Value of Local Patient and Stakeholder Committees in Patient-Centered Pragmatic Clinical Trials: The UTMB STRIDE Experience

Elena Volpi, MD, PhD and Rebecca Galloway, PT, PhD
University of Texas Medical Branch at Galveston
The STRIDE Study

• Pragmatic clinical effectiveness trial of a multifactorial fall injury prevention intervention implemented in primary care clinical practices (1 year pilot, 4 year main trial).

• Research question: Can redesigning primary care medical practices and engaging patients reduce serious fall-related injuries and improve other outcomes within real clinical care?

• Primary Outcome: Serious fall-related injuries.

• Approach: Patient-centered intervention combining elements of:
  – Individually-tailored, risk factor-based intervention
  – Utilizing existing evidence-based fall prevention community and health care services
10 Clinical Trial Sites, 86 Primary Care Practices

- Essentia Health
  Duluth, MN
- Partners HealthCare
  Worcester, MA
- University of Iowa Health Alliance
  West Des Moines, IA
- University of Michigan
  Ann Arbor, MI
- HealthCare Partners
  Torrance, CA
- UTMB
  Galveston, TX
- Reliant Medical Group
  West Des Moines, IA
- Mount Sinai Health System
  New York, NY
- Johns Hopkins Medicine
  Baltimore, MD
- University of Pittsburgh Medical Center
  Pittsburgh, PA
Patient Processes

• Central recruitment from the Yale Coordinating Center
  • Patient addresses pulled from EHR
  • Mailout recruitment packet with: Dr. letter, STRIDE letter, study brochure, summary consent form, screening card and opt-out card
  • If screening card returned and positive, follow up call from Yale RAC
  • Verbal consent
  • Cluster randomized (clinic) to Falls Care Manager-based intervention or SOC
  • Intervention includes in depth fall risk evaluation and application of best practices for fall prevention
• Enrollment period: 20 months (August 1, 2015 – March 31, 2017)
  • Completed enrollment of 5451 participants
• 20-40 months of follow up (ends Nov 30, 2018)
Specific Aims of the LPSCs

- Train investigators, patients, and stakeholders on how to optimally engage in this research partnership
- Establish the processes for bidirectional engagement and communication within the context of this trial
- Refine jointly with patients and stakeholders a multi-factorial strategy that uses an individually-tailored, risk factor-based approach aimed at reducing serious fall injuries and improving patient well-being at your local site
University of Texas Medical Branch
Local Patient and Stakeholder Council

Patient/ Caregiver Perspective

- Gloria Ellisor
- Shirley Bridges (Members since Year 1)
- Bill Love, Jr
- Mike Conwell
- Marge Mathers
- Ed Beasley

Community Partners

- Helen Appelberg, D.Min (Co-chair Emeritus)
- Alice Williams, MS, LBSW (Libbie’s Place)
- Jymann Davis, M.S., CFCS (Texas A&M AgriLife)
- Curtis Cooper (Houston-Galveston AAA)
- Michelle Sierpina, PhD (OLLI)
- Cathy Elton, PT
- Kshitiya (Kay) Kulkarni, OTR, PhD, MPH

UTMB Health

- Summer Rae Filidei-Chapman, RN, BSN (Falls Care Manager)
- Mukaila Raji, MD, MS, FACP
- Rebecca Galloway, PT, PhD, GCS, CEEAA (Co-chair)
University of Texas Medical Branch
Local Patient and Stakeholder Council
Local and National Engagement

• UTMB STRIDE LPSC meets 4 times/year

• Agenda items evolve across stages STRIDE study

• Rebecca Galloway (Co-chair) facilitates bi-directional communication with STRIDE NPSC and serves on NPSC intervention and physical components committees
**UTMB LPSC Hot Topics**

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<td>• STRIDE Orientation &amp; LPSC role development</td>
<td>• Outpatient PT referral process (new stakeholder invited)</td>
<td>• Additional patient stakeholders</td>
<td>• Closure strategies for final FCM visit</td>
<td>• Dissemination planning - continued</td>
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<td>• Community-based exercise (CBE) resources</td>
<td>• CBE resources – continued</td>
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<td>• Home Exercise Video</td>
<td>• LPSC &amp; community engagement in fall prevention - continued</td>
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<td>• Home modification resources</td>
<td>• Recruitment strategies</td>
<td>• Retention strategies</td>
<td>• LPSC &amp; community engagement in fall prevention</td>
<td>• Sustainability options for LPSC post STRIDE study</td>
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<td>• Recruitment story postcard</td>
<td>• Post hospitalization follow-up</td>
<td>• Fall event reporting</td>
<td>• Dissemination planning (local and national resources)</td>
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1 in 3 adults over 65 will fall.

Together, we can prevent falls.

“I thought falls were caused by accidents and could not be prevented. Then my doctor told me that falls are preventable.

**I value my independence more than anything.** I am active, involved in my community and do everything I can to keep from falling.”

Helen, 85
Galveston, TX
Recruitment Problems

• By month 12 of the 20-month enrollment period UTMB had recruited only ~160 patients out of the planned 600!
• Review of the recruitment record showed (relative to other clinical sites):
  • Strong return of screening cards
  • Many positive screening cards
  • Moderately lower number of answers to follow up phone call
  • Large number of declined participation at the first call
  • Many calls ending within 8-10 seconds with a “No, thank you”.
• We brought the problem up to the LPSC.
• LPSC questions:
  • What shows up on caller ID? (CT # or local # but not UTMB name)
  • Where are the callers from? (Anglo: North East; Spanish: Caribbean, Uruguay)
  • Do they leave a voice message (many people screen calls)
  • What does the script say? (culturally appropriate?)
LPSC Recruitment Recommendations

• Change recruitment strategy from central calls to calls from UTMB phones to capture patients who screen phone calls. ✓

• Presence of local study personnel at practice sites, have cards available and explain central phone call process. X

• Enlarge copy of recruitment postcard to display at OLLI and clinics. ✓

• Local consent face-to-face for positive screeners, particularly important for those with low health literacy, language barriers or other types of communication impairment. X

• Reason for doing the STRIDE study should be at the beginning of the script and should include prevention of fall-related injuries. ✓
Results of Implementation of LPSC Recommendations

• October 2016:
  • We sent one local study coordinator to the Yale RAC for training
  • Study coordinator bilingual (Spanish), born on Galveston island (BOI)

• November 2016:
  • Local coordinator started calls to non-responders and new potential patients, using a UTMB phone displaying “UTMBHealth” on caller ID.
  • Until then we had recruited 198 total patients.

• By March 31st, 2017, we had reached 541 patients recruited!

• Using the local caller per LPSC recommendation our average recruitment rate went from 16 patients/month to 85 patients/month!
Home Exercise Manual Feedback

• LPSC reviewed 35-page manual
• Practiced following exercise instructions
• Tom Storer, PhD incorporated feedback into final draft distributed to Falls Care Managers
LPSC Community Engagement

• LPSC planned interactive booths inspired by STRIDE evidence-based interventions

• OLLI sponsored event space

• Bridge PTA to DPT students, PT faculty, physician, nurse practitioner, nurse, community resource providers

• 51 community attendees
Questions?

http://www.stride-study.org

http://www.utmb.edu/scoa