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# 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

He receives royalties from the BACS and the MCCB

# 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

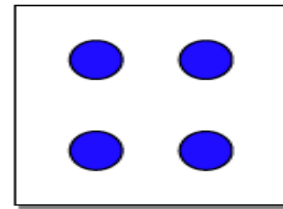
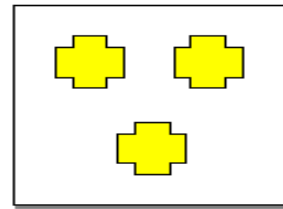
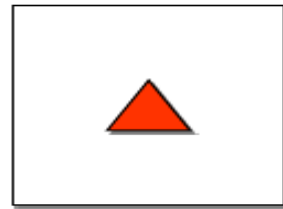
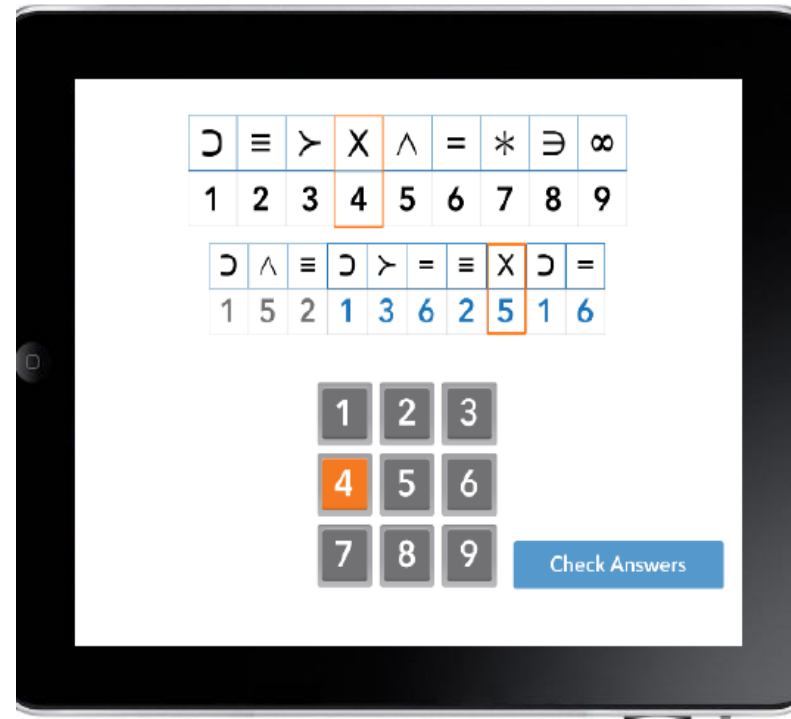
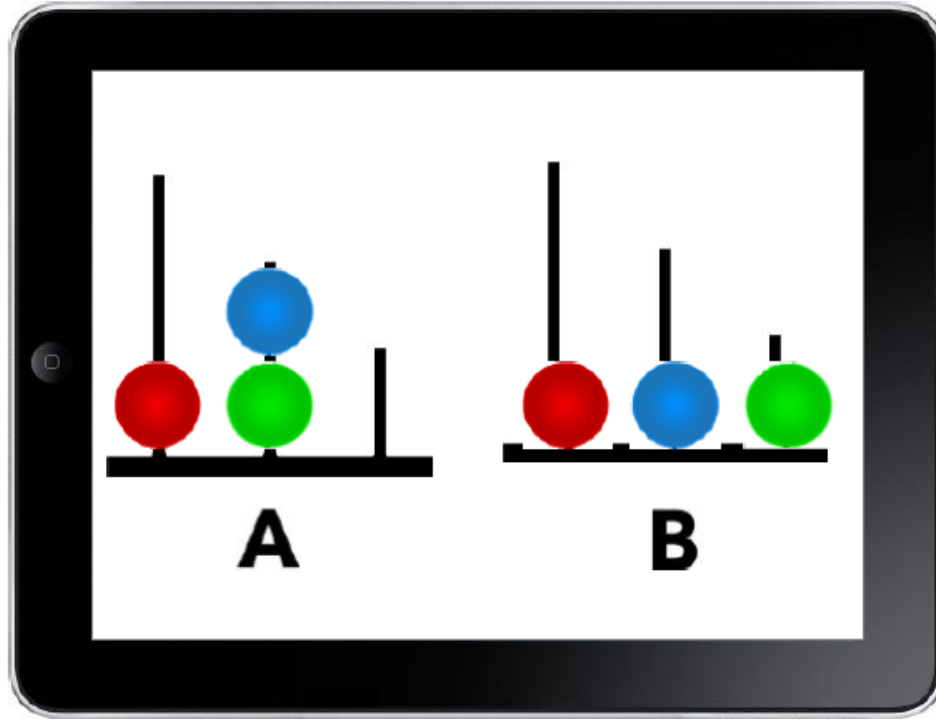
- Performance-based assessments
  - Cognition
  - Functional Capacity
- Interactive PRO assessments
  - Ecological Momentary Assessment (EMA)
- Passive Observations
  - Wearables
  - Location surveillance

# Goals and Strategies for Performance-Based Assessment

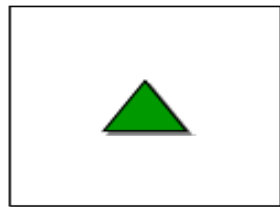
- Develop an alternative delivery for existing paper and pencil assessments
  - Examine convergent validity with standard measure
- Develop a de-novo Computerized assessment
  - Validate directly against outcomes of interest
- In office, tester-assisted assessments
- Remote, walk-up or internet strategies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

# BAC tower of London

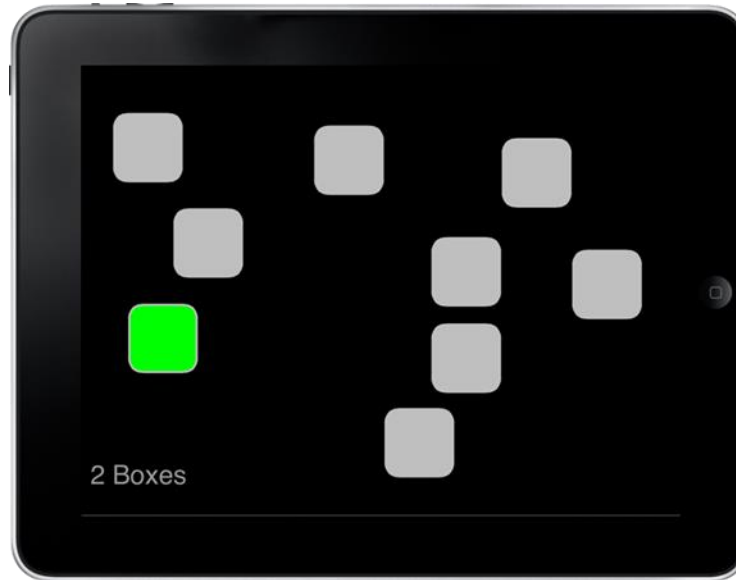
# BAC Symbol Coding



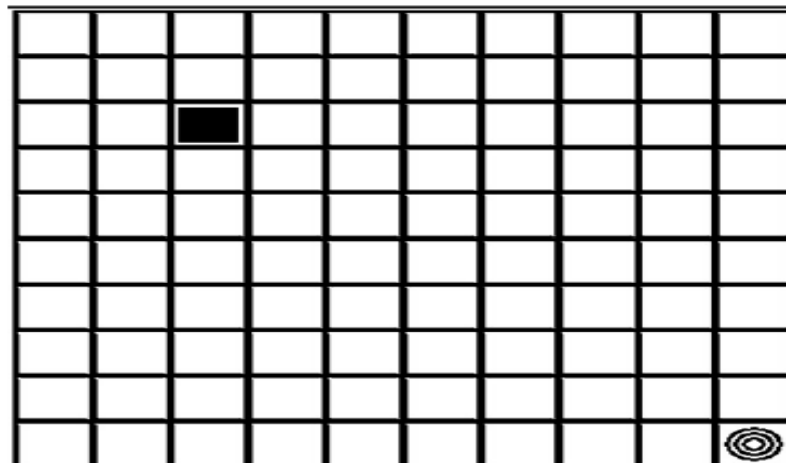
PAR  
Computerized  
WCST



## 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

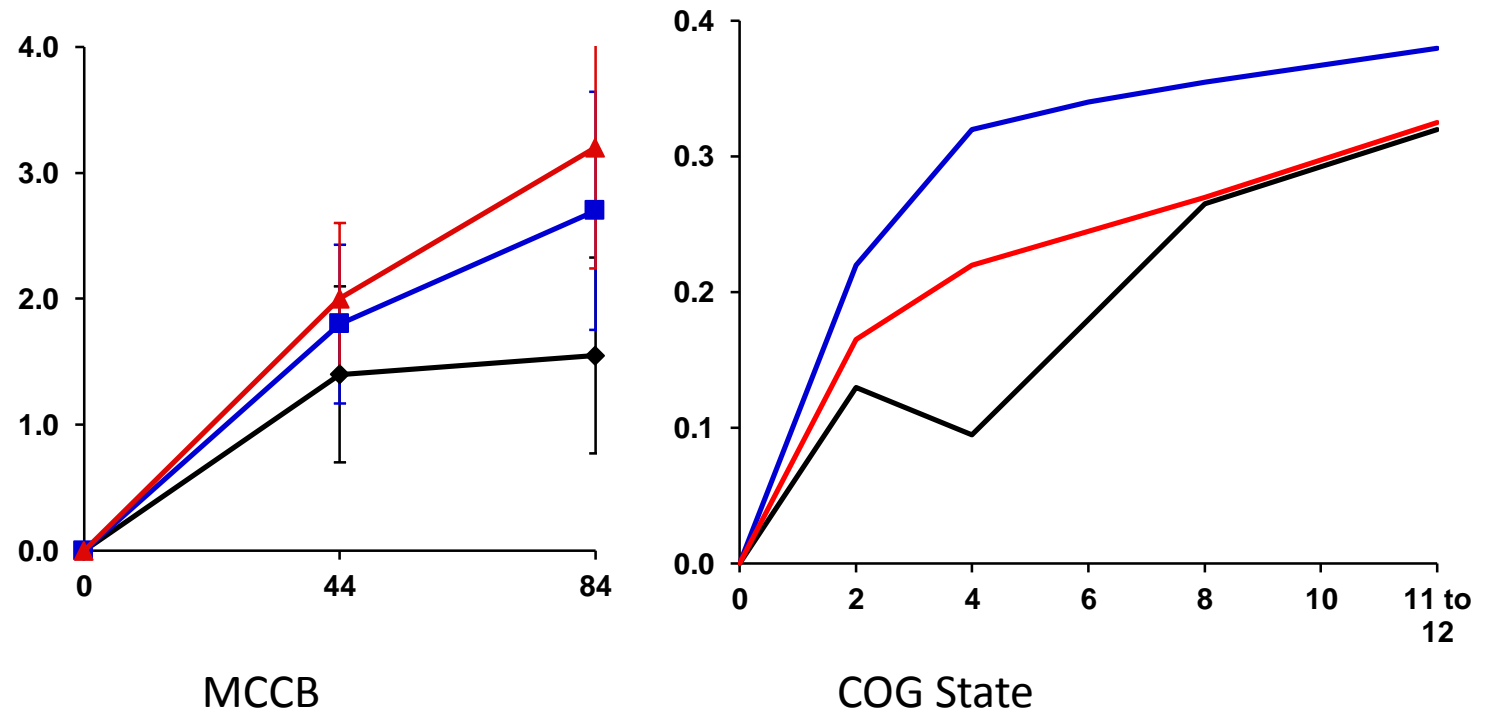
# Special Considerations: Norms

- 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?

UCSD PERFORMANCE-BASED SKILLS ASSESSMENT (UPSA) RA: tnguyen PN: P. 1006

Quarters      Dimes      Nickels      Pennies

Your answer:

Some of your friends are coming over to your apartment tonight for dinner. You have a special meal planned and you wrote down all the necessary ingredients in a recipe. Your task today will be to buy the ingredients you need from the store.

← Exit

 **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.

CONTINUE

i-Function

INSERT BILLS FACE UP

TRANSIT CARD

... and many more ATM/debit cards

# 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 be 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/Studying
  - 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/Studying
  - 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.