Families Declining Enrollment in BabySeq Cite Lack of Interest in Research, Logistical Challenges

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NEW YORK (GenomeWeb) – Only about 7 percent of families approached to take part in the BabySeq Project of Brigham Women's Hospital and Boston Children's Hospital eventually enrolled, with many citing a lack of interest in research, study logistics, and privacy concerns as reasons for declining to participate.

The project launched as part of the National Institutes of Health's Newborn Sequencing in Genomic Medicine and Public Health (NSIGHT) consortium with the goal of examining how integrating sequencing information affects the medical care of both healthy and ill infants. The project aims to enroll 480 newborns and their families into its randomized trial.

But not all families approached for the study ultimately took part. In a new study led by Brigham and Women's Richard Parad and appearing in Genetics in Medicine this week, the BabySeq team examined the reasons parents gave for declining to take part. Many pointed to a lack of interest in research, burdensome study logistics, feeling overwhelmed, privacy issues, or concerns about what results might reveal as reasons for why they did not enroll.

"Understanding parental concerns around research [newborn genomic sequencing] may inform future integration of nGS into newborn screening, predictive testing, and pediatric diagnostics," Parad and his colleagues wrote in their paper.

Between May 2105 and March 2017, the researchers approached 3,860 families to enroll in the study while either in a post-partum/well-baby nursery or in an intensive care unit that handles newborns. In this initial approach, they assessed parents' interest in research in general and in the BabySeq study in particular. Those who were interested were invited to attend an information enrollment session with a genetic counselor. At that session, descriptions of the study design, potential risks and benefits, and possible study implications, as well as a copy of the consent form, were provided.

Most families, 80 percent, declined to participate off the bat, often because they were not interested in taking part in any research. Another 10 percent were discharged or transferred before a response was obtained.

But 10 percent agreed to attend the informational enrollment session, and of those, 67 percent signed up for the study.

Overall, 6.9 percent of the families approached ultimately enrolled in the study. This, the researchers noted, is in line with findings from the National Institutes of Child Health and Development neonatal network and highlights the general difficulty of recruiting patients during the postpartum period, when their lives are busy. It is also similar to what study researchers reported at the 2016 American Society of Human Genetics annual meeting.

The researchers asked a subset of families why they declined to take part, and 499 of the 1,760 families queried provided a specific reason beyond a lack of interest in any research. Of the reasons given, study design or logistics was the most common, at 42 percent. Other neonate studies have also found that parental concerns about study logistics and follow up have influenced recruitment, suggesting to the researchers that this issue isn't unique to genomic studies.

Other reasons for declining to take part included feeling overwhelmed, privacy or discrimination concerns, and a lack of interest in or feeling uncomfortable with genomic sequencing.

The reasons families gave for declining to take part after attending the enrollment session were slightly different than those of families who declined at the outset. The latter largely gave reasons unrelated to newborn genomic sequencing, such as study design, logistics, or feeling overwhelmed. But those who declined to take part after attending the enrollment session were more likely to cite the potential implications of sequencing as a reason. For instance, the parents professed concerns about their child's future ability to obtain insurance, as well as discomfort with possibly learning unfavorable or uncertain results.

These reasons for declining to enroll could give insight into what barriers wider implementation of newborn sequencing might face, the researchers noted.

"The outcomes of this study reveal the influence of risk communication during the education process and informed consent, and identify concerns about privacy, discrimination, and return of results in some parents," they wrote.

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