, changes in parent perception of child vulnerability,¹⁹ or knowledge of information that consciously or unconsciously alters how they bond with their child. Parent-child bonding, therefore, could be negatively impacted by the sheer stress of parents receiving disappointing information about their child; higher levels of parent stress have been related to increased likelihood of insecure attachment.³⁰ Therefore, although it is important to measure parent-child bonding, we must also measure parenting stress, anxiety, and how parents respond to results from the study to determine whether these variables mediate the relationships between parents receiving genomic information and parent-child bonding.

Self and Partner Blame

It is well established that the birth of a child is stressful on a marriage.^{31,32} That stress may be compounded by genomic sequencing of the child. A parent's reaction of blaming him or herself for passing deleterious genetic variants on to his or her child in response to receiving the child's genomic sequencing results has the potential to cause psychosocial stress³³ and may make individuals more prone to depression.³⁴ Blaming one's partner, alternatively, for passing deleterious genetic variants on to their child can facilitate feelings of resentment that might result in increased marital conflict or lowered marital satisfaction. Therefore, we are assessing self and partner blame, as well as marital conflict and satisfaction, in the BabySeq Project.

For the issue of self and partner blame, we can look to the genetic counseling literature^{34,35} to inform our hypotheses. We know from existing studies that there is potential for parents to blame themselves or blame their partners for conditions identified via genetic testing in children. Whether parents blame themselves or their partner in

the first place depends on various factors, such as the person's tendency to feel guilt or blame, variations in guilt and blame across genders, and the nature of the disease itself. In genetic counseling research and practice, experts have warned about higher potential for self-blame for mothers when conditions have X-linked inheritance.^{34,36} In a study in parents with children with X-linked and autosomal recessive conditions, researchers found that mothers were more likely to blame themselves than their partner, whereas fathers were more likely to blame mothers when the condition was X-linked compared with autosomal recessive.³⁴

The potential for self and partner blame highlights the importance of communicating genomic information to parents in ways that are sensitive to this phenomenon. Systematically studying the impact of return of genomic results on self and partner blame will inform future studies and interventions that seek to prevent psychosocial stressors to families that could result in disruptions to the family system.

IMPLICATIONS FOR THE FUTURE OF NEWBORN GENOMICS

One of the aims of the BabySeq Project is to explore the psychosocial impact of genomic sequencing, compared with standard of care (ie, state-mandated newborn screening), with parents of newborns who are placed into the NICU and parents of newborns who did not need placement into the NICU. Rather than focusing only on the psychological impact on parents, we are exploring the impact on the entire family system by measuring perceptions of child vulnerability, parent-child bonding, and self and partner blame. This project draws on existing psychological and genetic counseling literature to shed light on what we believe is the inevitable future of pediatric medicine. However,

there are several challenges to understanding the psychosocial impact of newborn genomic sequencing.

The psychosocial effects of newborn genomic sequencing must be assessed longitudinally. Although it is possible that parents will change their perception of their child and blame themselves or their partner shortly after the return of results from genomic sequencing, to fully appreciate the long-term benefits and risks to the family it is important to measure these factors throughout the child's development. If there are differences between those who are sequenced and those who are not sequenced regarding perceptions of child, bonding, and self and partner blame, it will be impossible to determine whether those differences present for a specific period of time or if they persist beyond the first year of the child's life unless there is longitudinal follow-up. In addition, accurate evaluation of parent-child bonding and attachment requires assessment over time and, ideally, beyond the first year of life.

However, there are several challenges to conducting a longitudinal cohort study in newborns. First, within the frame of a 5-year funding cycle, it may be difficult to follow a cohort further throughout child development. If long-term funding cannot be secured at the beginning of the study, then the best that can be done is to collect data for a limited period of time and obtain permission to recontact parents for continued longitudinal follow-up if and when the funding becomes available. Second, it is difficult to find measures for parents of infants that can be used across time, even within the first year of life. Unfortunately, the collection of child-related data in infancy often cannot be accomplished longitudinally with repeated measures; instead, constructs have to be examined with

different measures at different time points.

The best example of this is measuring parent perceptions of child vulnerability. The Child Vulnerability Scale (CVS) was developed with 4- to 8-year-olds.¹⁸ Although this scale has been used extensively with parents of children as young as 1 year old (adjusted age),²² it has not been validated for use in newborns and very young infants. Although some items in the CVS are appropriate for newborn infants (eg, I often check on my child at night to make sure she/he is okay), other items are less appropriate for parents of newborns (eg, My child gets more colds than other children I know).¹⁸ It may therefore be necessary to use the Vulnerable Baby Scale,³⁷ which was developed and validated with infants, early on in the infant's life and the CVS as the infant nears her second half-year of life. To ensure that the scales are measuring the same construct and establish concurrent validity,³⁸ it would be advisable to administer segments of both scales at multiple timepoints.

Researchers often prefer to study the effect of a particular childhood illness and/or specific genetic test on parenting and child outcomes to avoid variation in the sample diluting the results.³⁹ This precedence, however, has limited generalizability in the world of genomic sequencing given the vast variety of conditions and unique results sequencing can produce. Studying the impact of whole-genome or whole-exome sequencing challenges our ability to analyze research data with the use of traditional quantitative research methods. Creative methods of analysis will be needed to distinguish the types of results that have the greatest impact on parents, children, and the entire family system. Qualitative research methods may also be helpful in developing a deeper understanding of the impact of genomic sequencing during the

newborn period and the perceived psychosocial risks and benefits of sequencing on the parents, the child, and the family unit.

Despite these challenges, we feel it is especially important to assess both the risks and benefits of newborn genomic sequencing to infants, parents, and the family system as a whole. Many predict that technological advances and increasing affordability and medical utility will lead to a future in which every infant's genome will be sequenced at birth. According to Francis Collins, the director of the National Institutes of Health, "over the course of the next few decades, the availability of cheap, efficient DNA sequencing technology will lead to a medical landscape in which each baby's genome is sequenced, and that information is used to shape a lifetime of personalized strategies for disease prevention, detection, and treatment."⁴⁰ It is vital that we study the psychosocial impact of this, including the impact on family dynamics, so that we can more accurately identify the potential risks and develop interventions to protect against them.

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ABBREVIATIONS

BSHG: British Society for Human Genetics
CVS: Child Vulnerability Scale
NBS: standard newborn screening
AAP: American Academy of Pediatrics
ASHG: American Society of Human Genetics

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