



NIA IMPACT
COLLABORATORY
TRANSFORMING DEMENTIA CARE

**National Institute on Aging (NIA) IMbedded Pragmatic Alzheimer's Disease (AD) and
AD-Related Dementias (AD/ADRD) Clinical Trials (IMPACT) Collaboratory (NIA U54AG063546)**

**OUTCOME MEASURES FOR PERSONS
WITH SERIOUS ILLNESS:
A PRAGMATIC TRIALS PERSPECTIVE
VINCENT MOR, PH.D.**

Pragmatic Trials (Stage IV)

- Efficacious Phase 3 Studies are implemented under researchers' control
- Pragmatic trials seek to replicate Phase 3 results BUT embedded in functioning health care systems; interventions implemented by system staff
- Phase 3 studies collect primary patient outcomes using research staff
- Pragmatic trials rely on existing medical and administrative data for outcome ascertainment

Patient Relevant Outcomes

- Outcomes relevant to patients require special measurement; surveys, questionnaires, etc.
- Collecting Patient Reported Outcomes is complex & costly in Pragmatic Trials:
 - Consent needed;
 - Research data collectors in the clinic/hospital
 - Follow-up measurements can be missing
 - Recruiting controls

Health System Relevant Outcomes

- Health System leaders may host/study an intervention ONLY if it may solve problems
- New interventions must be integrated into existing workflow
- Quality Performance or Cost/Utilization Outcomes relevant to HCS Leaders
- May be willing to increase samples of patients in existing satisfaction surveys

How to Compromise?

Possible Solution

- Use short standard self surveys
- Use satisfaction surveys in standard use in HCS
- Do Separate post-test only interview by researchers
- Use internet login to obtain narrative content

Challenge

- Excludes cognitively, visually impaired;
- Response rates low
- Rules out cluster designs with passive controls
- Low and biased response rates; excludes digitally naïve

IMPACT

- <https://impactcollaboratory.org/>
- Funds pilots and demonstrations of non-pharm interventions focused on PLWD
- Have funded 20+ pilots and 6 demos of interventions in primary care, EDs, hospitals, nursing homes, Assisted Living & home care
- Learning from their experience how efficacious interventions can be replicated in HCS
- Major focus on pragmatic ascertainment of outcomes

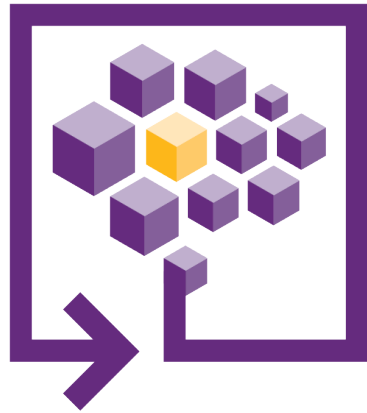


IMPACT Experience

- Hard to pragmatically identify care partners using EMRs
- Complex IRB issues sending material to patients but expecting family care partners to respond
- But for less pragmatic phase 4 studies, we've identified common and usable PROs and some using administrative data like satisfaction
- <https://impactcollaboratory.org/learning-resources/pcro-library/>

Summary

- Hard to obtain measured outcomes that are most relevant to patients in Pragmatic Trials
- There are special challenges for persons living with dementia
- HCS leadership are willing to host a study if they can see the benefit in relevant measures
- May be possible to extract more qualitative information from EMR in the future
- Now is a challenge to get PROs pragmatically



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