Stroke Transitional Care and the Continuum of Acute, Prevention, and Rehab StrokeNet Trials

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Disclosures

- Research salary support from
  - PCORI as co-PI of the COMPASS Study
  - AHRQ R01 co-PI of analyses to assess the cost of implementing COMPASS
- Ownership in Care Directions, LLC; a new company to commercialize the COMPASS-Care Plan

PCORI Disclosure and Disclaimer

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Disclaimer: All statements are solely those of the presenters and do not necessarily represent the views of PCORI or its Board of Governors or Methodology Committee.

NCT Number for ClinicalTrials.gov: NCT02588664

Objectives

- To describe what stroke transitional care looks like
- To provide the results of the COMPASS Study: A Transitional Care Model
- To discuss the potential impact of transitional care on StrokeNet trials
- To list the next steps for stroke transitional care models

Stroke Transitional Care

What does this look like?

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Background

- Over 50% of stroke and TIA patients are discharged directly home after a brief hospital stay (e.g. 3 days) or observation
- Multiple comorbidities, suboptimal risk factor management, residual disabilities and at risk for complication
- Recurrent stroke risk highest in first 30 days
  - Secondary prevention is critical

- Post-acute care is fragmented

- Effective transitional care (TC) is a priority for improved care coordination

Why is transitional care so hard?

- Lack of integration between hospital and outpatient settings
  - Different facilities and health systems
  - Different providers (primary care or specialist is out of network) and ineffective handoffs about the care plan post-stroke
  - Differences in insurance coverage (many home health agencies do not take certain types of insurance)
  - Variability in community resources
  - Distance between hospital and home—transportation can be a major barrier

Health Literacy and Transitional Care

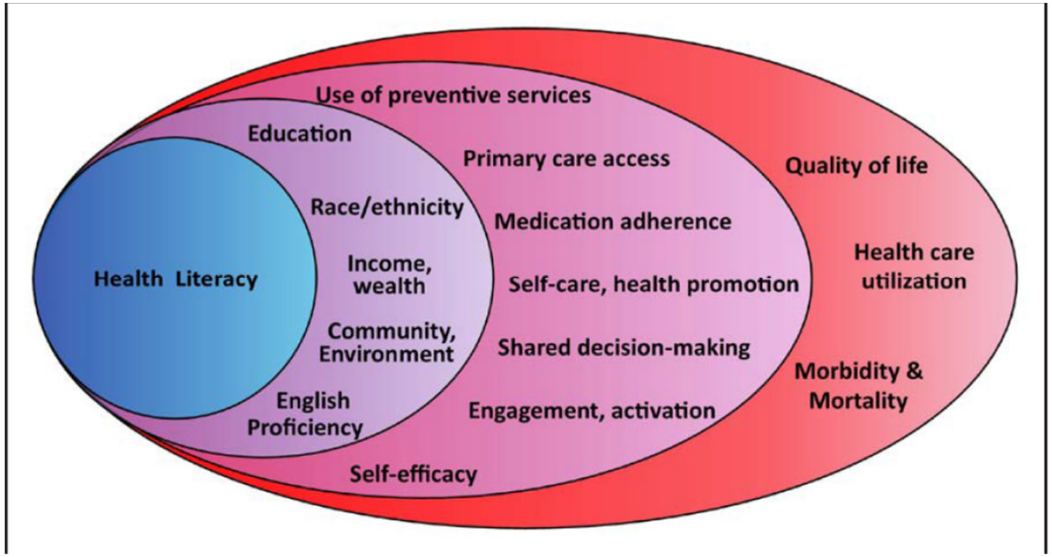
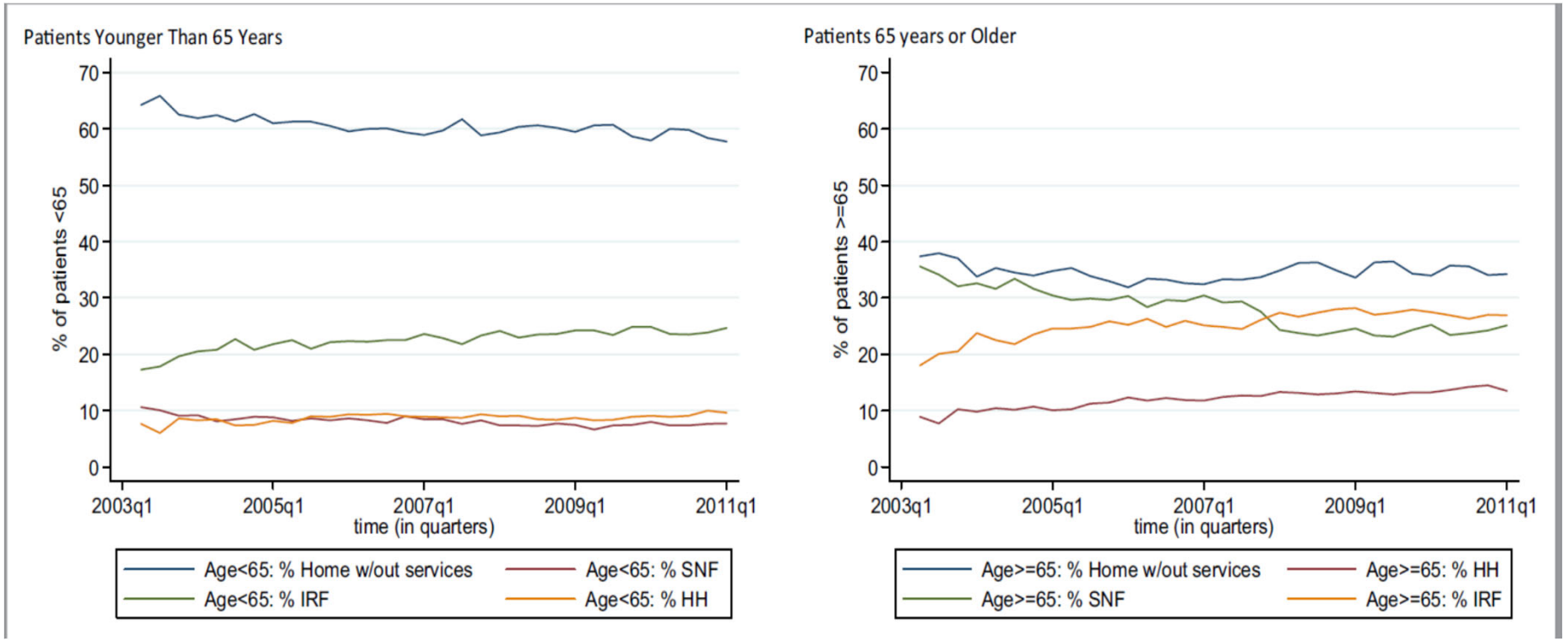


Figure 1. Health literacy nested within social determinants of health (education, race/ethnicity, income and wealth, community and environment, and English proficiency), which in turn are associated with a range of intermediate- and long-term health-care outcomes.

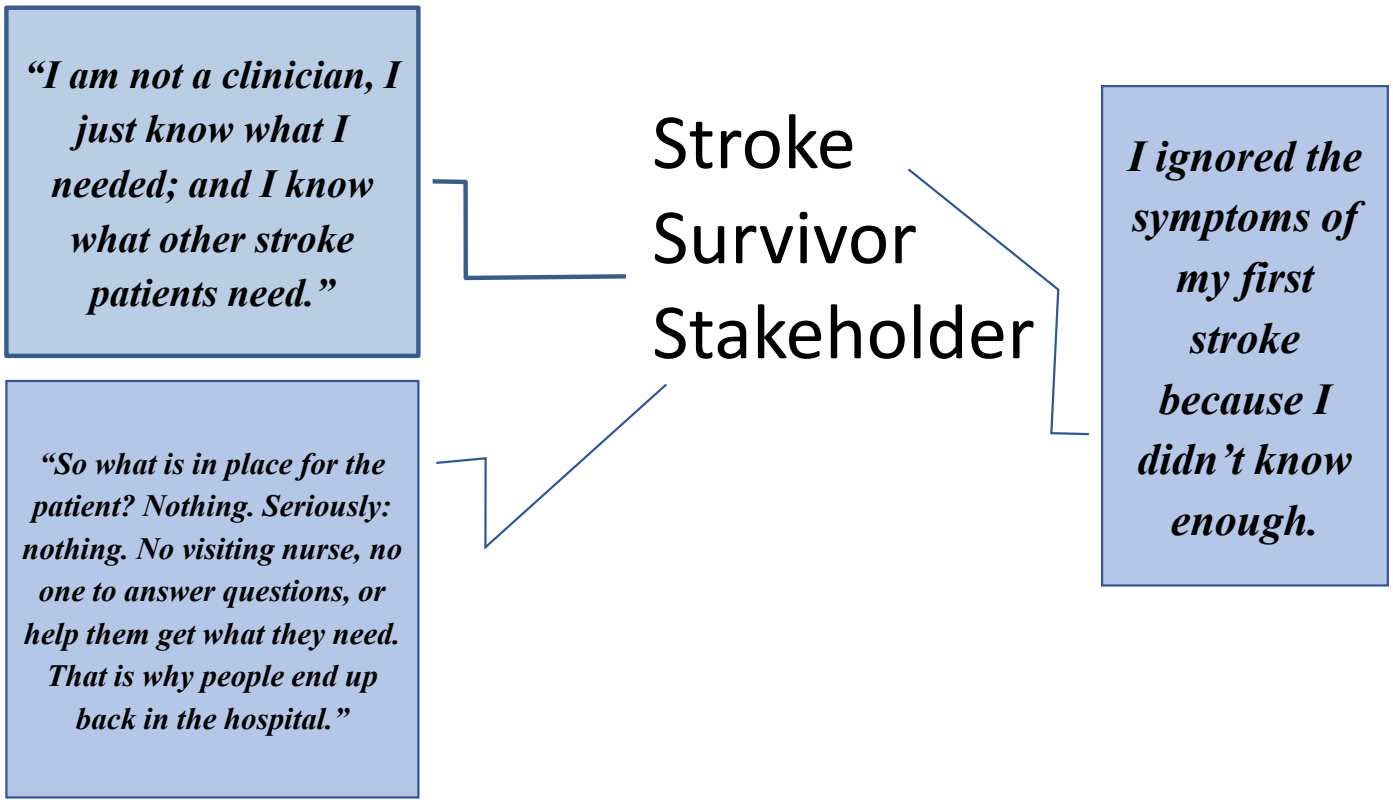
Magnani, et al. Circulation 2018;137

Many patients do not receive any post-acute stroke services



Prvu-Bettger, et al. JAHA 2015;4:e001038 doi: 10.1161/JAHA.114.001038

What do our stroke patients say about transitional care?



Stroke systems of care recommendations post-acute care

1. Stroke centers should use **organized approaches to ensure that all patients receive appropriate postacute care**
2. Stroke centers should adopt approaches to secondary prevention that **address all major modifiable risk factors** and are consistent with the national guidelines for all patients with a history or a suspected history of stroke or TIA.

Adeoye, et al. Stroke 2019;50:e187-e210

Stroke systems of care recommendations for post-acute care

3. A stroke system should **establish support systems** to ensure that all patients discharge from hospitals and other facilities to their homes have **appropriate follow-up with specialized stroke services when needed and primary care arranged on discharge.**

4. To standardize postacute care after stroke discharge, stroke centers should **comprehensively screen for postacute complications, provide individualized care plans during the transition of care, provide referrals to community services, and reinforce secondary prevention and self-management of stroke risk factors and lifestyle changes** to decrease risk of recurrent stroke.

Adeoye, et al. Stroke 2019;50:e187-e210

Centers for Medicaid and Medicare Services (CMS)

- Transitional Care Management (TCM) codes
- From date of discharge through first 30 days
- Only one provider can bill these codes, CMS will pay the first claim it receives

99495 TCM Moderate Complexity

Communication with patient and/or caregiver within 2 business days post-discharge
Medical decision making of at least moderate complexity
Face-to-face visit within 14 days post-discharge
Medicare fee schedule: $152.02

99496 TCM High Complexity

Communication within 2 business days post-discharge
Medical decision making of high complexity
Face-to-face visit within 7 calendar days post-discharge
Medicare fee schedule: $214.76

Hospital Survey Stroke Transitional Care

TCM Components	TCM qualifying services of all 41 hospitals, n (%)	Hospitals with 1 TCM component, n (%)	TCM definition met (all 3 components), n (%)
Telephone f/u 48-72 h		15 (36.6)	**13 (31.7)**
Face-to-face provider f/u within 14 d		**31 (75.6)**	
>80% of patients with PCP appointment w/in 14 d	15 (36.6)		
Stroke f/u with neurology w/in 14 d	**4 (9.8)**		
F/u within 14 d any PCP, specialist, APP	26 (63.4)		

13 or 32% of hospitals reported services that met TCM criteria
One third of hospitals used stroke service personnel for telephone f/u

Prvu Bettger, et al. Neurology 2019;92:1-8.

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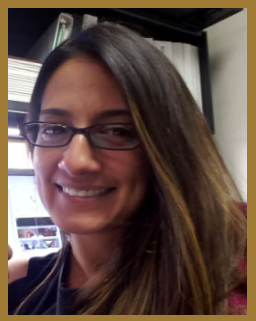
COMprehensive Post-Acute Stroke Services (COMPASS)

Transitional care model tested in real world practice



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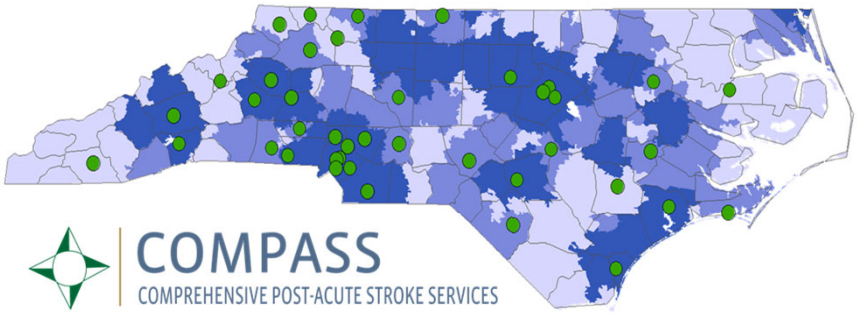
Objective

- Evaluate effectiveness of comprehensive transitional care versus usual care on patient-centered outcomes after stroke or TIA 90 days after discharge
- Primary outcome: Stroke Impact Scale-16 (functional status)
- Secondary outcomes: BP self-monitoring, survival, incident falls, disability (modified Rankin Score), depression, self-rated health, satisfaction with provider communication and care coordination

Pragmatic Trial of Transitional Care Management



- Cluster-randomized pragmatic trial
- 40 randomized hospital units in North Carolina
- 5,882 patients discharged home
- Transitional care was implemented in clinical workflow, consistent with CMS policies and reimbursement
- Primary outcome: 90-day functional status using Stroke Impact Scale (SIS-16)

Duncan et al. 2017 *BMC Neurology*, 17(133); Duncan et al. A Randomized Pragmatic Trial of Stroke Transitional Care: The COMPASS Study (under review)

Intervention: A Comprehensive Care Model

2 Day Call	Clinic Visit by Day 14	30 Day Call	60 Day Call

Care Team:

- Advanced Practice Provider (APP) or Physician
- Post-Acute Care Nurse Coordinator (PAC)

Intervention Highlights:

- Digital tool to assess functional and social determinants of self-management and health
- Individualized care plans:
  - Secondary Prevention
  - Rehabilitation and Recovery
  - Caregiver Support
  - Referrals to Community Resources
- Quality performance measures

Numbers
Know your numbers - blood pressure, blood sugar, cholesterol, etc.

Engage
Be active - engage your mind and body

Support
Ask for help - for yourself and your caregivers from community resources

Willingness
Be willing – manage your medicines and lifestyle choices

Bushnell et al. 2018 *American Geriatrics Society*, 66(5).

Patient Characteristics

	Intervention (N=2689)	Usual Care (N=3193)
Age, mean years (SD)	68.0 (13.8)	66.3 (13.9)
Female sex, %	48.3	51.9
Race, %		
White	79.1	67.2
Non-white	20.9	32.8
Diagnosis, %		
Stroke	63.3	64.0
TIA	36.7	36.0
NIH Stroke Scale Score, median (IQR)	1 (0-3)	1 (0-3)
Missing	*45*	*120*

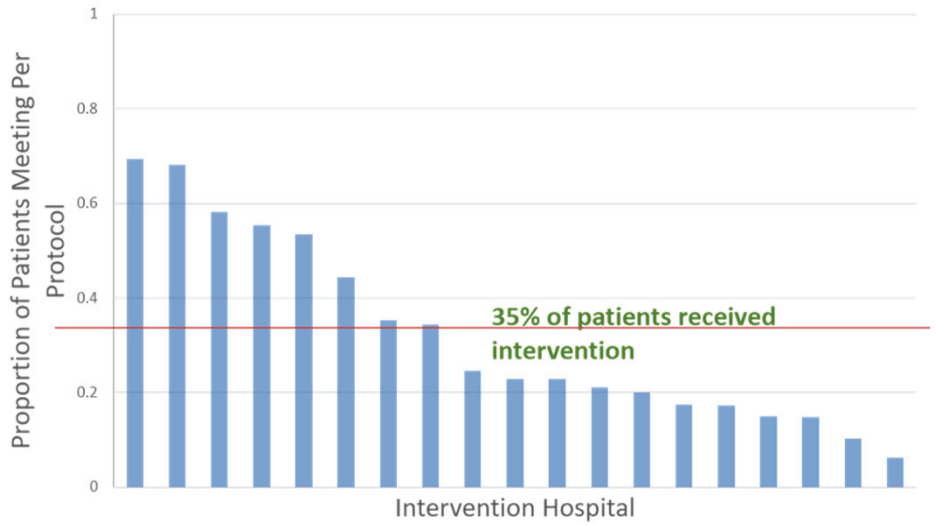
Duncan et al: Randomized Pragmatic Trial of Stroke Transitional Care The COMPASS Study. Circ Qual Cardiovasc Outcomes 2020; Volume 13, Issue 6, June 2020;: e006285. https://doi.org/10.1161/CIRCOUTCOMES.119.006285

Statistical Analyses

- Primary analysis: Intention-to-treat (ITT) compared intervention versus usual care using mixed linear/logistic regression with random effect for hospital
- Adjustment for age, sex, race, stroke severity (NIHSS), and diagnosis
- Inverse probability of ascertainment weights accounted for outcome nonresponse

Duncan et al: Randomized Pragmatic Trial of Stroke Transitional Care The COMPASS Study. Circ Qual Cardiovasc Outcomes 2020; Volume 13, Issue 6, June 2020;: e006285. https://doi.org/10.1161/CIRCOUTCOMES.119.006285

Variable Receipt of Care Model Across Hospitals: Implementation Analysis



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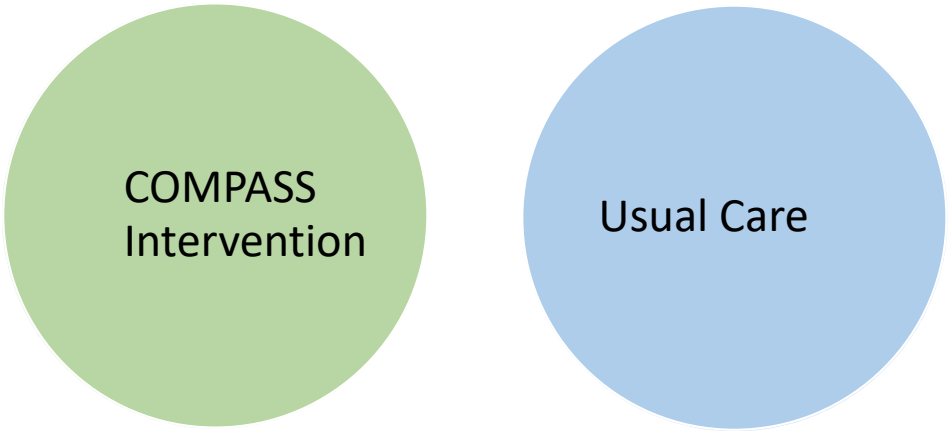
- **System-level barriers**: consistent staffing, competing priorities, did not enroll or schedule patients prior to acute care hospital discharge.
- Only 58% of hospitals delivered the intervention uninterrupted

Primary Results: Intention to Treat (ITT)

- All of the patients in the “COMPASS Intervention” group compared to all of the patients in the “Usual Care” group.



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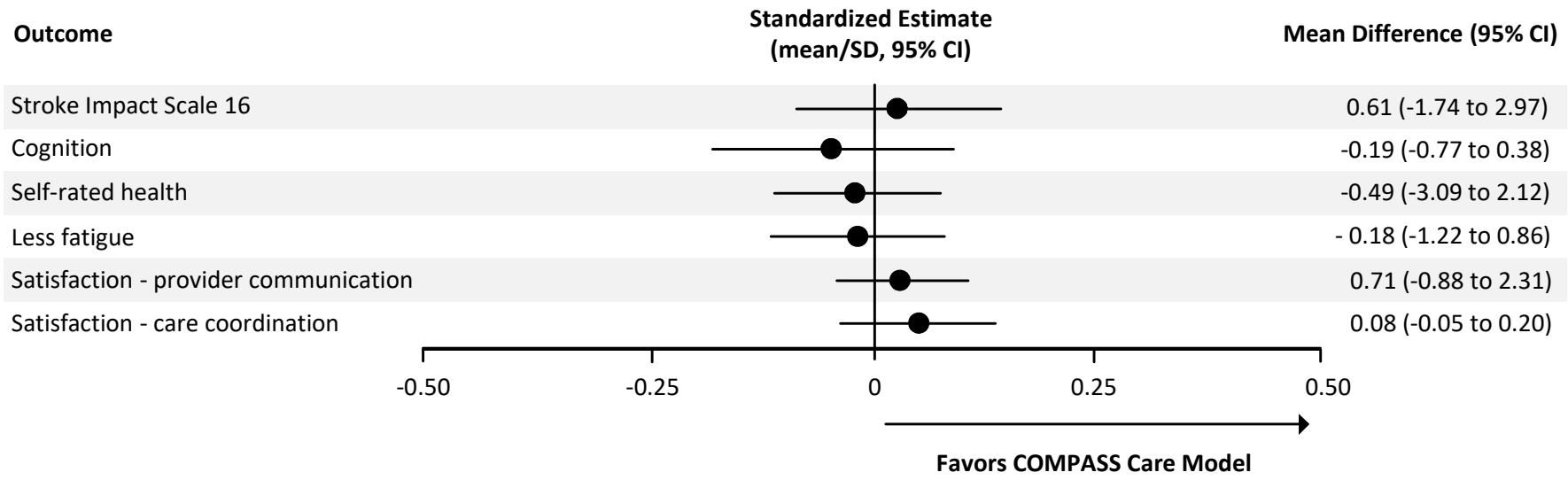
Results: SIS-16

Outcome	Intervention	Usual Care	Adjusted ITT Treatment Effect (95% CI)
Functional status (SIS-16)	80.6 ± 21.1	79.9 ± 21.4	0.61 (-1.74 to 2.97)

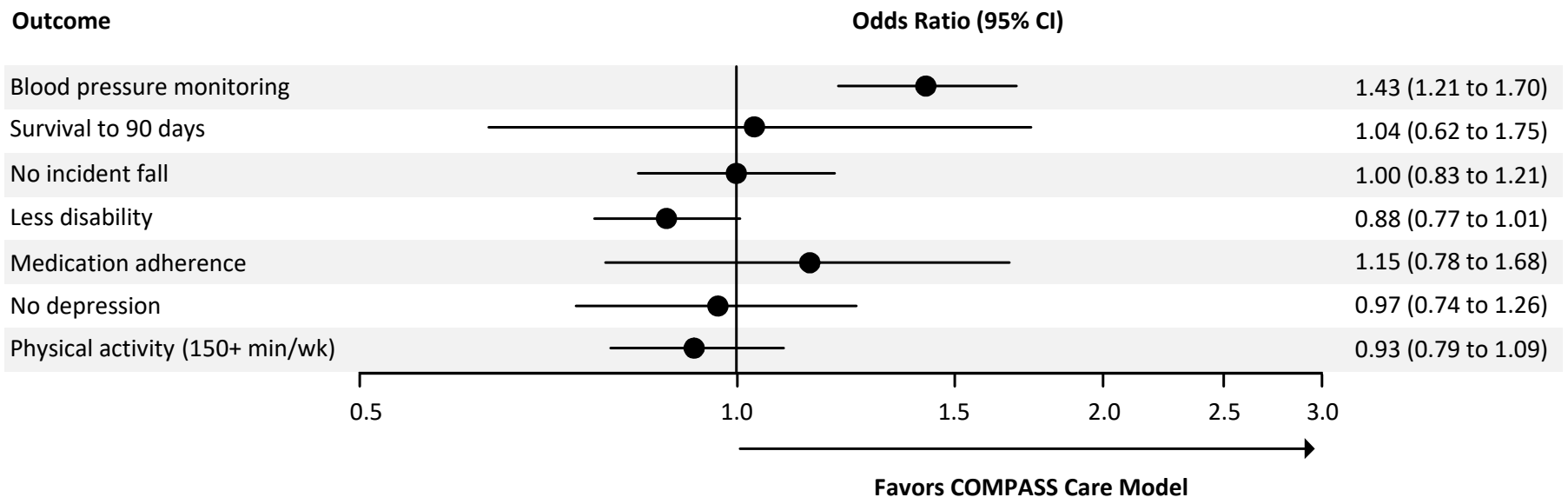
Linear mixed model included hospital-specific random effect and was adjusted for randomization stratum, stroke diagnosis, NIHSS score, age, and race. Inverse probability weights accounted for outcome nonresponse.

Duncan et al: Randomized Pragmatic Trial of Stroke Transitional Care The COMPASS Study. Circ Qual Cardiovasc Outcomes 2020;Volume 13, Issue 6, June 2020;: e006285. https://doi.org/10.1161/CIRCOUTCOMES.119.006285

Results: ITT Secondary Outcomes: Continuous



Results: ITT Secondary Outcomes Categorical



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Readmissions Analysis with Claims

Medicare linkage to COMPASS participants

Bushnell, et al. Does Receipt of COMprehensive Post-Acute Stroke Services (COMPASS) Transitional Care Reduce Readmission Rates? ESO/WSO 2020; presented November 6, 2020.

Baseline Characteristics of Hospitals and Patients by Study Arm for those with baseline CMS Medicare FFS Coverage		
	Treatment Arm	
Characteristic	**INV (N=1070)**	**UC (N=1196)**
Hospitals		
No. of hospital units	19	20
Joint Commission Primary Certified Stroke Center - n (%)	868 (81.1)	910 (76.1)
Academic affiliation - n (%)	276 (25.8)	519 (43.4)
Urban-rural classification – n (%)		
Metro	591 (55.2)	1012 (84.6)
Micro	355 (33.2)	176 (14.7)
Rural	124 (11.6)	8 (0.7)
Patients		
Age mean years (SD)	74.9 (10.15)	73.9 (10.49)
Female sex - n (%)	525 (49.1)	654 (54.7)
White race - n (%)	912 (85.6)	908 (76.6)
Stroke – n (%)	649 (60.7)	702 (58.7)
TIA – n (%)	421 (39.4)	494 (41.3)
NIHSS Score(median (IQR))	1 (0-3)	1 (0-3)
Medical history & comorbidity - n (%)		
Hypertension	850 (79.4)	948 (79.3)
Prior Stroke	229 (21.4)	278 (23.2)
Prior TIA	132 (12.3)	148 (12.4)
Atrial Fibrillation or flutter	204 (19.1)	217 (18.1)
Heart Failure	99 (9.3)	131 (11.0)
Coronary Artery Disease	267 (25.0)	281 (23.5)
Depression	97 (9.1)	149 (12.5)
Smoking in past year	143 (13.4)	178 (14.9)

Readmissions and Mortality
(Medicare Fee-for-service, Intention-to-treat Analysis)

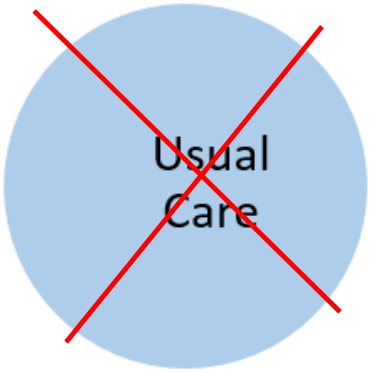
	Intervention %	Usual Care %	Intervention Effect (95% CI)
30d All-cause readmission	11.6	9.6	**OR:** 1.32 (0.88-1.97)
90d All-cause readmission	22.2	19.8	**OR:** 1.20 (0.90-1.59)
1yr All-cause readmissions	38.7	36.3	**HR:** 1.05 (0.91-1.22)
1yr Stroke readmissions	6.7	5.0	**HR:** 1.26 (0.90-1.77)
1yr Mortality	8.5	8.8	**HR:** 0.93 (0.70-1.23)

- Overall, one fifth were readmitted at 90 days, and over one third were readmitted within a year.
- 30d risk of readmission was similar between intervention and usual care patients

Bushnell, et al. Does Receipt of COMprehensive Post-Acute Stroke Services (COMPASS) Transitional Care Reduce Readmission Rates? ESO/WSO 2020; presented November 6, 2020.

Results: Within Intervention Hospitals

- We looked at just the COMPASS intervention group and compared the patients who GOT the intervention with the patients who did NOT GET the intervention.



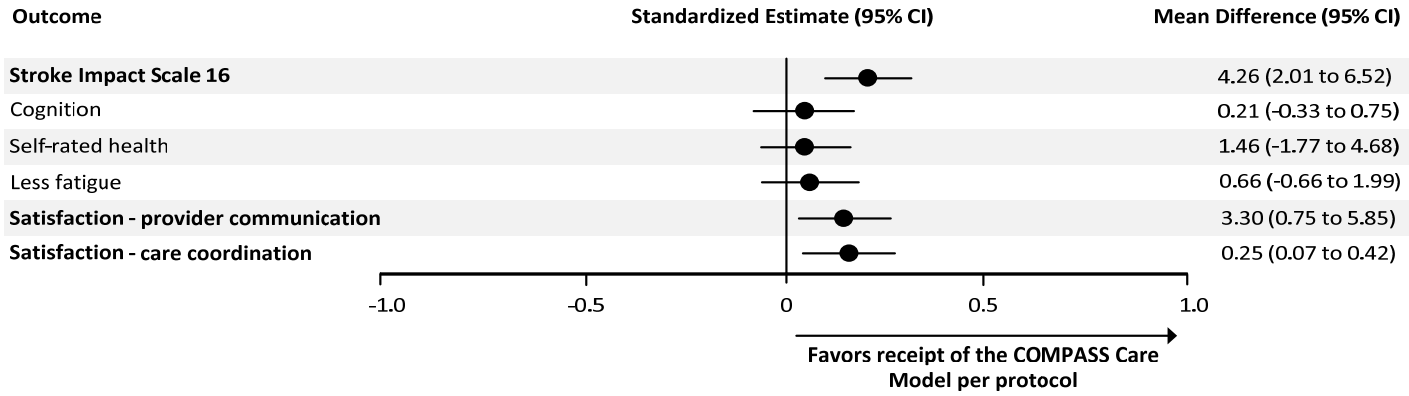
Duncan et al. A Randomized Pragmatic Trial of Stroke Transitional Care: The COMPASS Study (under review)

Post-Hoc Within Hospital Treatment Effect Rationale

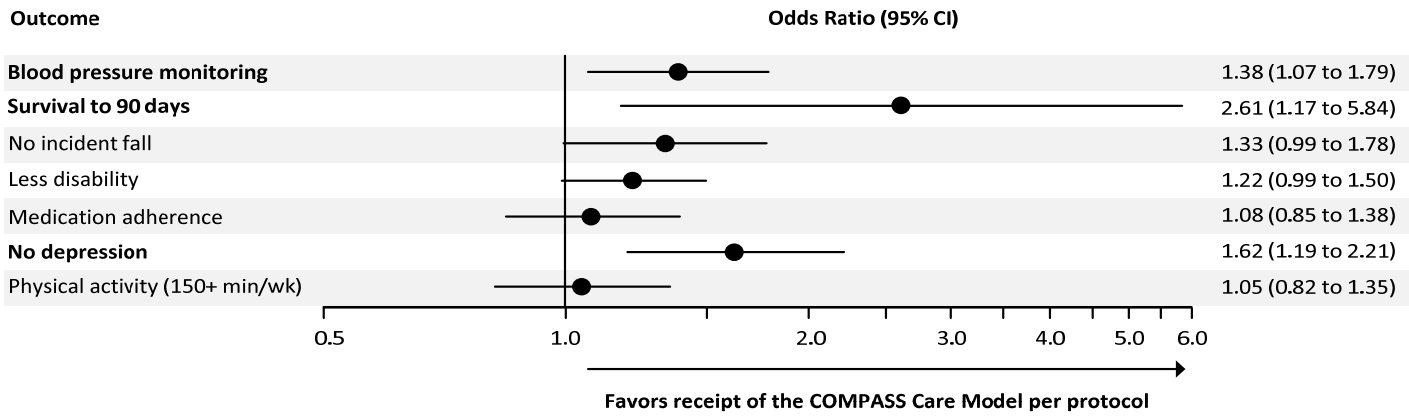
- Per protocol analysis assumes usual care hospitals offered little post-acute care. Yet usual care was heterogeneous and some hospitals may deliver TC
- Therefore, we estimated the average within-hospital treatment effect compared outcomes treated versus non-treated patients
- Adjustment for confounding using propensity scores

Duncan et al: Randomized Pragmatic Trial of Stroke Transitional Care The COMPASS Study. Circ Qual Cardiovasc Outcomes 2020; Volume 13, Issue 6, June 2020;: e006285. https://doi.org/10.1161/CIRCOUTCOMES.119.006285

Results: Post-Hoc within hospital treatment effects



B Other Secondary Outcomes



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Major Differences Between Functional Status and Readmissions Outcomes/Analyses

Functional Status at 90 days

- Dependent on receiving intervention AND capturing outcome
- Similar outcome capture in intervention and usual care groups, but 40% lost to f/u
- Clear linear relationship between discharge and outcome
- Unclear what services were utilized in each group

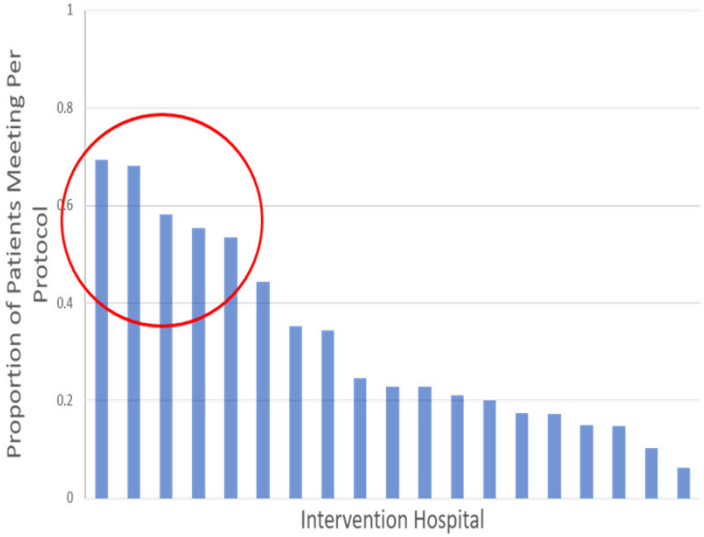
Readmissions at 90 days

- Analysis cohort based on Medicare beneficiaries and successful linking between COMPASS and claims
- Outcomes based on claims and “capture” rate is 100%
- Outcome could occur before the exposure to the intervention, limiting cause and effect conclusion
- Documentation of health care utilization and ambulatory visits

COMPASS: Lessons from Implementation

Pragmatic trials and tribulations

Characteristics of Successful Sites: Implementation Analysis



- **Commitment/Champion for the Model in Acute Care**
- Vision
- System Resources
- Flexibility/Collaboration
- Location of Practice (**Neurology Clinics**)
- New Standard of Care

Lutz et al. Implementation of a Transitional Care Model for Stroke: Perspectives from Frontline Clinicians, Administrators, and COMPASS-TC Implementation Staff. *The Gerontologist* 2020; Published online April 20 Doi.org/10.1093/geront/gnaa029

Gesell *et al. BMC Health Services Research* (2019) 19:978
https://doi.org/10.1186/s12913-019-4771-0

BMC Health Services Research

RESEARCH ARTICLE Open Access

Implementation of a billable transitional care model for stroke patients: the COMPASS study

Sabina B. Gesell[1*], Cheryl D. Bushnell[2], Sara B. Jones[3], Sylvia W. Coleman[2], Samantha M. Levy[4], James G. Xenakis[5], Barbara J. Lutz[6], Janet Prvu Bettger[7], Janet Freburger[8], Jacqueline R. Halladay[5], Anna M. Johnson[3], Anna M. Kucharska-Newton[3,9], Laurie H. Mettam[3], Amy M. Pastva[7], Matthew A. Psioda[4], Meghan D. Radman[2], Wayne D. Rosamond[3], Mysha E. Sissine[2], Joanne Halls[10] and Pamela W. Duncan[2]

Characteristics of patients who attended COMPASS clinic visit within 14 days

Characteristic	Odds Ratio	95% CI
Geographic area of residence		
Urban vs Non-urban	0.72	0.50-1.03
Diagnosis of stroke vs TIA	1.64	1.29-2.08
Prior History of Stroke/TIA	0.76	0.60-0.97
Distance to clinic		
< 15 miles	1.00	(reference)
15-29 miles	0.85	0.66-1.00
30-59 miles	0.71	0.50-1.00
60+ miles	0.33`	0.20-054

Gesell, et al. BMC Health Services Research 2019;19:978

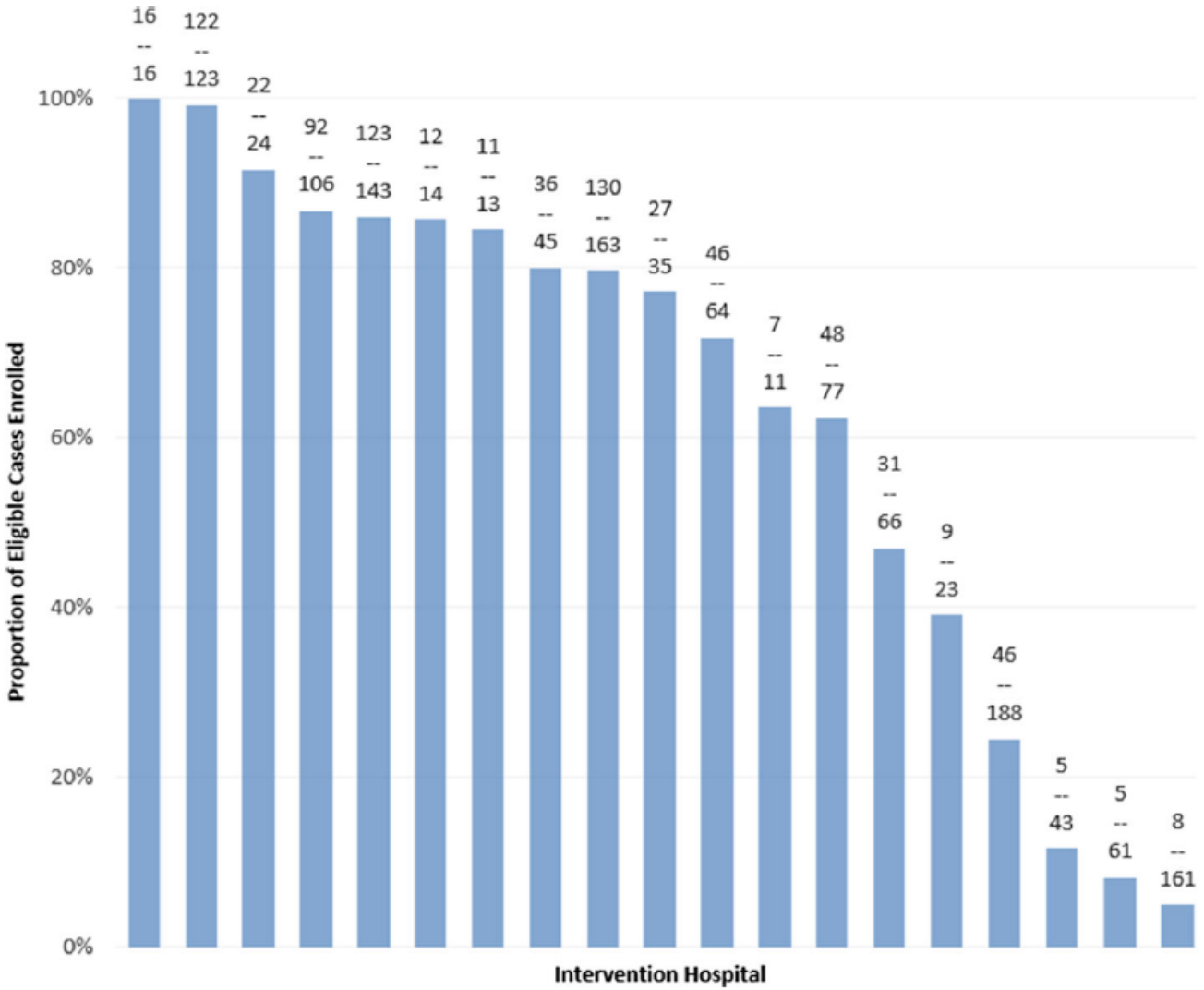


Fig. 3 Hospital-Specific Case Ascertainment. Bars represent the proportion of eligible patients enrolled at individual hospitals over the 4 months of case ascertainment audits. The numbers of patients enrolled out of all eligible patients during the audit period are indicated above each bar

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Transitional Care Management Uptake in COMPASS Hospitals

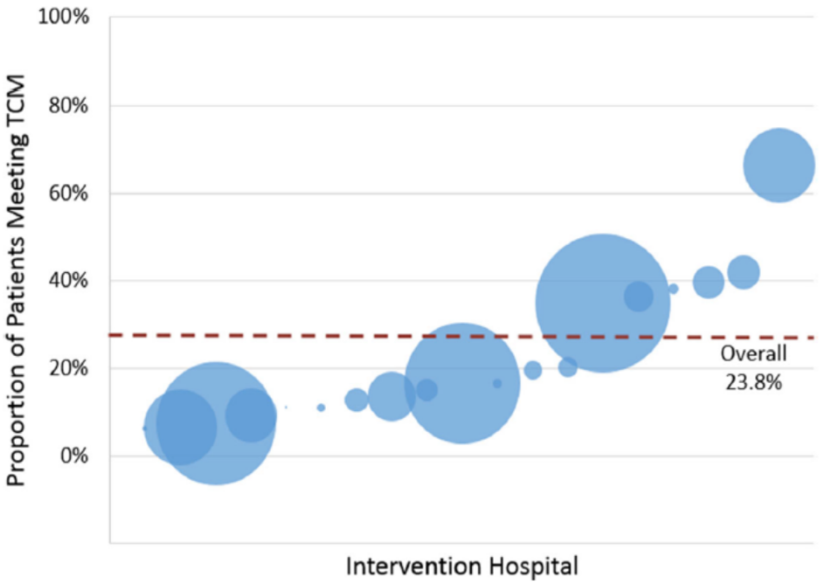


Fig. 4 Proportion of Patients Meeting Transitional Care Management (TCM) Criteria by Hospital. Circles represent the 19 hospitals that adopted the intervention and are scaled to represent the total number of enrolled participants. Values on the y-axis represent the proportion of patients that met TCM billing criteria

Gesell, et al. BMC Health Services Research 2019;19:978

COMPASS Trial in Transitional Stroke Care Navigating Towards True North

Matt Reeves Editorial

"Despite its failure to show a significant change in patient outcomes, the COMPASS study represents an important landmark in the development of large-scale transition-relation intervention work in acute stroke. The study has set the benchmark for how to prepare and study the implementation of complex interventions….

"The COMPASS study demonstrates that it is time to start addressing the problem of stroke transition with greater seriousness—the problem is complex and the challenges great, but the need of the patient with stroke and caregiver has never been greater."

Reeves. Circ Cardiovasc Qual Outcomes 2020

How does transitional care fit with StrokeNet trials?

Focus on acute and prevention trials

MOST

- What happens to patients enrolled in MOST in the early post-discharge transition?
- How many MOST patients are seen for clinical follow-up within the first 14 days?
- What impact would this transitional clinical care have on the primary and secondary outcomes?
- What proportion of MOST patients received rehabilitation?

ARCADIA

- Does transitional care impact enrollment?
- Does the quality of transitional care impact the primary outcome of stroke prevention?
- Does the quality of secondary prevention long term impact the primary outcome?

How to account for transitional care services in multi-center phase III trials

- Link to Claims
  - Lose a large proportion of patients and need to account for specific coverage for beneficiaries
- Link to Electronic Health Records
  - Increasingly used in pragmatic trials (ADAPTABLE)
  - Dependent on quality of documentation
  - Clinical Research Networks using this method (PCORNet and BP Control Laboratory)
- Patient reported outcomes via EHR portals, texting (Twillio), REDCap
- REDCap is now integrated with Epic through SMART on FIHR

Long term follow-up of chronic conditions: Link to clinical trials or interventions?

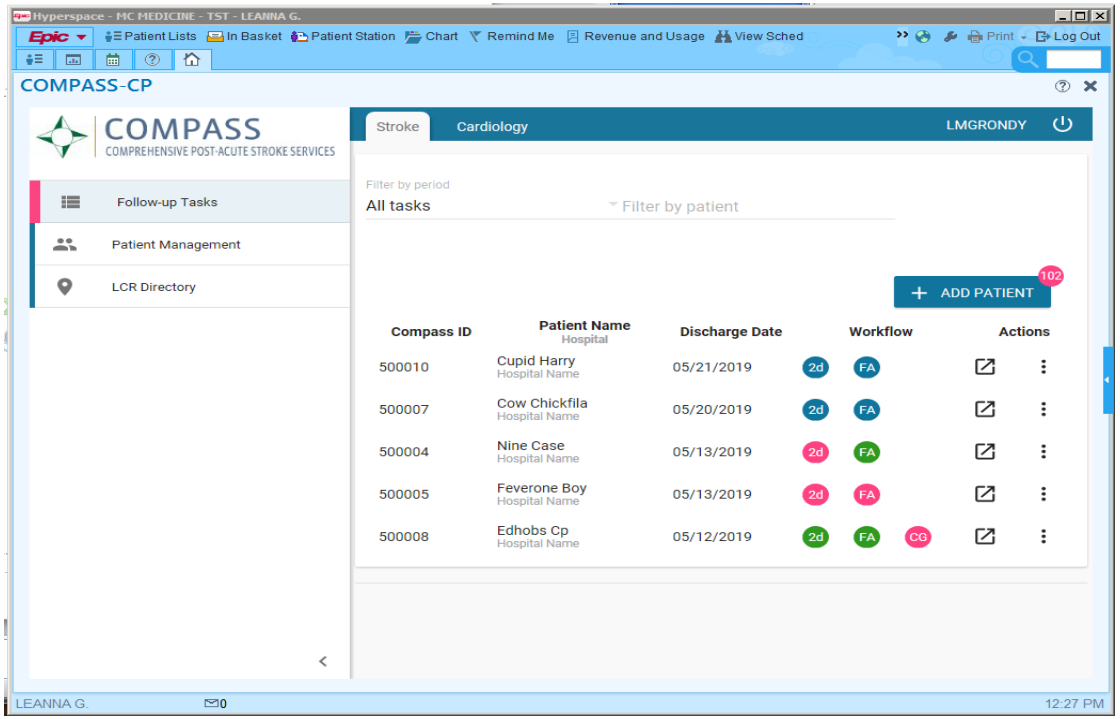
- **CMS Chronic Care Management coding**
- Requirements CPT 99490:
  - Minimum 20 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month in patients with:
    - multiple chronic conditions expected to last at least 12 months
    - Chronic conditions place patient at significant risk of death, acute exacerbation/decompensation, or functional decline
    - Comprehensive care plan established, implemented, revised, or monitored
- CPT 99487:
  - Same conditions as above
  - Moderate or high complexity medical decision making
  - 60 minutes of clinical staff time directed by physician or other qualified health care professional, per calendar month
- Patients sign consent for participation and have a co-pay

Next steps for COMPASS

Focused on secondary prevention

Advancements since the pragmatic trial

- COMPASS-CP has been integrated into Epic and the clinical workflow
  - Identifies patients with stroke ICD-10 codes in the hospital or ED



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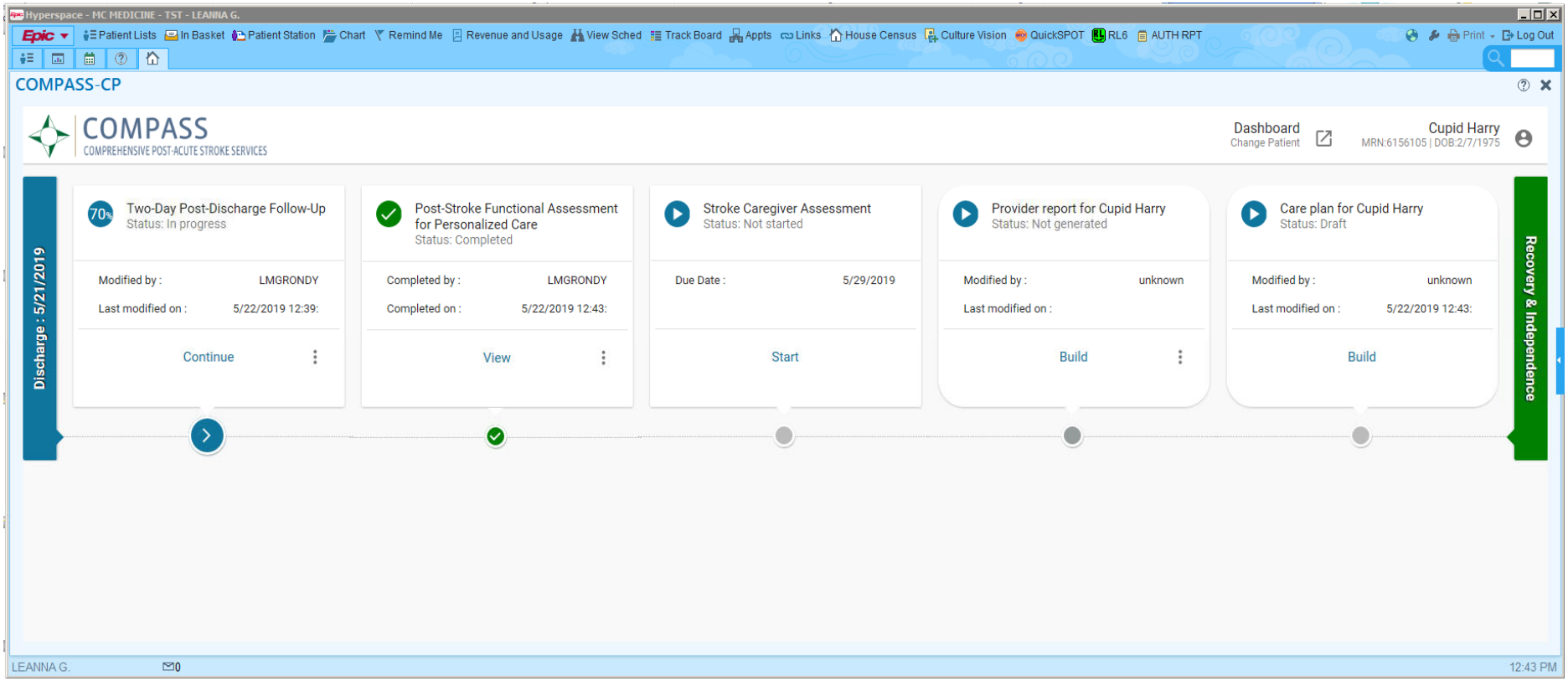
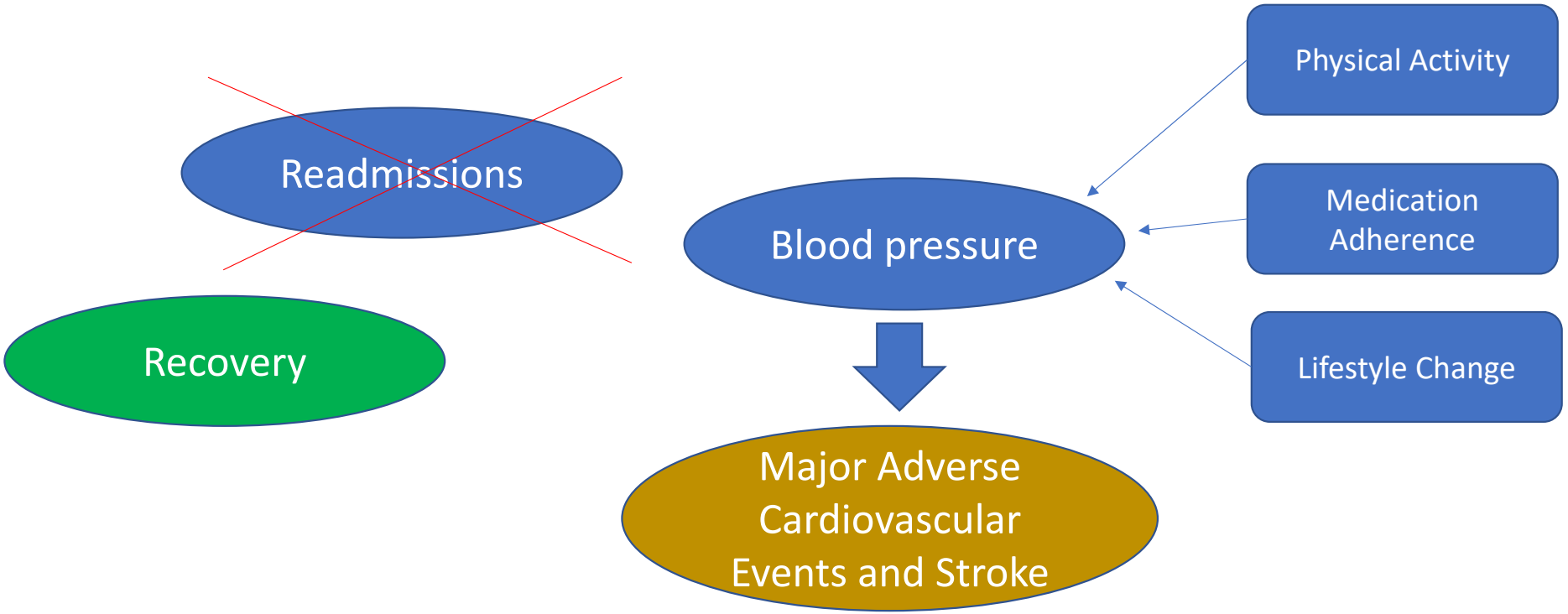
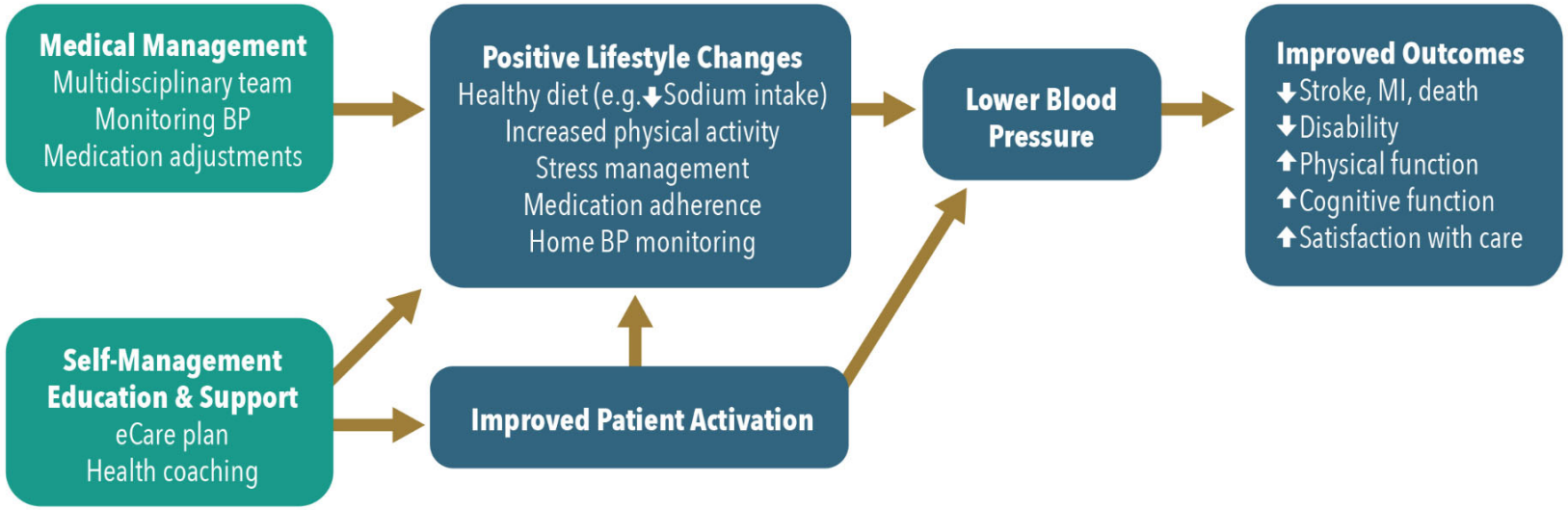
Dashboard and clinical workflow



What outcome is most relevant for stroke transitional care trials?



Conceptual model for BP management post-stroke



Take Home Messages

- Stroke transitional care is challenging and new models are not easily adopted
- More trials are needed to determine:

  1) the components of the ideal stroke transitional care model and

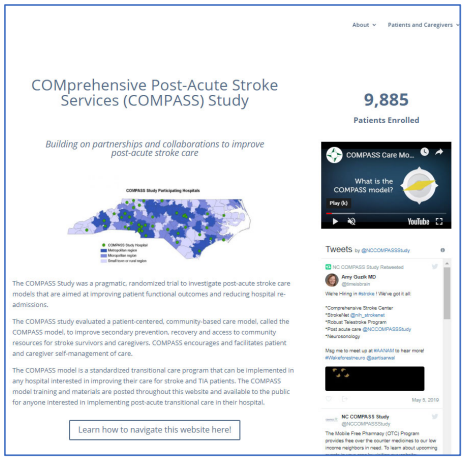
  2) which aspects of recovery and secondary prevention should include the post-acute transition
- Leaders in clinical trial design and clinical care can identify the appropriate outcomes that are achievable, and account for the implementation challenges for new models
- Transitional care could be aligned with a variety of stroke clinical trials (or vice versa) to reduce heterogeneity in trial follow-up

COMPASS Study Website and Resources

https://www.nccompass-study.org/

- Numerous resources are now freely available on the website:
  - Patient Educational Materials
  - Community Resource Directory
  - Training videos and Materials

- For full website tutorials contact:
  - Meghan Radman
  - 336-713-4367
  - mradman@wakehealth.edu



Team, Hospitals and Communities

A multidisciplinary team with a shared vision, respectful of diversity, accountable, committed to patient and community engagement, perseverance and innovation