Landscape of technology utilization for outcomes assessment in neuropsychiatric disorders

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Disclosures

• In the past 12 months Dr. Harvey has served as a consultant for:
  Boehringer-Ingelheim, Jazz Pharma, Lundbeck, Otsuka-America, Sanofi Pharma, Sunovion Pharma, Takeda Pharma, and Teva Pharma
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Domains of Outcomes Assessment

• Cognitive Functioning
• Functional Capacity
• Everyday Activities
  – Vocational/Productive
  – Residential/Self-Care
  – Social Functioning
How is Technology Deployed?

• Create Computerized Cognitive tests
• Computerized Assessment of Functional Capacity
• Track activity and related biomarkers with wearable strategies
• Collect Patient Reported Outcomes Remotely
• Conduct ecologically valid passive observation
Global Strategies

• Performance-based assessments
  – Cognition
  – Functional Capacity
• Interactive PRO assessments
  – Ecological Momentary Assessment (EMA)
• Passive Observations
  – Wearables
  – Location surveillance
Goals and Strategies for Performance-Based Assessment

• Develop an alternative delivery for existing paper and pencil assessments
  – Examine convergent validity with standard measure
• Develop a de-novo Computerized assessment
  – Validate directly against outcomes of interest
• In office, tester-assisted assessments
• Remote, walk-up or internet strategies for self-administered assessments
  – Need to ensure that instructions are understood and performance is monitored
BAC tower of London

BAC Symbol Coding

PAR
Computerized
WCST
CANTAB  Spatial Span

Groton Maze Learning Test
Delivery of Assessment

• Standard computer
  – Need Mouse Skills
• Touchscreen
  – Development challenges, but easier to perform
• Tablet
• Smartphone
  – Challenging for testing certain populations because the font is too small
• Sensor
• Video/access monitoring/surveillance
Factors Influencing Performance-Based Assessments

- Age
- Education
- Familiarity with language
- Experience with testing
- Experience with testing technology
Critical Requirements for any Valid Performance-Based Assessment

• Reproducible range of scores
  – Utility as a repeated measure
    • Test-Retest Stability
    • Understanding practice effects
    • Convergence of Alternative forms
Considerations for all Performance-Based Assessments

• Norms
• Alternate Forms
• Missing Data
Special Considerations: Norms

• Norms are critical for multiple purposes
• Norms are also costly to do correctly and are commonly not done right
• A common practice is to take everyone who has ever taken the test and consider that the normative sample. Is this a general population sample?
Special Considerations: Alternate Forms

• Certain cognitive assessments are particularly prone to practice effects
  – Memory Tests; Problem solving tests; functional capacity tasks
• Alternate forms are commonly proposed as a solution and are easy to create
• Development of alternate forms is more complicated than development of norms
• Poorly developed alternate forms are a significant problem in treatment trials
What would make two forms or tests identical?

- Correlation is not enough; a large correlation can reflect small overlapping variance: \( r = .7 \) is only 50% shared variance
- The two tests must produce reliable scores at each corresponding point in the distributions for each test: impairment or lack thereof must be reproduced precisely
Special Considerations: Missing Data

- Paper and pencil cognitive assessments are often characterized as leading to missing data and as less systematic than computerized assessments.
- In essentially every study where a comparison can be made, computerized tests lead to more missing data.
- This applies to in-person administered computerized tests; could be a bigger problem with remote delivery.
Special Considerations for Cognitive Assessments

• Do we try to replicate important cognitive domains?
• Do we try to develop a test that yields a highly comparable total score when referenced to existing measures?
  – MCCB total score
  – ADAS-Cog
  – BACS
• What is highly comparable?
Special Considerations for Functional Capacity Assessments

• What strategy do you use?
  – A VR-like sequence of activities such as the VRFCAT?
  – A series of realistic but not necessarily related tests like the CFAS?
  – An adaptation of a paper and pencil measure?

• What is the outcome measure?
  – Accuracy or time to completion?
Metro/Bus

Task 1

In this task, you will learn how to purchase tickets using a kiosk. There are different ticket kiosk systems around the world. This is a fictional kiosk system. It is very similar to those you may find in the major cities in the US and around the world.
Ecological Momentary Assessment

• Samples behavior in real time
  – Where are you?
  – How are you with?
  – What are you doing?
  – How are you feeling?

• Has been shown to feasible for dense sampling

• Has been shown to be feasible in the populations of interest
Special Features of EMA

• Can sample informants in the same time frame
  – Can also sample multiple informants: Parents, teachers
• Can embed other assessments like NP tests
• Can turn on the GPS
• Can evaluate activities and as a function of context
  – Alone vs. with someone
  – Time of day outside office hours
  – Mood state influences
• Can do event-based sampling
  – Page us when you have an eating binge
  – Page us when you are thinking about a suicide attempt
Typical EMA Assessment Sequence

• Where are you?
  – Home
  – Away

• Are you?
  – Alone
  – With Someone

• Right now are you? (Click all that apply)
  – Resting
  – Sleeping/drowsing
  – Just sitting
  – Watching Television
  – Eating
  – Cooking
  – Cleaning the house or yourself
    • Cleaning or folding clothes
    • showering, shaving, brushing teeth
  – Reading/Studyng
  – Playing a Video game or surfing the web
  – Playing a musical instrument
EMA Assessment continued

- Who are you with?
  - Roommate
  - Friend
  - Partner

- What are you doing?
  - Resting
  - Talking
  - Just sitting
  - Watching Television
  - Eating
  - Cooking
  - Cleaning the house or yourself
    - Cleaning or folding clothes
    - showering, shaving, brushing teeth
  - Reading/Study
  - Playing a Video game or surfing the web
If you are away ...?

• Are you traveling?
  – Yes/No
• If yes

  – How are you traveling?
    • Walking
    • Taking a bus or other transportation
    • Riding a bicycle, driving yourself
    • Getting a ride
      – In a private car
      – In a taxi
      – In a shuttle
If you are not traveling are you

– At work
– At school
– At a doctors appointment
– At a clinic
Sample populations suited for EMA

• Mood and bipolar disorders
  – Mood alterations
  – Suicidal ideation
• Negative Symptoms of Psychosis
• Daytime sleepiness
• ADHD and related conditions
• Episodic behaviors
  – Eating Binges
  – Temper Tantrums
Passive Assessment: Wearables

• Many commercial options available
  – Validity data is improving but some challenges remain
• Can track
  – Activity
    • Steps per day, hour, week
    • Outlier periods (0 steps in an hour vs. 3000; steps in the middle of the night)
  – Sleep
    • Total, Stages, interruptions, daytime sleeping
  – Heart Rate
Conditions where wearables are most appealing

• Negative Symptoms
• Mood disorders
• Studies of agitation
• Hyperactivity
• Daytime sleepiness
Passive Assessment: Location Surveillance

- Can set home sensors at home
- Very accurately measure some things without paging and requiring a response
  - Where are you?
    - Bedroom, bathroom, TV room
  - How much do you move?
    - Gait
- What are you doing?
  - Telephone and computer use
  - Driving
  - Medication self-administration
Conditions well Suited to Location Surveillance

• Aging related conditions
  – Development of MCI found to correlate with a within-person change in computer use and general activity levels
• Negative Symptoms in schizophrenia
• Mood disorders with anergic symptoms
Combined Strategies

• The same platform can be used to do multi-channel assessment
  – Tablet-based assessments of cognition and functional capacity
  – Tablet-based EMA platforms
  – Tablet-based residence of wearable apps

• EMA pages can be used to trigger completion of cognitive and functional capacity assessments
General Limitations for These Strategies

• Adherence to protocols for home-based assessments
  – Can a tester be bypassed effectively?

• Adherence to EMA probes
  – What if the participant does not answer or fails to page the sponsor when something happens?

• Privacy concerns for surveillance studies
  – Hard to imagine proxy consent for impaired populations

• Charging, maintaining, wearing, and carrying devices
  – Can use the technology to monitor adherence through convergent information
Upcoming Presentations

• The rest of the presentations address these content areas
• They include regulatory and methodological/practical considerations
• These strategies have significant promise for the future, but may require a series of sensible development steps in order to meet validity requirements.