Lessons from Multisite Research: The Good, The Bad, and The Ugly

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STRIDE: A Multisite Pragmatic Trial to Reduce Serious Falls-related Injuries

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Yale University

David B. Reuben, MD
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Lessons From Multisite Research Webinar
January 5, 2016
Background

- 1/3 of older Americans fall each year
  - 20-30% of these have moderate to severe injuries (e.g., hip fractures, head trauma)
  - Leading cause of fatal and nonfatal injuries
  - < 50% discuss their falls with PCP
- Despite evidence that falls can be prevented by multifactorial intervention, the quality of care for falls remains poor
The STRIDE Study

- **Sponsors:** Patient-Centered Outcomes Research Institute (PCORI) and National Institute on Aging (NIA)
- **Joint Principal Investigators**
  - Shalender Bhasin (Partners): Communicating
  - Tom Gill (Yale)
  - David Reuben (UCLA)
- **14 Pepper Centers**
- **Data Coordinating Center:** Yale
Can redesigning medical practices and engaging patients to improve quality reduce serious falls-related injuries and improve other outcomes?
Cluster-randomized, parallel group superiority trial with practices stratified by healthcare system and patients nested within practices

Unit of randomization is the practice

6000 participants recruited across 10 sites
  - 75 participants from each of 80 practices over 18 months

Study duration: 5 years
The Patients

- Community dwelling persons
- 75 years of age or older
- One or more risk factors for falls
  - Fallen and hurt self in the past year
  - Fallen 2 or more times in the past year
  - Fear of falling because of balance or gait
The Intervention

- Specific care process demonstrated to reduce risk of falls
  - Literature-based
  - Experts operationalizing these into algorithms
  - All are standard of care
- Systematic implementation into health care settings
  - Practice redesign to improve quality
    - Co-management with RN Falls Care Manager (FCM)
    - Decision support (algorithms)
    - Information systems (software)
- Patient/caregiver engagement and activation
- Linkage to community-based resources
With patient/caregiver, collaborate in:

- Assessing risks of falling
- Creating a risk-reduction care plan
- Implementing the plan
- Coordinating multiple providers
-Promoting patient self-management
- Monitoring the patient’s progress
- Helping the patient/caregiver overcome obstacles (using motivational interviewing)
Risk Factors Addressed

- High-risk medications
  - alcohol use
- Postural hypotension
- Visual impairment
- Foot problems and footwear
- Osteoporosis
- Home safety
- Leg strength, mobility, and balance

*Identify/ Activate community assets/ resources
Gain confidence / skills for minimizing fall risk*
Serious fall injuries operationalized as those leading to medical attention, including:

- non-vertebral fractures
- joint dislocations
- head injuries
- lacerations
- other major sequelae of falls

All falls regardless of injury

Well-being

- Physical function and disability
- Anxiety and depression
- Falls efficacy
## Components of STRIDE Care

<table>
<thead>
<tr>
<th>Screening</th>
<th>Risk Assessment</th>
<th>Patient Self-Management</th>
<th>Intervention</th>
<th>Follow-up (clinical and outcomes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central by Yale for most sites</td>
<td>Patient, Caregiver, FCM, OT</td>
<td>Patient, FCM, PCP</td>
<td>Patient, Caregiver, FCM, PCP, Site Clinical Director, Specialists, Community resources</td>
<td>Patient, caregiver, FCM, PCP Outcomes by Yale</td>
</tr>
</tbody>
</table>

TG, DR
Challenges and Barriers

- Screening and recruitment
- Standardizing the intervention
- Integration into practices
- Other
Central vs. clinic-based
- Central: 9 sites
- Clinic-based: 1 site

Central screening
- delays in receiving lists of age-eligible patients
- errors in some lists
- varying levels of IT expertise and responsiveness

Clinic-based screening
- frequency of rescreening and transmission of results
Recruitment

- Done centrally across all sites
  - for clinic-based screening site, need to close loop so patients who decline participation are not recruited
- Varying number of age-eligible patients across sites and practices
  - ideal would be to enroll the same number of participants within each practice
Standardizing the Intervention

- Recruiting RN Falls Care Managers (FCMs)
- Developing clinical protocols
- Training FCMs, initial and ongoing
- Identifying community-based resources for exercise
- Ensuring that evidence-based falls prevention methods are used by home health and outpatient PT
- Maintaining fidelity
Integration into Practices

- Identifying space and support
- Communicating with PCPs
- Documenting in the EHR
- Using resources within the health care system
- Organizational complexity
- Joint sponsorship
- Finite resources
Questions
Lessons Learned from the NIH Collaboratory Health Care Systems (HCS) Interactions Core

Eric Larson, MD, MPH
Vice President for Research, Group Health; Executive Director and Senior Investigator, Group Health Research Institute
Lessons Learned from the NIH Collaboratory Health Care Systems (HCS) Interactions Core

Pragmatic clinical trials integrate healthcare research into everyday practice to address issues relevant to patients, clinicians, and delivery system leaders.

Lessons Learned from the NIH Collaboratory Health Care Systems (HCS) Interactions Core

A successful pragmatic clinical trial starts with a strong partnership between researcher and healthcare system, goes through a rigorous objective evaluation of the ability of the partner healthcare system(s) to participate, and ends with evidence about sustainable ways to improve care, as well as a long term scientific relationship.

Karin E Johnson, et al., A guide to research partnerships for pragmatic clinical trials, BMJ 2014;349:g6826
Framework for Pragmatic Clinical Trial Partnerships

Karin E Johnson et al. BMJ 2014;349:bmj.g6826
Common questions for researchers and healthcare providers considering a pragmatic clinical trial include:

- What would motivate a clinic, hospital, or entire healthcare organization to participate in a research study, given the existing demands on clinical staff?
- How can a pragmatic intervention be designed to fit the workflow within which it will be administered?
- What features do the intervention and trial need to ensure sustainable, translatable results?

Karin E Johnson, et al., A guide to research partnerships for pragmatic clinical trials, BMJ 2014;349:g6826
“Trials without tribulations: Minimizing the burden of pragmatic research on healthcare systems”

Six case studies generated by interviewing researchers, physicians, and delivery system leaders of six pragmatic trials funded by the Collaboratory.
Case 1: Establish a partnership from the get-go

*build on previous collaborations if possible*

- Establish a partnership from the beginning of a pragmatic clinical trial, starting with identifying the research question. Even with a research topic that is a high priority for clinicians, researchers must respect the providers who interact with patients, for example by not scheduling study-related patient visits during the busiest clinical times.

Case 2: Do a pilot project
test the partnership and identify issues to correct before a larger trial

Doing a small pilot project is essential for discovering unanticipated hitches, checking cost estimates, and optimizing study efficiency by adjusting the study protocol. As a result of one pilot, a study arm was eliminated that turned out not to be feasible. Moreover, the early success of a pilot can make it easier to recruit additional clinics into the trial.

Critical pilot questions include:

- Are sufficient patient numbers and data available for the analysis?
- Can data be collected at all clinical sites?
- How do the sites vary in services and capabilities?
- Can the system’s regulatory and administrative infrastructure support approval and oversight by ethics committees and review boards?
- Will the intervention add long-term value to the system?

Karin E Johnson, et al., A guide to research partnerships for pragmatic clinical trials, BMJ 2014;349:g6826
Case 3: Take advantage of existing hospital and health system infrastructure

for example, templates for quality improvement programs

- Listen to your frontline healthcare workers. They understand the workflow issues. Having local leadership involved and accountable, and making in-person visits to recognize local efforts is highly effective in maintaining compliance and enthusiasm.

Case 4: Minimize the impact on clinical workflow

_for example, in the patient recruitment and data collection steps_

- Ease the burden of study participation on the clinical staff by collecting only the data that are necessary for answering the research questions, making use of data elements that will be available through routine clinical care, and using systems already in place.
- Be prepared to compromise.

Case 5: Be as automated as possible

reduce data burden at the local level by automating interventions as much as possible without overwhelming delivery system IT staff

- Automated interventions, when feasible, can make study participation easier for delivery systems, physicians and clinical staff.
- Identify co-investigators or primary contacts at each intervention site who are knowledgeable about the study and their own system and are respected by people within their system. These people can provide you with local solutions to problems.

Case 6: Researchers are the tail, not the dog

*always keep in mind the main goal for all stakeholders: improving healthcare*

- Keep in mind that the purpose of the healthcare system is not to do research, but to provide good healthcare.
- Understand that even though healthcare system leaders consider the study a high priority, they must consider other priorities both within departments and broader health systems. Investigators should identify partners or champions in delivery system leadership but understand those partners will have competing priorities.

Be flexible throughout and be prepared to adjust the study design as needed.

Tailor pragmatic trial study procedures to the unique culture and workflows of each delivery system, to be feasible.

Expect the unexpected.
Questions?
Lessons From Multisite Research Webinar

January 5, 2016

Where Multi-Site Studies and Team Science Intersect

Rebecca A. Silliman, MD, PhD
Professor of Medicine and Epidemiology
Boston University Schools of Medicine and Public Health
Roadmap of Presentation

- Definition of multi-site studies vs. team science
- Personal history of multi-site/team science research as principal investigator (PI)
- Reflections on what went wrong and what went right
- Avoiding mistakes
Scientists Need to Learn How People Operate
**Team Science**: a collaborative and often cross-disciplinary approach to scientific inquiry

- Draws researchers who otherwise work independently into collaborative groups organized around a shared interest
Team – a group working together; two or more draft animals harnessed to a farm implement (pull in the same direction)

Collaborate – to work with others; to cooperate with an enemy that has invaded one’s country (play in the sandbox together)
Distillate of Definitions

- Shared vision
- Trust
Models of Multi-site Studies - I

- Centralized investigative team chosen by PI
  - Deployment of research staff to work with clinical staff (site = office practice)
  - One geographic location

- Dispersed investigative team chosen by PI
  - Experienced site PIs working with experienced research staff
  - Track record of collaboration with PI and each other on similar projects
  - Multiple dispersed geographic sites
Dispersed investigative team chosen by Research Network leadership

- Junior to mid-career investigators from different research cultures
  - Skill sets and needs not known
  - Research settings and capabilities not known
  - No existing relationships with PI

- Multiple dispersed geographic sites

- First year of meetings for grant planning and project start-up by telephone
What Can and Did Go Wrong?

- Under appreciation of:
  - How long it takes to build trust and the causes of distrust:
    - Academic vs. Non-academic
    - Previous history of unequal collaborations
  - Prior relationships among team members (both positive and negative)
  - The importance of a written publications policy and prioritizing dispersed first authorships over efficient production of papers
What Can and Did Go Right?

- Mentoring within the team and by example
- Engaging early career investigators
- Consistency of behavior
- Emphasis on quality science with dispersed authorship: 22 papers
- Continued building of trust and grant success
How to Avoid Mistakes - I

- Read about team science:
- Know your strengths and weaknesses
- When possible, choose your team members; when not possible, get to know their strengths, weaknesses, and needs
- Meet in person early and often
- Develop a shared vision for the research
- Live your values: integrity, accountability
How to Avoid Mistakes - II

- Make processes and procedures explicit, including roles and expectations.
  - Newer strategies, like Dropbox, allow for greater transparency by being a repository for all written documents that all can access.
- Listen, listen, and listen some more
- Communicate, communicate, communicate
- Remember that trust is fragile and conflict will happen
- When everyone is pulling in the same direction, the team wins
Strong science will get you funded, but poor interpersonal relationships will kill your science
- Pay attention to and invest in both

Reason for optimism: Our younger colleagues “get it.” Pay attention to their collaboration strategies, including the use of social media
Questions?