A Pragmatic Trial for Comprehensive Post-Acute Stroke Services funded by PCORI

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Introduction: The Team

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  – Assistant Professor, Social Sciences and Health Policy, Public Health Sciences, Wake Forest School of Medicine
WHY A TRIAL OF COMPREHENSIVE POST-ACUTE STROKE SERVICES?

Cheryl Bushnell, MD, MHS
Stroke impact

• 795,000 strokes occur each year, and about \( \frac{1}{4} \) are recurrent events

• Over 4.4 million people with disabilities from stroke living in U.S.

• 2\text{nd} leading cause of death in the world, but 5\text{th} leading cause of death in the U.S.
  – Improvements in acute stroke care is likely reducing mortality

Stroke care: The journey

1996
FDA approves IV rtPA

2003
AHA/ASA GWTG—Stroke and CDC’s Paul Coverdell Registry launched

2012
Joint Commission Comprehensive Stroke Center certification

2014-15
Bundled payments and ACOs
Stroke care: The journey

• Acute stroke care greatly improved through quality metrics and core measures for public reporting

1996
FDA approves IV rtPA

2003
AHA/ASA GWTG—Stroke and CDC’s Paul Coverdell Registry launched

2012
Joint Commission Comprehensive Stroke Center certification

2014-15
Bundled payments and ACOs
Stroke Care: Many gaps remain

- 42% of stroke patients were not referred to any post-acute care (Gage, et al. U.S. DHHS 2009)
- No performance indicators for processes of care after discharge
Evidence for interventions that improve post-acute care

- Transitional care management (Naylor, et al. Health Affairs 2011;30:45-54)
  - Only covers the first 30 days

- Early supported discharge (Fearon, et al Cochrane Database Syst Rev 2012):
  - Hospital-based stroke team provides coordinated care (rehab, prevention, support) in the home
  - Standard of care in U.K. and Canada
  - Never been implemented in the U.S.
Direction for pragmatic trials

• Can an intervention to improve care for stroke patients regardless of the settings and providers be adapted to the U.S. health care system?

• What might be the best setting for testing a complex intervention for post-acute care?
BUILDING ON PARTNERSHIPS AND COLLABORATIONS TO IMPROVE STROKE CARE

Coverdell Registry in NC (North Carolina Stroke Care Collaborative):
Wayne Rosamond, PhD
Senator Paul Coverdell - Georgia (R)
1939-2000
- Died of stroke while in Congress
- Congress funds Paul Coverdell National Acute Stroke Registry
- Mandates CDC to create registry

Mission
- Measure, track, improve acute stroke care
- Decrease rate of premature death and disability
- Eliminate disparities in care
- Support development of systems of care that emphasize quality of care across the spectrum of care
CDC invited proposals from state health departments for implementation of Coverdell

Intensive QI efforts to close gaps in recommended vs. actual care

NC State Health Department partners with UNC

First 4 states funded for implementation in 2004

- NC, GA, MA, IL

Currently eleven states funded (NC, AR, CA, GA, IA, MA, MI, MN, NY, OH, WI)
NC Stroke Care Collaborative Participating Hospitals (n=54) by Region 2015
### Characteristics of NC Stroke Care Collaborative Hospitals, 2015

<table>
<thead>
<tr>
<th>NCSCC Hospital Characteristics 2015 (n=54)</th>
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<tbody>
<tr>
<td>Characteristic</td>
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<tr>
<td>Teaching hospital</td>
</tr>
<tr>
<td>Hospital location</td>
</tr>
<tr>
<td>Urban</td>
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<tr>
<td>Micropolitan</td>
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<tr>
<td>Small town or rural</td>
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<tr>
<td>Hospital bed size, mean</td>
</tr>
<tr>
<td>&lt;100 beds</td>
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<tr>
<td>100-300 beds</td>
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<tr>
<td>≥300 beds</td>
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<tr>
<td>JC Primary Stroke Center</td>
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<tr>
<td>‘Get-with-the-guidelines-Stroke’ participant</td>
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NCSCC Activities

• Custom made, interactive, web-based data management tool
• Network and sharing of best practices
• Quality improvement working group
• Regional quality improvement workshops
• Quality improvement monthly webinars
• Linkage with EMS database
• Grant program for hospital specific QI innovations
NC Stroke Care Collaborative: Receipt of Defect-free Care, 2005-2015

% of patients receiving defect-free care

Calendar Year (by quarter)
Summary

• Progress in improving acute care
• Post-acute care improvements needed
• NCSCC provides the platform and partnerships needed to close the post-acute stroke care gaps
COMprehensive Post-Acute Services (COMPASS) Model:
Cheryl Bushnell, MD, MHS

THE CARE MODEL
COMPASS: A Multidimensional Intervention

• Care Model that creates processes for post-acute care

• Use of current reimbursement models
  – Transitional Care Management
  – Chronic Care Management

• Quality Performance Indicators to measure processes of care
COMPASS team intervention

- Post-acute Coordinator (RN):
  - Perform the 2-day follow-up phone call
  - Provide education prior to discharge
  - Coordinate appointments with NP and PCP
  - Provide community referrals (e.g. stroke survivor support group) and other support during the intervention

- Nurse Practitioner/Physician Assistant
  - See patients within 7 to 14 days in clinic for TCM billing
  - Establish an individualized care plan with the patients and the families
  - Provide referrals to home health, outpatient therapy, falls prevention, neurological assessment, cognitive and depression screen, medication management, secondary prevention, community services
  - Support PCP, provide notes and communications related to post-acute care
31 year old, white female, living in rural NC, high school graduate, associate’s degree (stroke at 22)
Stroke patient voices

31 year old, white female, living in rural NC, high school graduate, associate’s degree (stroke at 22)

“With my brain not working properly, it was important to have things explained slower, and in non-medical terms. It was also important for the doctors and the therapists to explain it multiple times—not to assume I knew why I needed this.”
Stroke patient voices

31 year old, white female, living in rural NC, high school graduate, associate’s degree (stroke at 22)
Stroke patient voices

31 year old, white female, living in rural NC, high school graduate, associate’s degree (stroke at 22)

“Stroke is just as hard on family members. They carry a large portion of the weight of recovery.”
Stroke patient voices

60 year old, white male, living in urban NC, member of the business community
Stroke patient voices

60 year old, white male, living in urban NC, member of the business community

“After the stroke I had new prescriptions…I couldn’t dispense my medications into daily doses. This math deficit was not recognized until I got home. I lived alone and I had to take care of myself and I was unable to cope.”
Stroke patient voices

60 year old, white male, living in urban NC, member of the business community

“After the stroke I had new prescriptions…I couldn’t dispense my medications into daily doses. This math deficit was not recognized until I got home. I lived alone and I had to take care of myself and I was unable to cope.”

“A follow-up phone call has got to be the prime piece that has to happen in stroke recovery.”
Finding The Way Forward

NUMBERS
➔ Know your numbers: BP; A1C; Cholesterol etc

ENGAGE
➔ Be active: Engage your mind, your hands, your arms and your feet

SUPPORT
➔ Take advantage of Support systems/resources: Community, Family and caregivers

W’s
➔ Know these W’s
What medication are you on? Why are you on them? When do you take them?
E-care planning

• Compilation of:
  – Comprehensive post-acute assessment for patient’s ability to manage care and recovery, and their preferences, and goals

• The e-care plan follows the patient across providers and settings

• Consistent with CMS initiatives to incorporate social determinants of health
Quality Improvement and Web-based Feedback

• Candidate measures are:
  – % of patients called within 2 days
  – % of patients seen by NP/PA within 7 days and 14 days
  – % of eligible patients referred to rehabilitation or community services
What is the best way to test COMPASS?
Cheryl Bushnell, MD, MHS

PCORI PRAGMATIC TRIAL DESIGN
COMprehensive Post-Acute Stroke Service (COMPASS) Aims

• Primary aim: To determine the comparative effectiveness of COMprehensive Post-Acute Stroke Service model vs usual care on stroke survivor functional status at 90 days post-stroke

• Secondary aims:
  • Assess caregiver strain at 90 days
  • All-cause readmissions at 30 and 90 days
  • Mortality, health care utilization, use of TCM billing codes using claims data at 1 year
COMPASS: Pragmatic Population

• Inclusion criteria:
  – Patients who are discharged home from participating hospitals

• Exclusion criteria
  – Patients discharged to skilled nursing or inpatient rehab facility
COMPASS Design

• Cluster-randomized pragmatic trial
• Stratification by hospital characteristics: stroke volume (<100, 100-299, and >300) and primary stroke center status (6 strata)
• Primary outcome: Stroke Impact Scale-16 at 90 days (patient-reported outcome)
• Secondary outcomes: Modified Caregiver Stroke index at 90 days
  • All-cause readmissions at 30 and 90 days
  • Mortality, health care utilization, use of TCM billing codes using claims data
Study Design

NCSCC Hospitals
Study Design

NCSCC Hospitals

COMPASS

Usual Care

Follow-up
HOW IS THIS TRIAL PRAGMATIC?

Pam Duncan, PhD, PT
Pragmatic = Implementable and Sustainable

• Real World
• Real Practice
• Current Reimbursement
• Real Partners Across the Continuum
• Meaningful Patient Outcomes
Integrating COMPASS with new health care reimbursement models

• Work with health systems to implement Transitional Care Management Codes
• Explore possibilities of implementing Chronic Care Management Codes
• Implement Care Plans- e-care planning
Pragmatic design considerations

• All patients discharged from hospital to home receive assigned treatment
• Patient reported outcomes will inform care and measure success
• Assent for outcomes call rather than written informed consent
• Possible exclusions:
  – patients discharged outside of certain radius from hospital or outside NC
  – Hospitals with less than minimum stroke discharges per year
• Maintain consistency with PCORI methodological standards
PCORI – What Does Engagement Mean?

• Meaningful involvement of patients, caregivers, clinicians, and other healthcare stakeholders throughout the research process—from topic selection through design and conduct of research to dissemination of results.

• Such engagement can influence research to be more patient centered, useful, and trustworthy and ultimately lead to greater use and uptake of research results by the patient and broader healthcare community.
## Influential Leaders

### Patients/Caregivers
- To be representative of NC (race, sex, urban/rural, SES)
- Justus Warren
- AHA/ASA
- Primary Care

### Community Coalitions
- *PACC*
- HH
- AAA
- Outpatient Neurologist
- Primary Care
- AHEC
- Hospital
- Pharmacy
- Patient/Caregiver
- Local Health Department
- Stroke Support Group
- Faith Leader
- EMS

### Therapy (SLP, OT, PT)
- HH Stakeholders
- Outpatient Therapies
- Rehab MD
- Falls Coalitions
- Community Based Exercise Programs

### Community Stakeholders
- AAA
- CCNC
- DHHS
- Falls Coalition

### Education
- AAA
- Existing Networks
- Hospital based CEU

### Hospitals
- Area Agency on Aging
- Rural Health Network
- Palliative Care Network

- Area Agency on Aging
- Rural Health Network
- Palliative Care Network

- Stroke Program Manager
- QI
- Pharmacy
- Primary Care
- Medical Director
- NP
- Rehab Representation
Community Coalitions

• Coalitions at each site
• Who?
  – Hospital Stroke Team Member
  – Primary Care Provider
  – Outpatient Neurologist
  – Rehabilitation providers (Home Health, Outpatient Therapist)
  – Area Agency on Aging for community services
  – Pharmacies
  – Stroke Support Groups
  – Local Patient and Family Caregiver
  – Local Health Department
Thank you for this opportunity

DISCUSSION