0.3 *Thank you for taking the time to participate in this interview. All of your answers are confidential and will not be shared with your / your child’s care team. We will record this interview and transcribe it. We will then look at your answers together with other people who complete an interview – so we cannot identify who you are.*

*Your responses will help us to design future research studies.*

*We want to start with some questions about your family.*

Do you have any other children beside your baby \_\_\_\_ born at \_\_\_\_ who participated in our study?

How old are they?

Were they born in the US?

*If your child(ren) were born in the United States, then they were screened through the Newborn Screening program.*

***NBS explanation***

*Newborn screening is the testing of all newborns born in the United States for a panel of diseases that are treatable. Each state has a slightly different panel of 31-76 diseases that are tested. Testing in NY is free. Testing is done by taking a few drops of blood from the baby’s heel shortly after birth prior to discharge from the hospital. The baby’s pediatrician is informed of the results, and any repeat testing or treatment that are necessary are available within the first 2 weeks of life.*

Do you have any questions about the current newborn screening policies as I have described them?

*The initial testing performed is a screening test, meaning that only a fraction of the babies who are positive on the screening test truly have the disease. Babies who are positive on the screening test then go onto either repeat the screening test or take a more definitive diagnostic test. The percentage of babies with a positive screening test who then go onto have a positive diagnostic test ranges from 1-50% depending on the condition. That means that in some cases, only a small percentage of the babies who screen positive really have a disease, but we take great care not to miss any babies with these conditions since treatment is available and effective. Most treatments require a change to a specialized formula or a medication. Rarely involved medical procedures such as bone marrow transplant are required.*

Do you have any questions about that information as I have described it?

**Opinions about characteristics of conditions screened**

1. *There are many diseases that have a genetic component that are not currently on the panel. The reason for that is because historically it has been very expensive to do genetic testing, and these conditions are quite rare. However, over time the cost of genetic testing has decreased. In addition, we are considering testing several conditions, so that collectively the conditions are not as rare. Some of these genetic conditions have good, effective, safe, inexpensive treatments that are currently available.*

What are your thoughts about your baby being tested for those conditions?

1. *Conditions included on the newborn screening panel can range in severity from those that involve minor lifestyle changes to those that can be lethal or extremely debilitating.*

How would define severity of a disease? OR What symptoms or traits would you consider severe?

How does the severity of a disease change your intention to have your newborn tested for those conditions?

1. *Some of the genetic conditions do not yet have approved treatments available, but treatments are being testing in clinical trials/research studies and look promising. However, because they are new and still in development we know less about the effectiveness or side effects of these treatments. Without treatment, these conditions can be fatal or result in intellectual disability.*

What are your thoughts about your baby being tested for those conditions?

1. *Some of the genetic conditions do not yet have approved treatments available, and people are working on treatments, but treatments could be years away. Without treatment, these conditions can be fatal someday or result in intellectual disability.*

What are your thoughts about your baby being screened for those conditions at birth?

1. *There could be breakthroughs in treatment for genetic diseases like gene therapy that might suddenly allow for treatment for many rare genetic conditions.*

How would that change your perspective, if at all?

1. *The newborn screen could include conditions that have symptoms appear later in the life of the child.*

What is your opinion of screening for conditions where symptoms and treatment would not begin until 10 years of age?

What is your opinion of screening for conditions where symptoms and treatment would not begin until 18 years of age?

1. *Because we are using a genetic testing system, we are screening for genetic changes that can cause disease. For some changes, some people may not have any medical symptoms of the disease for many years or ever, though they have the mutation for that condition.*

What are your thoughts about screening for these conditions where many may have the mutation but no symptoms for many years or ever?

1. *Some of these conditions can be hard to diagnose, and one benefit of newborn screening is that everyone would have access to this information for free, and a diagnosis is less likely to be delayed. That could be a benefit even if there is no treatment.*

How does this affect your feelings toward newborn screening?

1. *What are your concerns, if any, about how learning this information could impact your child’s medical insurance and ability to get life insurance or long-term care insurance?*

**Desirability of Expanded NBS**

1. *Do you know anyone who distrusts medical research? What are their concerns?*
2. *What could we do to make people more comfortable about medical research, specifically around newborn screening?*
3. *You or someone you know may have had a negative interaction with the medical system. Thinking about these interactions, if in any way, how does this factor into your thoughts about expanding newborn screening?*
4. *Some people might have concerns that having too much information could have a negative impact. How do you feel about this*

What are benefits of expanded newborn screening that you see for your family?

What are concerns you have about expanded newborn screening for your family?

What would be a helpful method of explaining this information to families?

1. *We could save the child’s genetic information so we can go back and look at it in the case that you want to look for other possible genetic diagnoses. The information would be saved in a secure way. It would not be shared with anyone.*

What are some ideas to ensure that this is something helpful and not harmful to families?

1. *As we mentioned earlier, a positive screening result does not always mean that the child actually has the condition. The tests are evaluated with the goal of diagnosing all patients and not missing anyone, so more tests will screen positive than actually have the condition. There is also a small possibility that a baby who screens negative may still have the condition, though this is unlikely.*

What concerns do you have about what we just described as a false positive?

What concerns do you have about what we just described as a false negative?

1. *We are curious about helping families to feel informed when making decisions about newborn screening for their family.*

What concerns, if any, do you have about the information being safe?

What could we do to lessen these concerns?

1. *We understand this is an extremely difficult situation and creates a need for in-depth education.*

When would you want to start learning about newborn screening for your child?

What information would you need to feel informed and make an informed choice?

How do you want this information delivered?

1. *In terms of making an informed choice, if you were deciding about choices for screening your baby:*

Tell me about what information you would need about the diseases themselves to make this choice?

How would you feel about choosing groups of diseases rather than specific diseases in particular?

If you would feel comfortable consenting to screening to groups of diseases, based on the scenarios we discussed what would be most critical to know in choosing?

1. *There are potentially over 100 different conditions that could be added to the panel and it is likely too much information to explain each condition.*

How would you feel about making general choices about information you would not want to learn about, for example you don’t want to learn about conditions that are not fatal, and then the doctor uses your choices to determine if a specific result is or is not returned to you?

1. *Thank you so much for your help and your insights. We understand these can be difficult scenarios to think about and can be upsetting but we really appreciate your efforts in helping us. We have some final basic demographic questions that we are asking everyone so we can understand who we have been speaking with*.

What do you identify as your race/ethnicity?

Do you identify as Hispanic or Latino or not?

What is your highest earned level of education?

Are you employed or do you work solely in the home?

How old are you?

Are you married?

What type of health insurance do you have?

Do you have any other thoughts you’d like to share?

Thank you so much for your time and thoughts. We greatly appreciate it. We are very committed to ensuring that our work goes to further helping all babies have the best chance for a healthy life.