Development of the NC NEXUS Decision Aid
Implications for parental education and newborn screening

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Project Team

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Combined Areas of Expertise

- Health communication
- Health literacy
- Informatics and computing technology
- Human computer interaction
- Graphic design
- Pediatrics
- Genomics
### The Problem:
- Typical consent forms:
  - Often more than 10 pages long
  - Contain medical terminology and concepts beyond average health literacy
  - Require lengthy individual interactions
  - Do not provide knowledge or help people clarify values
- Traditional consent models will be problematic as NGS becomes more pervasive in research and practice for population studies

### NC NEXUS Decision Aid Overview

<table>
<thead>
<tr>
<th><strong>Our Approach – the NC NEXUS Decision Aid:</strong></th>
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<tbody>
<tr>
<td>• Explains genomic information at a lay level</td>
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<td>• Applies communication science strategies including principles of plain language, clear communication, and health literacy</td>
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<td>• Uses text, graphics, and audio to convey challenging concepts</td>
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<td>• Includes values clarification exercises</td>
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<th><strong>How it meets participant’s needs:</strong></th>
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<td>• Facilitates informed decision making</td>
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<td>• Eases the enrollment process</td>
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<td>• Reduces decision making burden</td>
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“Decision aids differ from usual health education materials because decision aids make explicit the decision being considered, and provide detailed, specific, and personalized focus on options and outcomes for the purpose of preparing people for decision making.”

– Cochrane Review (2014)
Development – How Did We Gather and Use Parental Input?

Formative Interviews with Parents
- Recruited 33 couples who were married or in committed relationship
- Examined how couples communicate with each other and make decisions about genomic screening results for their child
- Revealed importance of letting couples complete the decision aid together
- Showed that different results categories evoked distinct decision processes–informed how content was organized around multiple decision points

Discrete Choice Experiment
- Online experiment with 1,289 parents of young children (ages 5 or younger)
- Stratified by race and gender
- Demonstrated how the characteristics of genetic disorders influence parental decisions about which sequencing results are most important to know
- The information helped select disorders to use as examples in the decision aid

User-Centered Design

- Used best practices, theory, and guided by international decision aid standards
- Followed iterative process to develop, test, and refine the decision aid
- Applied plain-language principles to address differences in health literacy
- Conducted user testing to understand areas of confusion related to content and navigation
- Interface allows users go at their own pace, repeating and reviewing information as needed

Lewis et al. *Pediatrics* (2016)
Decision Aid – contains 4 “sections”

- **Traditional Newborn Screening and Similar Conditions**
- **Non-Medically Actionable Childhood Conditions**
- **Medically Actionable Adult Onset Conditions**
- **Carrier Status**
Topics Covered in Decision Aid

- How to use decision guide
- What is newborn screening?
- What is genomic sequencing?
- What is the NC Nexus Study?
- Reasons for and against participating
- Decision and next steps
What Makes Our Tool Unique?

<table>
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<th>Interactive, can be deployed on multiple platforms</th>
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<tr>
<td>Theory-driven</td>
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<tr>
<td>Input from users and clinicians</td>
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<td>Plain language as much as possible</td>
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<td>Interactive sorting exercise (shown here)</td>
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<tr>
<td>Iterative user-centered design and testing process</td>
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</table>
What is a medically actionable childhood condition?

1. Rare and serious
2. Begin during childhood
3. Can be improved with early treatment
4. Benefits of treatment outweigh risks

What is newborn screening?

Conditions found by newborn screening are rare

13 out of every 10,000 babies born in the U.S.

13 out of 10,000
What is genomic sequencing?

- People can have different forms of the same gene
- Most gene differences have no effect on health
- But some lead to health problems
- Genomic sequencing is a way to look for gene differences
What if you decide to have genomic sequencing for your child?

Overall Progress: 26%

1. 1 hour visit to UNC Hospitals
2. Sign a consent form
3. Your child's spit will be used for sequencing
4. Learn results for medically actionable childhood conditions
Question to Help Parents Make a Decision

- Will genomic sequencing help you learn things that are important to you?
  - Yes
  - No

- Do you have enough information to make a decision about having genomic sequencing for your child?
  - Yes
  - No

- Are you prepared to learn genomic sequencing results for medically actionable childhood conditions?
  - Yes
  - No

- Are you interested in learning if your child has gene differences that can cause medically actionable childhood conditions?
  - Yes
  - No

- Are you confident you can decide?
  - Yes
  - No
Here are the reasons that are important to you.

**REASONS FOR HAVING GENOMIC SEQUENCING IN NC NEXUS**

- Knowing your child has a genetic condition may help him or her get early treatment and support services.
- Genomic sequencing may help scientists make better tools for finding serious conditions before people get sick.
- You would rather not wait to see if any problems occur to find out if your child may have a genetic condition.
- My own reason for

**REASONS AGAINST HAVING GENOMIC SEQUENCING IN NC NEXUS**

- Waiting for genomic sequencing results may cause you to worry or feel anxious.
- Knowing that the NC NEXUS study team will have your child’s genomic sequencing results makes you uncomfortable.
- You are satisfied with knowing that your child will have standard newborn screening.
- Reason for 1
- Reason for 3
Making a decision about genomic sequencing.

Overall Progress: 88%

Do you want your child to have genomic sequencing for conditions like those found in newborn screening?

- No, I do not want my child to have genomic sequencing
- I'm not sure
- Yes, I want my child to have genomic sequencing
NC NEXUS Randomized Trial

- 400 parents will participate and use the aid to make decisions about categories of information.
- 1/3 will be randomized to ‘control’ only meaning they make decision about conditions like those on current NBS panel, 2/3 to additional ‘decision’ categories.
- Decision confidence, conflict, distress, and other outcomes will be monitored over four month follow-up.
- Will allow us to evaluate the extent to which the decision aid supports informed decision making.
For more information:

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