

# **FEASIBILITY AND BARRIERS FOR A NATIONAL ITEM BANK: IF WE BUILD IT WILL THEY COME?**

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# Introduction

- IRT and CAT methods are currently under evaluation for different disease areas and domains
- IRT-based measures are not widely accepted in clinical and health services research
- IRT-based methods and CAT provide innovative solutions to challenges of assessing health status in subjects with varying problems and trajectories of change over time

# Introduction (cont'd)

- It is technically feasible to develop and implement IRT-based, tailored testing
- There is considerable research and measurement work required to bring these methods into practical application
- If financial support was available it is possible to develop and test and national item bank and necessary software
- Uncertain whether instrument developers, clinical researchers, health products industry and regulatory agencies would fully accept IRT-based measurement approach

# Objective

- Presentation focuses on barriers and practical application of IRT-based measures
- Perspective of key stakeholders:
  - Instrument developers
  - Clinical researchers and clinicians
  - Pharmaceutical industry
  - Federal regulatory authorities

# Instrument Developers

- Vested interest and ownership of existing static health status measures
- Financial and academic issues associated with maintaining status quo
- Some developers are working on item banks and IRT-based measures, but will these be proprietary?

# Instrument Developers (cont'd)

- What is the incentive for developers of existing measures to contribute items to national item bank?
- If national item bank is built may be no (or little) need for current static measures
- No easy solutions, requires:
  - Involvement of broad range of researchers in development and psychometric evaluation of item bank and measures
  - Feasible and practical financial models

# Clinical Researchers

- For clinical researchers, significant barriers may be:
  - Lack of understanding and familiarity with IRT-based methods
  - Residual skepticism about patient reported outcomes in some clinical areas (i.e., CNS)
  - Practical issues and feasibility
- IRT-based and CAT requires computer availability
  - May not be practical in many clinic settings
  - Potential increase in research-related costs

# Clinicians

- Need practical and easily applied and understandable measures (clinometrics)
- Clinicians may not care about precise measurement of single domains, but may need tools to assist in diagnosis and evaluation
  - For example, in pain assessment after ascertaining pain intensity, next questions may need to focus on:
    - mobility,
    - activity limitations, and
    - function to determine best treatment (or to evaluate treatment)
  - Can IRT-based measures be developed with logical branching networks to assist clinicians in efficiently evaluating patient status for treatment decision-making?

# Regulatory Agencies

- FDA and other regulatory agencies have little (no) experience in IRT and CAT methods
- Focus is on static, disease-specific health outcome measures and documentation on instrument development, content validity, psychometric qualities, and responsiveness and interpretation (i.e., MID)
- Issues associated with validation and documentation of ePROs
- Cognitive discontinuity associated with IRT-based and tailored health outcome measures

# Pharmaceutical Industry

- Driven to some extent by FDA guidance and perspective
- Few companies will select IRT-based measures if they are not acceptable to FDA
- IRT-based and CAT may prove acceptable to FDA if industry can document evidence supporting content validity, good psychometric properties, and guidance on interpretation of results
- For industry the key issue is whether the additional expense associated with application of CAT in clinical trials will result in increased probability of demonstrating effectiveness of new treatments

# Interim Solution for Industry and Regulatory Agencies

- Continued dialogue among health outcomes researchers, psychometricians, industry researchers, and regulatory agencies
  - Methods for incorporating IRT-based CAT into clinical trials
  - Documentation of psychometric characteristics
  - Interpretation of findings
- Initially start with ‘static’ health status assessments based on IRT methods and tailored to specific disease indications (interim step)
- Accumulate experience and test feasibility and responsiveness of CAT in clinical trials as secondary or exploratory endpoints

# Financial Considerations in Maintaining National Item Bank

- Significant challenge in developing a business and revenue model to support organization for maintaining national item bank and related software
- Balance between unrestricted and open access and financial viability
- Example: IOM Institute for Health Technology Assessment, great idea no real commitment and support from industry and health insurers

# Financial Considerations in Maintaining National Item Bank (cont'd)

- Without cooperation and support from federal agencies, clinical researchers, instrument developers, industry and health insurance and managed care organizations, it is unlikely to survive
- Explore potential financial models:
  - Users fees and/or royalties
  - Education Testing Service model

# Summary and Conclusions

- If we (they) build it, will they come?
- Well maybe, but it depends on the extent to which key stakeholder groups accept and find IRT-based methods useful, practical and feasible for specific applications
- Need for continued dialogue and education regarding value of IRT and CAT
- Demonstration of advantages and value for financial investment for IRT-based and CAT measures
- Focus on practical application and acceptance-related issues are critical