Social Cognition Outcomes Measures

Jennifer Janusz, Psy.D., ABPP-Cn
Neurocognitive Outcomes Working Group
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)

Brain Development and Integrity

Attention/Executive Function

Communication

Social Cognition

Internal and External Factors

SOCIAL SKILLS
- Adjustment
- Competence
- Participation
Socio-Cognitive Integration of Abilities Model (SOCIAL; Anderson and Beauchamp)

- **Brain Development and Integrity**
  - **Attention/Executive Function**
  - **Communication**
  - **Social Cognition**

**SOCIAL SKILLS**
- Adjustment
- Competence
- Participation

**Internal and External Factors**

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: COGaitive outcomes Rating Acceptance Tool for Endpoints

**Domain:**
- [ ] Executive Function
- [ ] Attention
- [ ] Processing Speed

**Measure:**

**Rater:**

**Date:** ___/___/___

**RATINGS**
3=Solid data and published information supporting its use in NF
2=Good preliminary data and relevant information but needs more work
1=Limited data but information suggests potential
0=No/poor data information
*Half ratings (.5, 1.5, 2.5) can be used if needed*

<table>
<thead>
<tr>
<th>Rating Criteria</th>
<th>Rating (0-3): use in NF trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patient characteristics:</td>
<td></td>
</tr>
<tr>
<td>Age range (e.g., child, adolescent, adult)</td>
<td></td>
</tr>
<tr>
<td>Normative groups (e.g., general, NF, oncology, other, # subjects)</td>
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</tr>
<tr>
<td>2. Used in published studies:</td>
<td></td>
</tr>
<tr>
<td>Number and types of studies (e.g., descriptive, clinical trials)</td>
<td></td>
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<tr>
<td>3. Test appropriateness for clinical trials endpoint:</td>
<td></td>
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<tr>
<td>Test specificity/purity (how pure is the measure to the domain/skill it is developed to measure?)</td>
<td></td>
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<tr>
<td>Test targets one or more of the known or future endpoints for NF clinical trials directly</td>
<td></td>
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<tr>
<td>4. Scores available:</td>
<td></td>
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<tr>
<td>Types of scores available (e.g., raw, standardized, domain, total; gaps in normative data)</td>
<td></td>
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<tr>
<td>5. Psychometric Data:</td>
<td></td>
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<tr>
<td>Reliability (e.g., internal consistency, test-retest)</td>
<td></td>
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<tr>
<td>Validity (e.g., construct, discriminative)</td>
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<tr>
<td>Factor analysis</td>
<td></td>
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<tr>
<td>Practice Effects/Availability of Alternate Forms/Time between testing information</td>
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</tr>
<tr>
<td>6. Feasibility:</td>
<td></td>
</tr>
</tbody>
</table>

**Cost (for test instrument, protocols, and scoring):**

**Length (time to administer/completed):**

**Ease of administration/challenges to administration:**

**Qualifications to administer test (level of training):**

**Appropriateness for alternative testing settings (e.g., clinic, etc.):**

**Other languages available:**

**Overall impression for use in NF Clinical Trials (Pros-Cons) – Is the measure a critical Primary Outcome Measure?:**

**Level of Acceptance (Committee Decision):**
- [ ] Primary outcome measure
- [ ] Secondary outcome measure
- [ ] Not acceptable at this time; further information needed (specify)
- [ ] Not acceptable (no further review)

**Committee Notes/Comments:**

**Total (mean):**
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 *Please complete this section prior to the phone call*  Rating 0-3

<table>
<thead>
<tr>
<th>Feasibility</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>• 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)</td>
<td></td>
</tr>
<tr>
<td>• Scale for responses is easy to understand</td>
<td></td>
</tr>
<tr>
<td>• Questions are easy to understand</td>
<td></td>
</tr>
<tr>
<td>• How long does it take to complete this test? ____</td>
<td></td>
</tr>
<tr>
<td>This is a reasonable amount of time</td>
<td></td>
</tr>
<tr>
<td>• This questionnaire is relevant to an area of difficulty for people with NF1</td>
<td>MEAN</td>
</tr>
</tbody>
</table>

RATING
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

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

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
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- Children’s Communication Checklist-2

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

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

Jennifer.Janusz@childrenscolorado.org