NOVEMBER 14-18, 2018 | BOSTON, MASSACHUSETTS

THE GERONTOLOGICAL SOCIETY OF AMERICA®

Momentum Discussion

Clinical Trials and Older Adults – Strategies to Drive Older Adult Participation

Panelists: Stephanie Studenski, Jay S. Magaziner, Roger Fielding

November 17, 2018

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MORE OLDER ADULTS IN CLINICAL TRIALS!

Goal

Increase awareness, recruit stakeholders,

create a mechanism for continued action

and follow-up at GSA 2019

Agenda

- Three brief presentations to set the stage for what we know
- Comments from key stakeholders
- Input from attendees
- Action items to sustain and accelerate momentum!!

MORE OLDER ADULTS IN CLINICAL TRIALS!

The Problem

- While older adults have the greatest prevalence of many illnesses, and are most likely to use medications and treatments, they are consistently under-represented in clinical trials.
- Thus, there is an inadequate evidence base about relative treatment benefit and harm across the broad scope of older adults.
- This is especially concerning among older persons with advanced old age, multiple morbidity, polypharmacy and/or frailty.
- In consequence, patients, families, providers, health care organizations and policy makers lack information to guide care planning.

WHY ARE OLDER ADULTS UNDER-REPRESENTED IN TRIALS?

- Clinical trial research principals prioritized specificity of effect and minimal confounding over greater generalizability. Older adults are scientifically “messy”?
- Regulatory agencies are mandated to focus on diseases, disease-specific outcomes and mechanisms linking pathophysiology to outcome; older adults with multiple conditions can cloud findings and non-disease-specific treatments lack a pathway to approval.
- Older adults can be difficult to recruit and manage due to:
  - Pragmatic issues of access and participation
  - Eligibility restrictions
  - Increased risk of loss to follow up
  - Increased risk of adverse events (both related and not related to the intervention)
  - Human subject and ethical concerns related to consent, safety and at times, over-protectiveness
  - All of which can lead to increased time, effort and cost.

WHO CARES?
STAKEHOLDERS

- Older adults
- The rest of us who love our elders and hope to live long enough to become one ourselves!
- Providers
- Scholars
- Health Care Systems
- Advocacy Organizations
- Research organizations – topical and methodological priorities and funding
- Treatment developers – PhRMA, Devices, surgeries, care pathways…
- Policy Organizations
- Payers – insurers, governments

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PRACTICAL CHALLENGES FOR INCLUSION OF OLDER ADULTS IN CLINICAL TRIALS

- Sensory deficits can affect many aspects of study conduct
  - Explaining study and obtaining informed consent
  - Asking questions and administering evaluations
  - Vision problems will require that everything be done verbally
  - Hearing problems will require that everything be done visually
- Mobility limitations
  - Travel to study sites will be more difficult
  - May require special assistance from others to travel to study sites
  - May limit ability to complete some evaluations/procedures

PRACTICAL CHALLENGES FOR INCLUSION OF OLDER ADULTS IN CLINICAL TRIALS

- Cognitive limitations
  - Confusing cognitive impairment with competence to provide informed consent
  - Assistance in understanding study and what involvement entails
  - Special justification for inclusion of cognitively impaired in studies
  - Surrogate consent
  - Limited ability to answer questions and perform some evaluations/procedures
  - Use of alternative ways of obtaining information—proxies, medical records, direct observation
  - Limited ability to follow directions for evaluations and adhering to interventions

PRACTICAL CHALLENGES FOR INCLUSION OF OLDER ADULTS IN CLINICAL TRIALS

- Participant fatigue
  - Order of asking questions and doing evaluations/procedures
  - Breaking evaluations into multiple sessions
- Making participation beneficial for ALL persons involved
  - Selecting an appropriate control treatment/procedure
- Gatekeepers
  - Family members act to ‘protect’ older persons from participating
  - Institutional officials may limit participation of those in their care

PRACTICAL CHALLENGES FOR INCLUSION OF OLDER ADULTS IN CLINICAL TRIALS

- Sponsors and scientists
  - Lack understanding of some of the practical challenges of including older persons
  - Avoid including older persons due to understanding the practical challenges
  - Insufficient resources for conducting study
  - Inability to identify and assign appropriate staff

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POTENTIAL SOLUTIONS

- Need to recruit older adults
- Age vs. Level of Functioning
- Inclusion/exclusion criteria
- Unique aspects of trial adherence in older adults
- Considerations of trial phase (I, II, vs III)

RECRUITMENT OF OLDER ADULTS

- Engage older patients
  - Conducting studies with older persons may require more time
  - More personnel time will require more resources
  - May need to develop alternate strategies for evaluation and delivery of interventions
- Include spouses/family members and caregivers in the research process (communication)
  - Can help to explain study to participants that need assistance
  - Can limit propensity to act as gatekeeper

RECRUITMENT OF OLDER ADULTS

- Create a network or database of older research participants or older adults advisory board
  - Can be advocates for clinical research participation
  - Seek advice on acceptability of study procedures and ways of conducting study to overcome any challenges that are identified
  - Seek advice throughout study—before setting up budget request, before starting study, and during all phases of project
- Involve “patient engagement office”

AGE vs LEVEL OF FUNCTIONING

- Age alone should not be an exclusion
- Screen for baseline level of function
- Specific functional criteria used would depend on the intervention but could include factors such as cognitive function or ambulatory requirements
- Screening using EMR
- Types of function include: performance tests, frailty, ADL/IADL assessment

INCLUSION/EXCLUSION CRITERIA

- Age alone should not be a reason for exclusion
- Consider risk vs. benefits
- Carefully consider inclusion/exclusion and keep in mind that being overly restrictive will limit enrollment of older adults (always consider safety)
- Study exclusions should be based on sound clinical reasoning
- Broad based inclusion criteria will ultimately enhance generalizability
- Education of IRBs

UNIQUE ASPECTS OF TRIAL ADHERENCE IN OLDER ADULTS – CONSIDERATIONS OF TRIAL PHASE (I, II, VS III)

- Managing inter-current illness/disruptions to treatment/plans to restart intervention
- Communication with participants healthcare team
- Minimizing “lost to follow-up”
- Consider enrollment in phase I if goal is a therapy for specifically older adults
- Consider alternative approaches to clinical trials (Virtual/mobile Clinical Research Center)
  - Administer all or some study procedures in participant’s place of residence

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Panel and Audience Discussion

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GSA 2018

ANNUAL SCIENTIFIC MEETING

The Purposes of Longer Lives

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