

Technical Abstract

Stroke mortality is 20-40% higher in North Carolina (NC) than in the overall United States. After discharge, stroke patients are at high risk for complications. Although a model of stroke post-care (early supported discharge) exists in Europe and Canada, it has not been adapted for and tested in the US, although our patients and stakeholders attest that post-acute care does not meet their needs. Transitional care services from hospital to home are now reimbursed by Centers for Medicaid and Medicare Services (CMS), but only for 30 days after discharge. We propose a pragmatic cluster randomized trial of 50 NC hospitals to determine the effectiveness of **Comprehensive post-acute stroke services (COMPASS)**, a patient-centered intervention uniting transitional care management services and elements of early supported discharge in stroke patients discharged directly home.

We will build on the successful North Carolina Stroke Care Collaborative (NCSCC) registry, a prospective stroke database in which 51 (of 113) hospitals in NC enroll patients. In preparation for COMPASS, we engaged these hospitals via webinars; they were enthusiastic about the COMPASS model. Over 80% of NCSCC hospitals have provided letters of support for participation.

The main question of this *pragmatic* trial is: Does implementation of COMPASS for all stroke patients discharged directly home improve functional outcomes as measured by the Stroke Impact Scale-16 (SIS-16) at 90 days post stroke? **The primary aim is to:** compare the COMPASS model versus usual care on stroke survivors' self-reported functional status at 90 days post-stroke. **The secondary aims are to determine if the COMPASS model:** 1) reduces caregiver strain (Modified Caregiver Strain Index, MCSI) 90 days post-stroke; 2) reduces all-cause 30- and 90-day readmissions; 3) affects mortality, health care use, continuity of care, and use of transitional care management billing codes, using claims data up to *one year* after stroke hospitalization; and 4) differentially affects primary and secondary outcomes by race, sex, age, stroke severity, and insurance status. Patients over age 18 admitted to a NCSCC hospital with a diagnosis of ischemic or hemorrhagic stroke or transient ischemic attack and discharged from acute care hospitalization to home will be included (about 6,000 patients/year).

NCSCC participating hospitals will be randomized (stratified by stroke volume and primary stroke center status) to receive COMPASS or usual care (control group) in Phase 1. In Phase 2, usual care hospitals will cross over to COMPASS, while the early intervention hospitals sustain the intervention using hospital-based resources. The trial has three integrated **intervention components:** 1) COMPASS, which combines transitional care services provided by advanced practice providers (APPs) and early supported discharge services coordinated by the APPs; 2) **COMPASS-funded post-acute care coordinators** who will engage patient and stakeholder communities to improve post-acute stroke comprehensive stroke services; and 3) development of a stroke metrics score card for NCSCC hospitals and primary care providers. Well-trained APPs and coordinators will have access to online learning and ongoing support/consultation from WFBH personnel and board-certified vascular neurologists.

We will assess 90-day and 1-year outcomes. 90-day outcomes will be assessed by telephone surveyors blinded to patient's group assignment. Patients will be informed about COMPASS in the hospital, and can opt out of 90-day phone follow-up at that time. Those who agree to be surveyed will be asked to provide informed consent at 90 day phone call to collect outcomes data and link their data to claims. **The primary outcome** will be patient-reported functional status (SIS-16). Secondary outcomes at 90 days include caregiver stress (MCSI); unadjusted 30- and 90-day all-cause readmissions captured via claims data; cognitive status, medication adherence, blood pressure management, depression, continuity of care, and use of community resources. One year post-stroke outcomes ascertained via claims data will include: mortality, recurrent stroke, use of transitional care management billing codes, proportion of patients with 7- and 14-day post-stroke hospitalization, physician follow-up, and health care use (emergency department visits, number of hospital admissions and inpatient days, and admissions to skilled nursing and inpatient rehabilitation facilities).

As the primary endpoint is a continuous variable, we will use a mixed model (including fixed and random effects) to compare COMPASS to control. The intraclass correlation, ρ , obtained from data collected at eligible NCSCC hospitals, is estimated as 0.036 based on preliminary data. Conservatively doubling this to 0.072 there is 90% power to detect a 0.259 standard deviation difference between COMPASS and control groups for the outcomes of interest. Additionally, there is 90% power to detect a 0.305 SD difference in any subgroup at least 20% of the overall sample.

This proposal is led by three highly experienced researchers as co-principal investigators. The team includes expertise in stroke care, large clinical trials, biostatistics, managing clinical registries, survey and acquisition of patient or proxy-reported outcomes, community-based practice improvement, building community coalitions to reduce readmissions, claims analyses, registry management, translating evidence into practice with large multi-site collaboratives, and engaging patients and stakeholders in research.

The planning phase of this project has been guided by our Patient and Stakeholder Engagement Committee. Each community will form a coalition to advise and support implementation of COMPASS, provide feedback to the team, and help create sustainability. If the COMPASS model shows effectiveness, our patients and stakeholders will be key partners to disseminate and implement COMPASS throughout the state and beyond.