Abstract

Background: Transitional care (TC) for the management of complex chronic conditions such as stroke requires multidomain interventions after hospital discharge (e.g., medication management, blood pressure (BP) control, social determinates, physical function, risk factor management). The Centers for Medicare and Medicaid Services (CMS) has established reimbursement models for TC management (TCM), and the scientific community is advocating for pragmatic trials to evaluate its uptake and effectiveness.

Objectives: The objective of the Comprehensive Post-Acute Stroke Services (COMPASS) study was to evaluate the real-world comparative effectiveness of a comprehensive, post-acute stroke TC model (COMPASS-TC) with CMS reimbursement to a usual care comparator with regard to 90-day functional status and other patient-reported and claims-based outcomes.

Methods: The COMPASS study was a pragmatic cluster-randomized trial. The COMPASS-TC intervention was patient-centered and assessed social and functional determinates of health to inform individualized care plans for secondary prevention and recovery, referrals to needed services and community based resources. It was designed to be consistent with the CMS requirements for reimbursements of TC for complex patients. Forty North Carolina (NC) hospital units were randomized 1:1 to the COMPASS-TC intervention (INV) or to maintain their usual care (UC), stratified by 4 levels defined by annual stroke patient volume and stroke center certification. In Phase 1, hospital staff from 39 units enrolled 6024 adult stroke and transient ischemic attack patients discharged home between 2016 and 2018. In Phase 2, hospitals randomized to UC in Phase 1 crossed over to receive COMPASS-TC, and hospitals randomized to INV sustained COMPASS-TC with their own resources. In Phase 2, 31 sites enrolled 4,066 participants. Ninety-day outcomes were evaluated by blinded telephone interviewers. The primary outcome was functional status (Stroke Impact Scale [SIS]-16); secondary outcomes were mortality, disability, medication adherence, depression, cognition, self-rated health, fatigue, care satisfaction, home BP monitoring, falls, and caregiver strain. The primary analyses were intention-to-treat with treatment effects estimated from generalized linear mixed models that included inverse probability weights to account for missing patient-reported outcomes

(PROs). Additional secondary outcomes were identified from claims using linkages to CMS Medicare fee-for-service (FFS; N=2262), NC Medicaid (N=382) and BCBSNC (N=277). Claims outcomes included readmissions (at 30 days, 90 days and 1 year), mortality, continuity of care (e.g., ambulatory care visits), TCM billing, skilled nursing and inpatient rehabilitation facility (SNF/IRF) use, and emergency department (ED) visits. Claims analyses were performed separately according to payer type. All analyses were adjusted for age, race, stroke severity, stroke type and history of stroke, as well as additional covariates considered in sensitivity analyses. Missing data were addressed through the use of multiple imputation procedures. Finally, we evaluated the sustainability of effectiveness in exploratory analyses using Bayesian Hierarchical Models to estimate the effect of phase.

Results: In Phase 1 intervention hospitals, 58% had uninterrupted intervention delivery. Only 35% patients at intervention hospitals attended a COMPASS clinic visit. The primary outcome was measured for 59% of patients and was not significantly influenced by the intervention. Mean SIS-16 (±SD) was 80.6±21.1 in INV versus 79.9±21.4 in UC. Home BP monitoring was self-reported by 72% of INV patients versus 64% of UC patients (adjusted odds ratio (OR), 1.43 [95% CI, 1.21, 1.70]). No other secondary PROs differed by arm. Within the FFS population, COMPASS-TC was associated with higher rates of ambulatory care visits (hazard ratio [HR]= 95% CI) and utilization of TCM billing (OR= 95% CI) compared with UC. No differences were present for readmissions, mortality, SNF admissions, or ED visits. The proportion of patients that received timely ambulatory care (i.e., at least one ambulatory care visit within 30 days) was substantially smaller in the Medicaid population (~12%) compared with FFS and BCBSNC (~89% and 78%, respectively). Similar to FFS results, there were no differences in all-cause readmissions, stroke readmissions, mortality, SNF/IRF admissions or ED visits between the INV and the UC groups among Medicaid or BSBCNC patients or in the Phase 2 Sustainability analysis. Of the 20 sites randomized to the COMPASS intervention in Phase 1, fifteen sustained the intervention in Phase 2; five opted not to transition over to the sustainability phase. Functional status and home BP monitoring remained stable overall between Phase 1 and Phase 2, both in adjusted analysis and in sensitivity analysis, suggesting that the effectiveness of the intervention was maintained when hospitals sustained the intervention on their own without

COMPASS study support. Functional status (SIS-16 score) remained stable between Phase 1 (mean 80.8, SD 20.8) and Phase 2 (mean 82.0, SD 19.8; mean difference 1.00; 95% CI -0.85, 2.93). Home BP monitoring remained stable between Phase 1 (67.9%) and Phase 2 (70.9%; OR 0.92; 95% CI 0.64, 1.20).

Conclusions: Although designed according to the best available evidence with input from various stakeholders and consistent with CMS TCM billing policies, COMPASS-TC was not consistently incorporated into real-world care. We found no significant effect of the intervention on self-reported functional status at 90 days post-discharge. Findings may reflect the low intervention uptake (35% in Phase 1) or indicate that a single TC visit was not sufficient to impact long-term healthcare utilization. Within the FFS population, COMPASS-TC was associated with significantly higher rates of ambulatory care visits and TCM billing compared with UC. There were no differences in other claims-based outcomes between INV and UC groups, among payer types, or in the Sustainability analysis.

Limitations: The pragmatism of this trial offered challenges. First, case ascertainment was incomplete. However, there was no evidence of selection bias by age, race, sex, stroke type, or severity. Second, the low proportion of patients that received the intervention limited power of the prespecified analyses. Third, outcome ascertainment was 59% and also lowered power to detect an effect.

Registration URL: https://www.clinicaltrials.gov; Unique identifier: NCT02588664.