From the Lab to the Clinic
Standards for the Translation of Neurocognitive Research

Natasha S. Hansen & Greg J. Siegle
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Introduction

- Neurocognitive research shows tremendous promise for translation to real-world clinics
- Unique opportunity to implement the highest standards of excellence

**Presentation Goal:** provide platform to share information, ideas & resources
Roadmap

- Why have standards?
- Specific standards to consider
- Standards application in neurocognitive research
- Existing standards resources
- Future standards goals
- Questions & Ideas
Why have Standards?

- Lay a foundation of good science on which to build
- Equal standards expected in other areas of medicine
- Win the respect of fellow researchers
- Demonstrate efficacy to clinicians
- Gain the trust of patients
- Insure the funding of insurance companies
- Prevent the grim alternatives
Gathering Standards

- Standards to Consider
  - Safety
  - Utility
  - Administration
  - Reliability
  - Validity
  - Norms
  - Affordability
  - Accessibility
  - Usability
Safety

- Method causes no harm

- Primary concern for implementation, building trust, FDA approval, insurance reimbursement

- MRI already scrutinized and deemed safe when certain conditions are met (e.g. no metal) (Kanal et al., 2004)

- Future Goal: accessible updated safety protocols

- Resource: safety concerns for high field strength MR systems (visual deficits?) (de Vocht & Kromhout, 2008)
Utility

- Method has practical value to assess or affect a clearly-defined, clinically-relevant construct

- Measures or affects a specific mechanism

- Significance demonstrated at the level of the individual (not only group)

- Activation is unique to one condition

- Results are interpretable by clinicians

- *Future Goals:* Z Scores for neurocognitive assessments
Standardized Administration

- Sites use similar procedures to get similar results

- Specified tasks for specified constructs
  - E.g. International Affective Picture System for emotional information processing (IAPS) (Lang, Bradley, & Cuthbert, 2005)

- Standardized procedures
  - Example: “dot-probe” task result variations (Donaldson, Lam, & Mathews, 2007)

- Future Goals: canonical versions, standardized test batteries

- Resource: multisite imaging parameters, tasks, analyses (fBIRN, 2013)
Reliability

- Results are replicable

- Test with healthy controls or patients?
- Signal expected to change pre-post intervention
  - Habituation effects – amygdala (Wright et al., 2001)
  - Decreases in startle response over time (Lee et al., 2009)
- Test reliability high within scanner type, but between-scanner reliability is low (Friedman et al., 2008)
- Future Goals: database of reliable tasks & corrections

- Resource: Correction for differences between scanners (Siegle et al., 2012)
Validity

- Method does what it claims

- Vulnerability to Type I & Type II error
  - fMRI artifacts: movement, RF noise, ghosting…
  - Correct for multiple comparisons (Bennett et al., 2010)

- Difference between patients and controls, not between diagnoses (e.g., startle reactivity in anxiety) (McTeague & Lang, 2012)

- *Future Goals*: statistical corrections & quality control required for peer-reviewed publication

- *Resource*: MRI quality control workshop, manual, and training videos (Hansen et al., 2013)
Norms

- Means & standard deviations available for healthy and clinical populations

- Current state of neurocognitive research
  - No norms for clinical group differences
  - No norms for change

- Large sample sizes required – time and expense!

- Future Goals: norms presented in reputable & accessible databases based on peer-reviewed studies

- Resource: Cloud-based services for scores
  (Goscinski et al., 201; Muehlboeck, Westman, & Simmons, 2014)
Affordability

- Method should come at a reasonable cost

- Current costs: questionnaires: under $5; thyroid test: $50; structural MRI: $500
  - Neurocognitive techniques not yet covered by insurance
  - Few can pay out-of-pocket

- Future Goals:
  - Insurance codes for neurocognitive assessments
  - Reasonably-priced proxies for fMRI

- **Resource:** EMOTIV wireless 14-channel EEG headset 
  starting at $400 (www.emotiv.com)
Accessibility

- Method is readily available

- Computers and smart phones not always available

- Major obstacle for fMRI:
  - Most hospitals: 1.5 T; Research: 3T or 7T
  - Hardware: headcoils, stimulus presentation
  - Software: pre-processing & analysis

- Future Goals:
  - Make computer-based assessments available online for access at libraries
  - Develop proxy procedures for fMRI (e.g. pupil dilation, EMOTIV)
Usability

- Collection and interpretation of data possible by novel users
  - Collection is relatively simple; interpretation requires expert knowledge – what to do?
    - Look to model of genetics labs
  - **Future Goals:**
    - Neurocognitive training workshops
    - Labs for interpreting fMRI etc.
    - Distribution of more usable novel technologies: wearable heart rate, skin conductance, consumer-grade EEG (e.g. EMOTIV)
Standards Resources I

- Excellent existing standards resources!
- Novel Assessment Technologies:
  - American Society for Testing Materials (ASTM) ([www.astm.org](http://www.astm.org))
    - Globally-recognized leader in standards for safety & quality
    - 30,000 technical expert members from 150 countries
  - Institute for Electrical Electronics Engineers (IEEE) ([standards.ieee.org](http://standards.ieee.org))
    - Standards for emerging technologies in engineering
    - Technical innovation experts form 160 countries
Standards Resources II

• Neuropsychological Assessments
  ➢ Textbook: Friedenberg, 1995

• Psychophysiological Assessments
  ➢ Published guidelines papers:
    ◦ General: SPR, 2012
    ◦ Heart rate: Jennings et al., 1991
    ◦ Electrodermal measurements: Fowles et al., 1991
    ◦ Electromyography: Fridlund & Cacioppo, 1986
Standards Resources III: fMRI

- **Methods and status of validity** (Frewen, Dozois, & Lanius, 2008)
- **Controls for Type I & Type II error** (Forman et al., 1995)
- **Best practices for multisite imaging** (fBIRN, 2013)
  - Task specifications, scanning parameters, analytic procedures
- **Human Connectome Project** (Van Essen et al., 2013)
  - Task battery standardization (Barch et al., 2013)
  - Quality control procedures (Barch et al., 2013)
  - Preprocessing decisions (Glasser et al., 2013)
- **Harvard Center for Brain Sciences**
  - Quality control workshop, manual, & videos (Hansen et al., 2013)
Five Standards to use Today

1. **fMRI standardized task battery complete with quality control & preprocessing instructions**
   (Human Connectome Project: Van Essen et al., 2013)

2. **Correct for multiple comparisons (especially using fMRI, EEG, or any other method requiring many tests)**
   (Bennett et al., 2010)

3. **Correct for differences across neurocognitive technology brands (e.g. MR scanner types)**
   (Siegle et al., 2012)

4. **Movement cut-offs for MRI scans: consider 2 millimeters**
   (Van Dijk, Sabuncu, & Buckner, 2012)

5. **Five-minute qualitative check on each MRI scan can significantly improve data quality**
   (Hansen et al., 2013)
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References


