

C3FIT (Coordinated, Collaborative, Comprehensive, Family-based, Integrated, and Technology-enabled Care):

A Pragmatic Randomized Trial for Stroke Care Delivery to Improve Patient, Caregiver, and Family Care

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BACKGROUND

- Patients recovering from stroke pass through **four nodes of care**:
 - Acute care
 - Post-acute in-hospital care
 - Subacute care (inpatient rehab, extended stay, etc.)
 - Chronic care
- Current Standard of Care:** Joint-Commission-certified Comprehensive and Primary Stroke Care focused on acute and in-hospital care
- Overarching goal of C3FIT:** To assess if the Integrated Stroke Practice Unit (ISPU), a novel, technology-enabled, coordination of care spanning all four nodes of care can improve outcomes at one year

METHODS

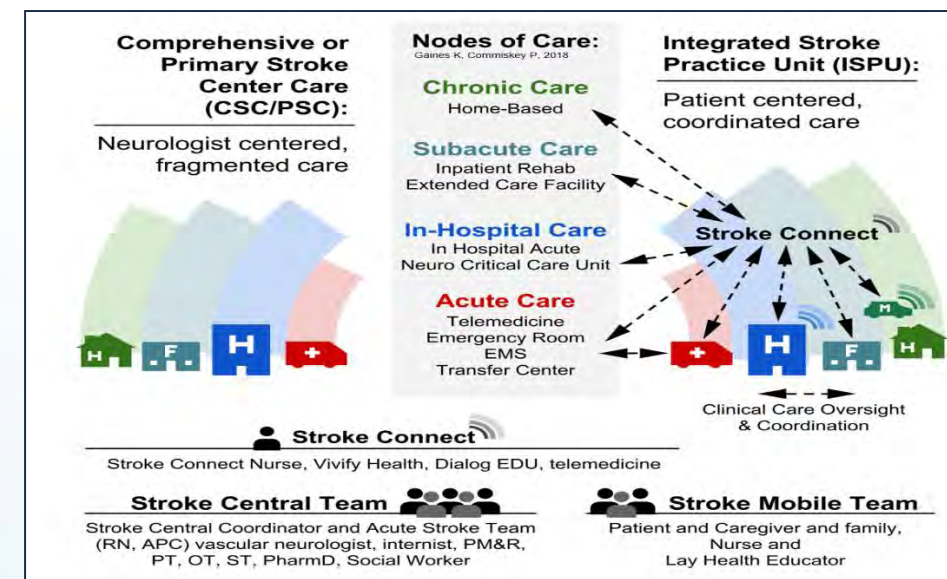
Design:

- A cluster randomized trial of 18 CSC/PSC-certified clinical sites
 - >9 sites randomized to manage patients using standard CPC care
 - >9 sites randomize to manage patients using coordinated ISPU care
- Randomization of sites stratified by geographic region and size
- Each site to recruit/follow: ~100 stroke patients
- Total sample size: ~1,800 stroke patients

COMPARATOR ARM DIFFERENCES

Item	Comprehensive Stroke Center (CSC) Model	Integrated Stroke Practice Unit (ISPU) Model
Time Focus	Acute care	Continuum of care for 1 year
Collaboration Mechanism	Monthly Stroke Committee	Stroke Central Daily interdisciplinary rounds
Goals	Process compliance	Patient-centered QOL Patient-centered functional outcome
Measurement	Performance measures	Functional outcome
Geography	Hospital-based Post hospital clinic Home Health Agency	Stroke Mobile Hospital and home based care delivery
Focus Of Modification	Care providers	Engagement of patient and family and/or caregiver
Key Post-Hospital Follow-Up Mechanism	Clinic	Home
Patient-centered Outcomes	No	Yes
Family/Home-based Care	No	Yes

METHODS



OUTCOMES

Type	Measure	Duration	Purpose
Primary	Stroke Impact Scale (SIS)	12 months	Quality of Life
	Modified Rankin Score (mRS)		Function
Secondary	SIS	3 & 6 months	Short-Term Function
	mRS		
	SIS	24 months	Durability of Intervention
	mRS		
Stroke Risk Factors	3, 6, & 12 months	Blood Pressure, Lipids, HBA1C, Smoking Status, BMI, Diet, Exercise	
Mortality, Recurrence, Readmission, Time at Home	3, 6, & 12 months	Mortality, Stroke Recurrence, Hospital Readmission, Time at Home Compared to At Institution	
Patient Depression and Caregiver Strain	3, 6, & 12 months	Severity of patient depression, strain on caregiver	

INCLUSION/EXCLUSION CRITERIA

Inclusion Criteria:

- Age 18+
- Clinical diagnosis as ischemic or hemorrhagic stroke
- English- or Spanish-speaking subjects
- Patient admitted within seven days of their index stroke event
- Patient discharged alive – not to hospice care
- Patient living at discharge within the geography of recruitment for that C3FIT site
- Pre-morbid mRS score of 0-1
- Patient and/or surrogate give informed consent to participate
- Patients who go to rehabilitation inpatient therapy (excludes hospice and outside geographic area of recruitment)
- Geographic proximity to hospital
- Pre-stroke mRS of 0 or 1

Exclusion Criteria:

- Patients not surviving to discharge
- TIA (even with demonstrable lesion on CT/MRI)
- Discharge admission to hospice
- Comorbidities anticipated to limit survival to less than 1 year

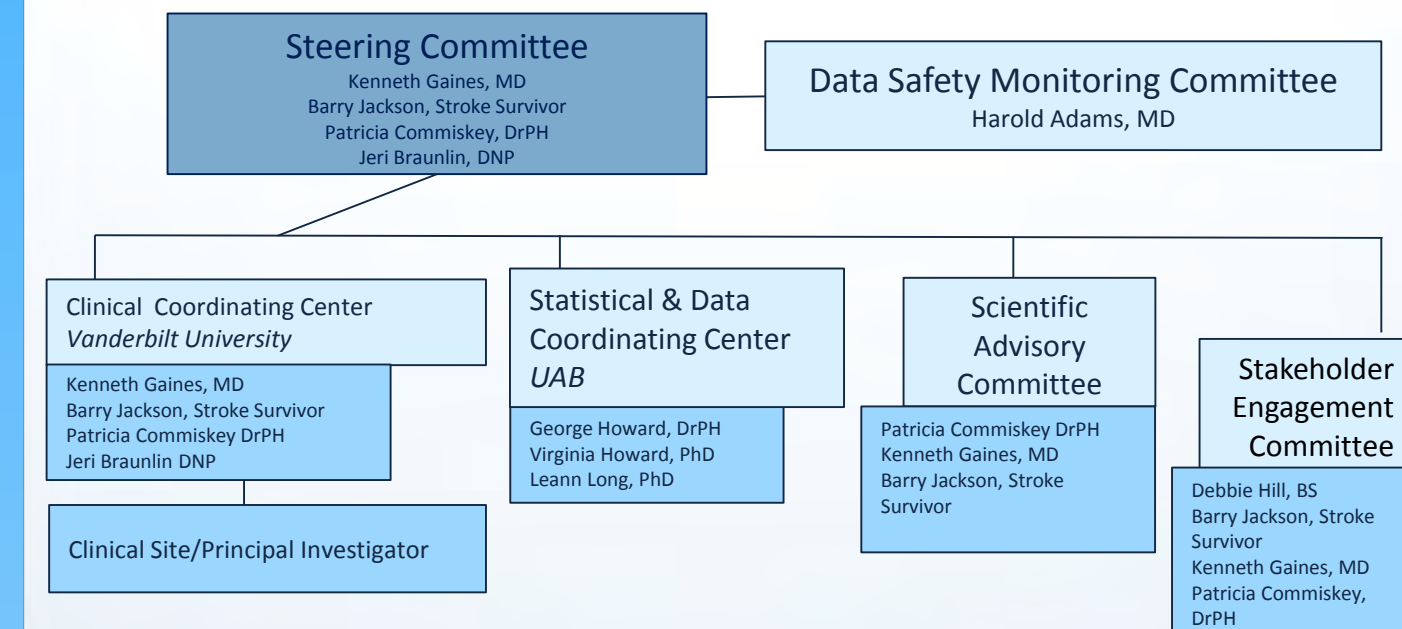
Statistical Considerations:

- Mixed model of Laird and Ware (hierarchical model)
- 90% power to detect treatment difference of 3.2 units on SIS

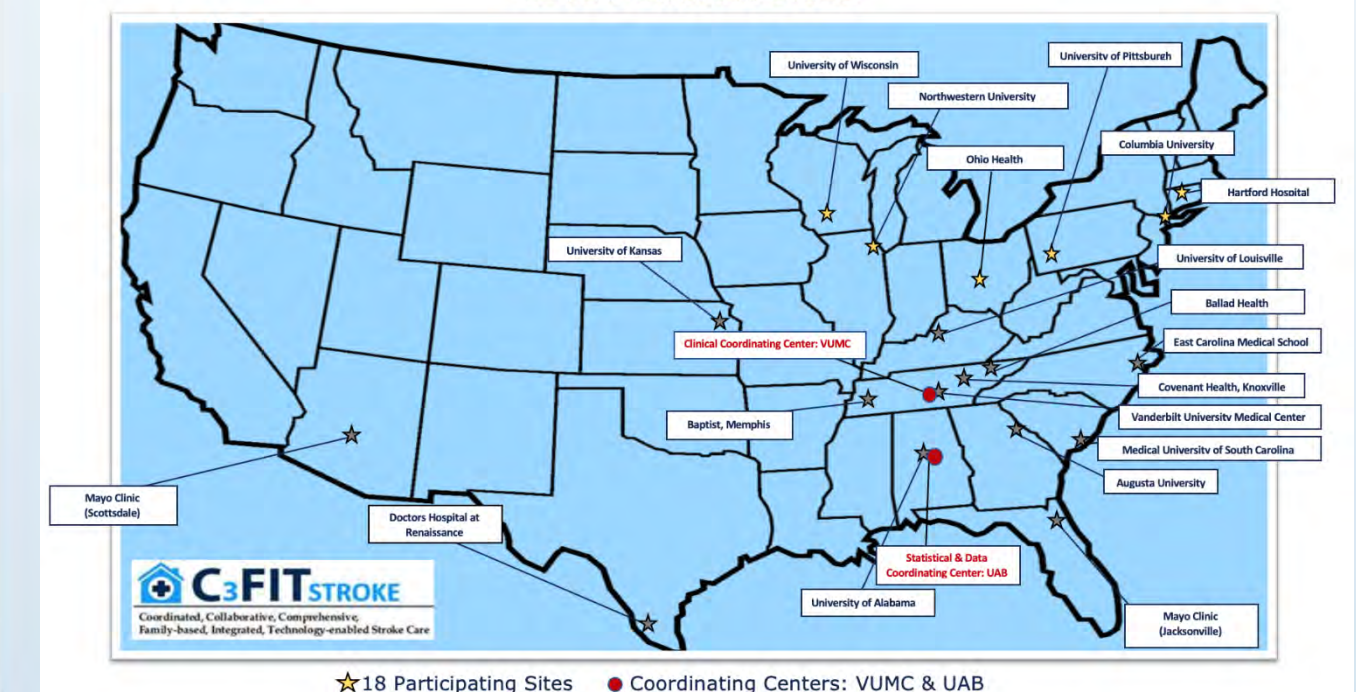
Timeline:

- Site training to begin September-October 2019
- Targeted enrollment to begin November 2019

C3FIT COMMITTEE STRUCTURE AND CLINICAL SITE MAP



C3FIT Clinical Sites



POTENTIAL BENEFITS FOR PATIENTS, CAREGIVERS, & ORGANIZATIONAL STAKEHOLDERS

Patients and Caregivers: Information gained through a comprehensive, integrated, family-focused delivery system.

- Access to results of C3FIT to inform their choices in health care.
- Potential for home care management in the ISPU arm, avoiding the stress, time, and travel costs for outpatient clinic visits.
- Having a team that monitors caregivers' stress levels and offers support.

Organizational Stakeholders: Access to high quality data to inform decisions regarding design and implementation of the most efficient and effective stroke delivery system.