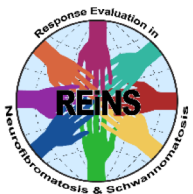


Social Cognition Outcomes Measures

Jennifer Janusz, Psy.D., ABPP-Cn

Neurocognitive Outcomes Working Group



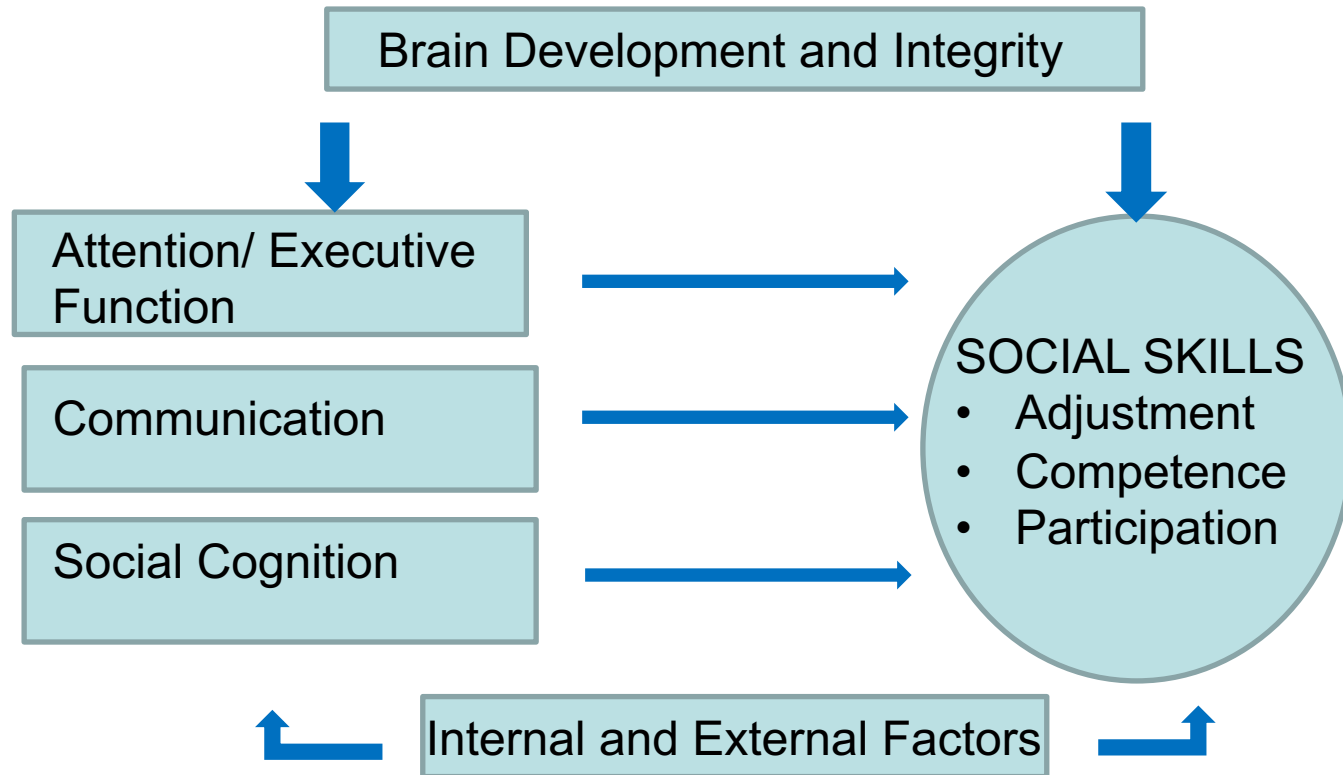
Response Evaluation In Neurofibromatosis Schwannomatosis
INTERNATIONAL COLLABORATION

Measures of Social Skills and Social Cognition

- Social skills are complex and multidimensional
 - Social awareness
 - Social cognition
 - Social communication
 - Social motivation
- Can be impacted by weaknesses in other cognitive areas
- Used the SOCIAL model as a basis for conceptualizing social skills

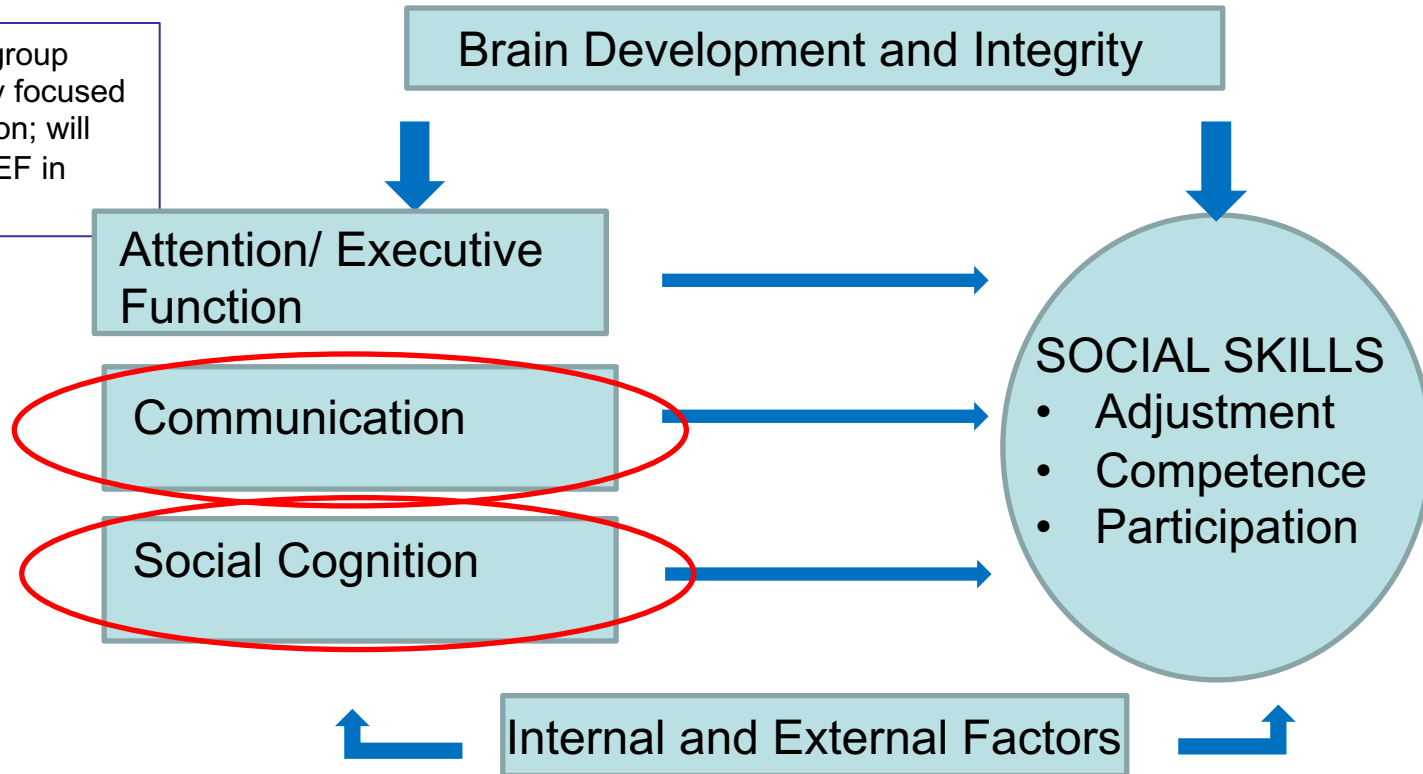


Socio-Cognitive Integration of Abilities Model (SOCIAL; Anderson and Beauchamp)



Socio-Cognitive Integration of Abilities Model (SOCIAL; Anderson and Beauchamp)

Working group previously focused on attention; will focus on EF in future



Identifying Appropriate Measures- What do we look for?

- Measure areas we are interested in
 - Communication and social cognition
- Well-designed measures (good psychometrics)
- Easily administered in clinical trials setting
 - Focused on parent questionnaires
- Previously used in clinical trials where social skills are an outcome measure



COGRATE: COGnitive outcomes Rating Acceptance Tool for Endpoints

Patient Representative Form



Measure:	
Rater:	Date: ___/___/___

RATING ANCHORS

- 3 = Strongly Agree
- 2 = Agree
- 1 = Disagree
- 0 = Strongly Disagree

Rating Criteria <i>Please complete this section prior to the phone call</i>	Rating 0-3
<u>Feasibility</u>	
<ul style="list-style-type: none">• Directions are easy to understand. Would you be able to complete this questionnaire if given it with no other explanation? (for example, how to fill out the form; time period to consider when rating)	
<ul style="list-style-type: none">• Scale for responses is easy to understand	
<ul style="list-style-type: none">• Questions are easy to understand	
<ul style="list-style-type: none">• How long does it take to complete this test? ____ This is a reasonable amount of time	
<ul style="list-style-type: none">• This questionnaire is relevant to an area of difficulty for people with NF1	
RATING	MEAN



RATING ANCHORS

3 = Good convincing data and published information supporting the tool's use in NF

2 = Good preliminary/early data and relevant information but needs more work

1 = Limited data but information suggests potential

0 = No data/poor data/information

**Half ratings (.5, 1.5, 2.5) can be used if needed*

Rating Criteria <i>This section can be completed during phone call based on group discussion</i>	Rating (0-3): for use in NF trials
<p>1. <u>Patient characteristics:</u> What is the age range that the tool can be used (e.g., child, adolescent, adult)?</p> <p>Is there information/data on how individuals with diseases such as NF perform on the tool/test? <i>Yes</i> <i>No</i></p> <p>If yes, which groups?</p>	
<p>2. <u>Used in published studies:</u> How many studies have been published using this tool (overall)?</p> <p>How many were clinical trials (a study with some type of intervention)?</p> <p>What age span was included in the published trials?</p> <p>How many published studies included individuals with NF?</p>	
<p>3. <u>Test appropriateness for clinical trials endpoint:</u> Does this tool test areas of learning, behavior, or cognition that are relevant to NF research?</p> <p>Do you think that the tool is important for future cognitive research in NF? <i>Yes</i> <i>No</i></p>	
<p><u>Overall Impression for use in NF Clinical Trials (Pros/Cons) – Is the measure an acceptable outcome measure based on your review and committee discussion?</u></p>	<p><u>Total (mean):</u></p>

Notes/Comments:



Measures Reviewed

After comprehensive literature review, the following measures were identified as relevant:

- Social Communication Questionnaire
- Social Skills Questionnaire
- Autism Social Skills Profile
- Profile of Social Difficulty
- Social Skills Checklist
- Social Competence Questionnaire
- Socialization scale, Vineland Adaptive Behavior Scales- 3
- Social Skills Rating System/ Social Skills Improvement System
- Social Responsiveness Scale-2
- Children's Communication Checklist-2



Measures Reviewed

After review by the working group, three measures met criteria for use in clinical trials (we have high standards!)

- ~~Social Communication Questionnaire~~
- ~~Social Skills Questionnaire~~
- ~~Autism Social Skills Profile~~
- ~~Profile of Social Difficulty~~
- ~~Social Skills Checklist~~
- ~~Social Competence Questionnaire~~
- ~~Socialization scale, Vineland Adaptive Behavior Scales-3~~
- Social Skills Rating System/ Social Skills Improvement System
- Social Responsiveness Scale-2
- Children's Communication Checklist-2

Problems with these measures included poor test characteristics, too narrow focus, and limited use in clinical trials

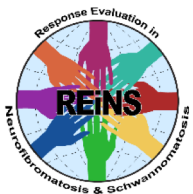


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- ~~Social Skills Checklist~~
- ~~Social Competence Questionnaire~~
- ~~Socialization scale, Vineland Adaptive Behavior Scales-3~~
- **Social Skills Rating System/ Social Skills Improvement System**
- **Social Responsiveness Scale-2**
- **Children's Communication Checklist-2**

These three measures were rated highly to capture social language, communication, and social cognition ¹¹



Computerized Measures

- Historically, cognitive abilities measures in clinical trials using paper-and-pencil tests
- Benefits of computerized measures of cognitive abilities
 - Specifically developed for use in clinical trials
 - Strong psychometric properties
 - Limited practice effects
 - Standardized administration
 - Reduces error and improves reliability across sites



Considerations for Use of Computerized Measures in NF1

- Challenge of not having disease-specific norms
 - Statistical properties of test developed using “typical” individuals and may be different for disease group
 - Other disease groups have seen similar difficulties with test statistics (Alzheimer’s, Parkinson’s)
- STARS trial data
 - Test-retest reliability of CANTAB ranged from unacceptable to moderate
- Measure’s ability to detect change is compromised if statistical properties are different for the disease group than for the norming population
- Consideration when using computerized measures in NF1 clinical trials



Reliability and Validity of Computerized Cognitive Outcome Tools in NF1 (CTF Research Award, Walsh PI)

- Collecting NF1-specific data for two computerized measures, Cogstate and NIH Toolbox, as well as lab-based measures
- Ages 8-16; NF1 group and neurotypical comparison group
- Data collected at two time points- initial assessment and second assessment 6-8 weeks later
- Currently recruited: controls $n = 17$; NF1 $n = 7$



Evaluation of Measures of Attention in Preschoolers with NF1

(NF Midwest; Klein-Tasman PI)

- Use of computerized measures in preschool population (ages 4-6 years)
- Collecting NF1-specific data for three computerized measures: Cogstate, NIH Toolbox, and K-CPT, as well as lab-based measures
- Data collected at two time points- initial assessment and second assessment 6-8 weeks later
- Currently recruited: NF1 n=17



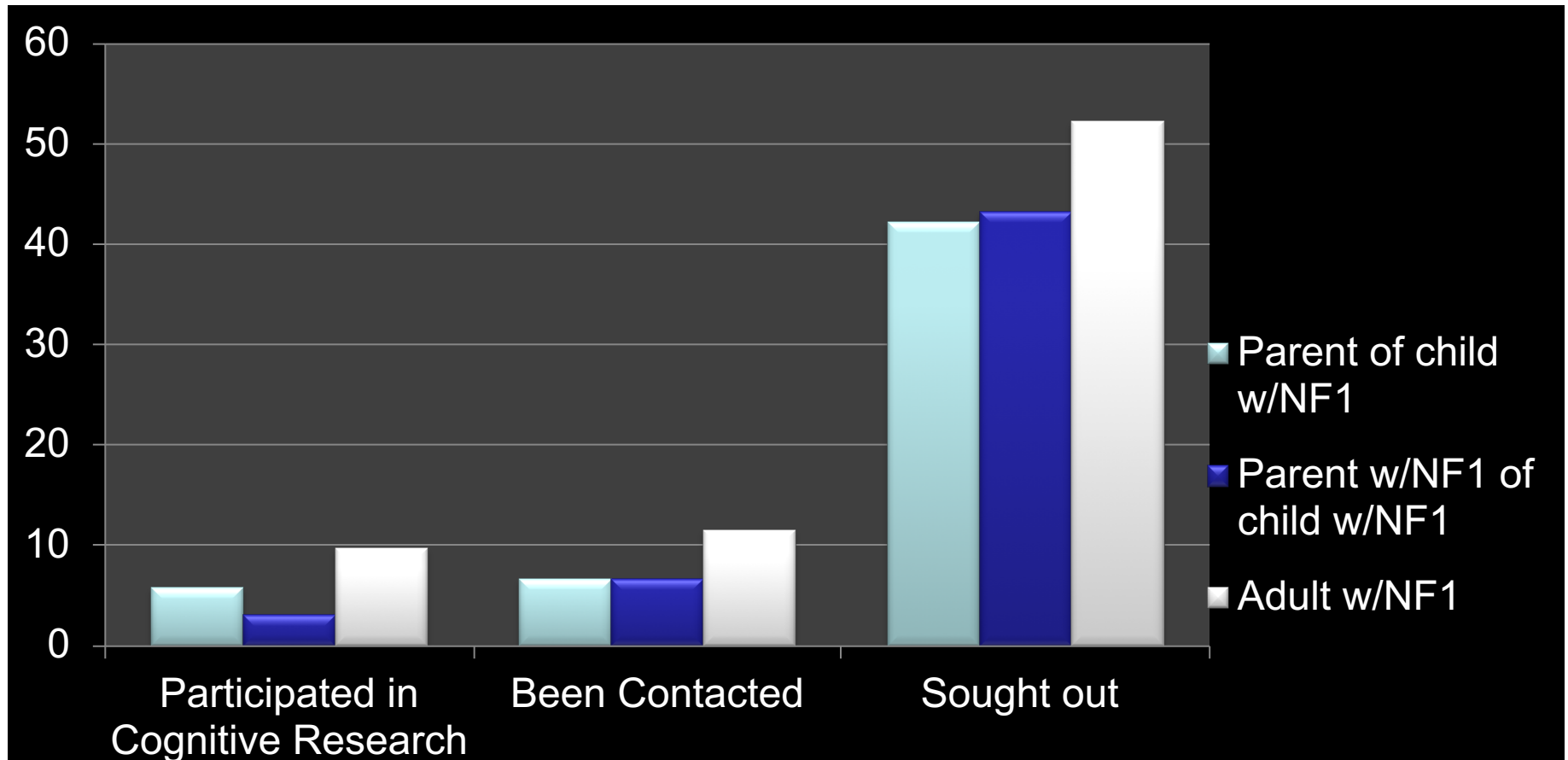
Computerized Study Findings

- Once studies completed, compare psychometrics of Cogstate, NIH Toolbox, and CANTAB for NF1 population
- Make recommendation for most appropriate battery for use in clinical trials with a cognitive endpoint

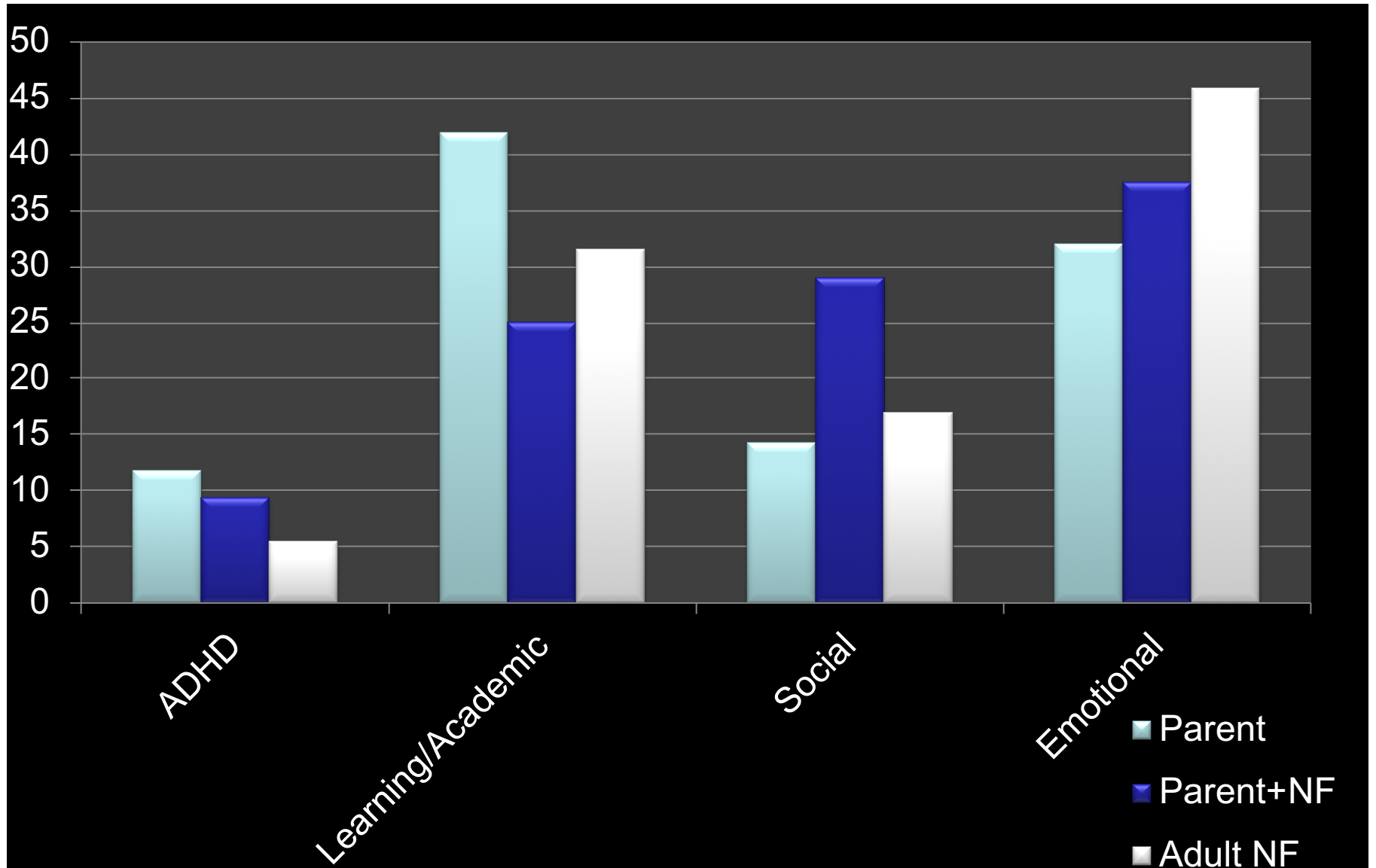


What's next?

- Importance of family and patient input
- Using patient survey data to guide next steps (Walsh; Hussey- patient representative)



Survey Data



What's Next?

- Reviewing academic measures
 - Reading, writing, math
 - Executive functioning skills
- Reviewing measures of emotional functioning for children and adults
 - Easier (?); frequently an outcome measure for intervention studies



Neurocognitive Committee

- Pete de Blank
- Allison de Castillo
- Deborah Gold
- Kristi Hardy
- Susie Henley
- Scott Hunter
- Tess Inker
- Jennifer Janusz
- Bonnie Klein-Tasman
- Staci Martin
- Stephanie Morris
- Jonathan Payne
- Tena Rosser
- MaryAnn Tamula
- Heather Thompson
- Karin Walsh
- Nicole Ullrich
- Pam Wolters

Patient Representatives

- Dena Hasselberg
- Maureen Hussey
- Melissa White

