

Development of the NC NEXUS Decision Aid

Implications for parental education and newborn screening

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NCNexus

Welcome to the NC NEXUS decision guide.

Overall Progress: 1%



1

Purpose of the study

2

How genes can affect your child's health

3

Genomic sequencing

4

Results that might be found

5

Decide if you want genomic sequencing

Project Team

Team Members

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Combined Areas of Expertise

- Health communication
- Health literacy
- Informatics and computing technology
- Human computer interaction
- Graphic design
- Pediatrics
- Genomics

NC NEXUS Decision Aid Overview

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

Our Approach – the *NC NEXUS Decision Aid*:

- Explains genomic information at a lay level
- Applies communication science strategies including principles of plain language, clear communication, and health literacy
- Uses text, graphics, and audio to convey challenging concepts
- Includes values clarification exercises

How it meets participant's needs:

- Facilitates informed decision making
- Eases the enrollment process
- Reduces decision making burden

The Value of Decision Support Tools/Decision Aids

*“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)

**Decision
aids are**

evidence-based
tools

intended to help
patients be an
active participant

assist in making
specific and
deliberated
healthcare
choices among
various options.

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

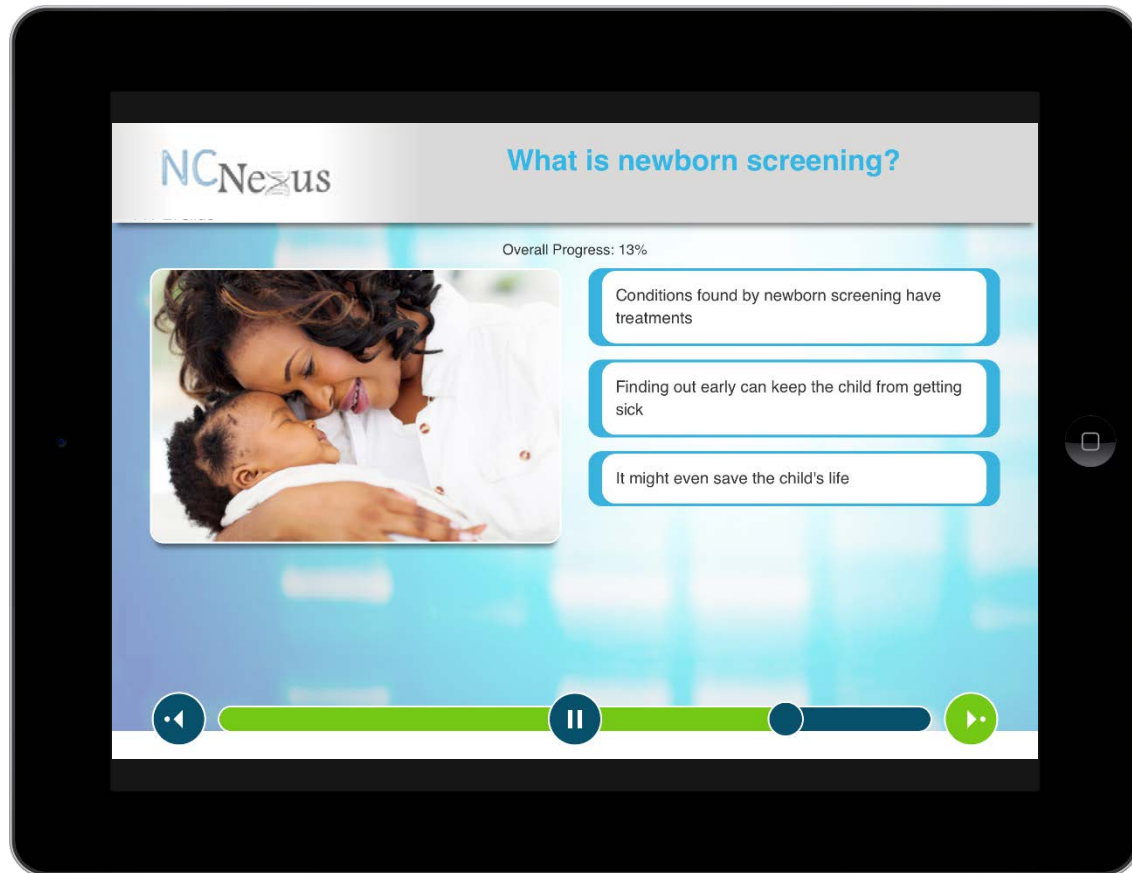
Development – How Did We Gather and Use Parental Input?

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

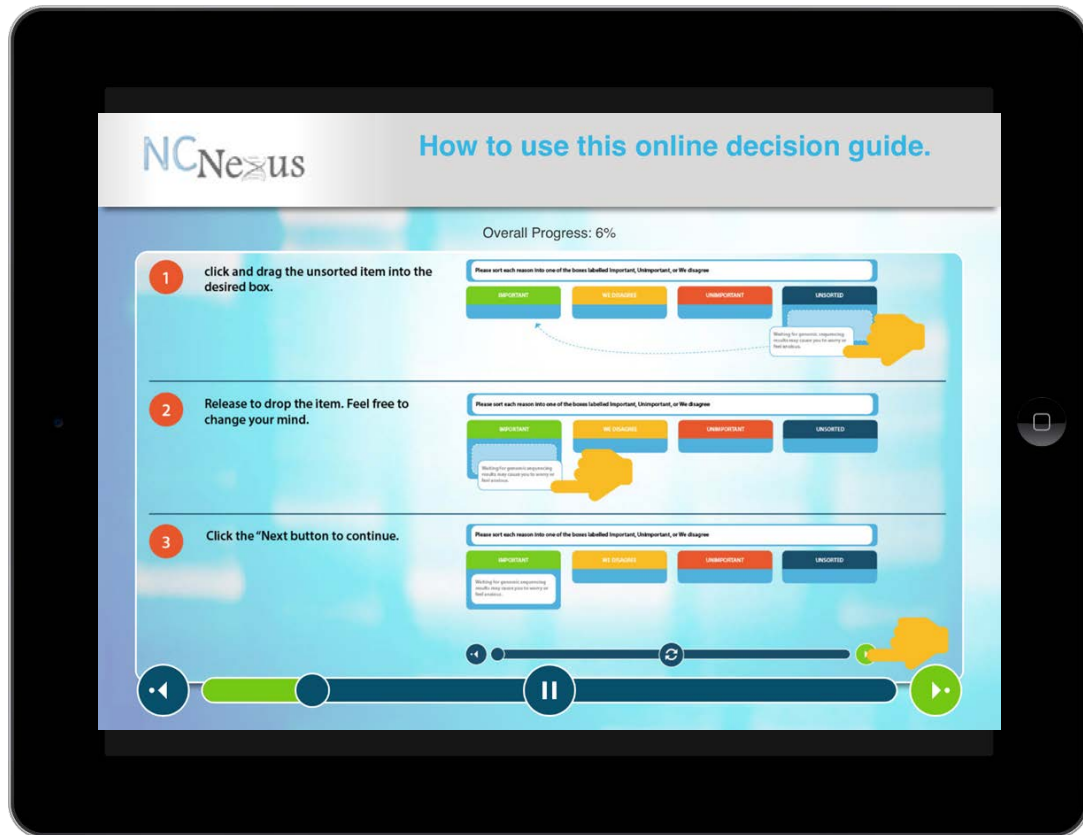
What is newborn screening?

What is genomic sequencing?

What is the NC Nexus Study?

Reasons for and against participating

Decision and next steps



What Makes Our Tool Unique?

Interactive, can be deployed on multiple platforms

Theory-driven

Input from users and clinicians

Plain language as much as possible

Interactive sorting exercise (shown here)

Iterative user-centered design and testing process



Screenshots – Condition Category Description and Risk Array

NC Nexus What is a medically actionable childhood condition?

Overall Progress: 20%

Medically actionable childhood conditions...

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

Navigation: Previous, Play/Pause, Next

NC Nexus What is newborn screening?

Overall Progress: 12%

Conditions found by newborn screening are rare

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

13 out of 10,000

Navigation: Previous, Play/Pause, Next

Screenshot – Addressing Difficult Terminology and Concepts

NCNeXus

What is genomic sequencing?

Overall Progress: 16%

1

2

SNP

- 1 People can have different forms of the same gene
- 2 Most [gene differences](#) have no effect on health
- 3 But some lead to health problems
- 4 Genomic sequencing is a way to look for gene differences

Navigation controls: Previous, Play/Pause, Next

Screenshot – How the Study Works

NCNexus

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

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Question to Help Parents Make a Decision

The screenshot displays the NC Nexus app interface. At the top left is the logo "NC Nexus" and at the top right is the title "Questions to help you decide." Below the title, it shows "Overall Progress: 84%". On the left side, there is a vertical image of a newborn baby. The main area contains five questions, each with a "Yes" or "No" button. The "Yes" buttons are green and the "No" buttons are blue. The questions are:

- Will genomic sequencing help you learn things that are important to you? (Yes button is green, No button is blue)
- Do you have enough information to make a decision about having genomic sequencing for your child? (Yes button is blue, No button is red)
- Are you prepared to learn genomic sequencing results for medically actionable childhood conditions? (Yes button is green, No button is blue)
- Are you interested in learning if your child has gene differences that can cause medically actionable childhood conditions? (Yes button is green, No button is blue)
- Are you confident you can decide? (Yes button is blue, No button is red)

At the bottom of the screen, there is a navigation bar with a back arrow, a progress indicator (a green bar followed by a blue bar), a pause button, and a forward arrow.

Screenshot – Values Clarification

The screenshot shows a tablet displaying the NC NEXUS Values Clarification tool. The interface is divided into two main columns: 'REASONS FOR HAVING GENOMIC SEQUENCING IN NC NEXUS' (green header) and 'REASONS AGAINST HAVING GENOMIC SEQUENCING IN NC NEXUS' (orange header). The overall progress is 80%. The 'For' column contains four reasons, with the last one being a text input field. The 'Against' column contains three reasons, with the last two being text input fields. A progress bar at the bottom shows the current position in the sequence.

NC NEXUS Here are the reasons that are important to you.

Overall Progress: 80%

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

Information about the risk for others in your family

Screenshot – Decision about Genomic Sequencing

NCNexus

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

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Next Steps – How Do We Know if it Works?

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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