Methods Papers

Randomized, Controlled Trial of an Intervention to Enable Stroke Survivors Throughout the Los Angeles County Safety Net to “Stay With the Guidelines”

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Background—Stroke is the leading cause of adult disability. Inpatient programs optimize secondary stroke prevention care at the time of hospital discharge, but such care may not be continued after hospital discharge.

Methods—To improve the delivery of secondary stroke preventive services after hospital discharge, we have designed a chronic care model–based program called SUSTAIN (Systemic Use of STroke Averting INterventions). This care intervention includes group clinics, self-management support, report cards, decision support through care guides and protocols, and coordination of ongoing care. The first specific aim is to test, in a randomized, controlled trial, whether SUSTAIN improves blood pressure control among an analytic sample of 268 patients with a recent stroke or transient ischemic attack discharged from 4 Los Angeles County public hospitals. Secondary outcomes consist of control of other stroke risk factors, lifestyle habits, medication adherence, patient perceptions of care quality, functional status, and quality of life. A second specific aim is to conduct a cost analysis of SUSTAIN from the perspective of the Los Angeles County Department of Health Services by using direct costs of the intervention, cost equivalents of associated utilization of county system resources, and cost equivalents of the observed and predicted averted vascular events.

Conclusions—If SUSTAIN is effective, we will have the expertise and findings to advocate for its continued support at Los Angeles County hospitals and to disseminate the SUSTAIN program to other settings serving indigent, minority populations.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT00861081.

Key Words: stroke ■ secondary prevention ■ risk factors ■ self-management ■ care coordination

Death and disability are major consequences of stroke, and healthcare costs related to stroke exceed $74 billion per year in the United States.1 Of the 795 000 strokes in the United States that occur each year, ≈23% are secondary strokes.1 The occurrence of a stroke or transient ischemic attack (TIA) is the strongest predictor of a repeat event.2 The overwhelming majority of strokes per year could be prevented by better control of modifiable risk factors, such as hypertension.3 However, the use of evidence-based therapies for secondary stroke prevention over the long term remains inadequate.4–7 Clinical inertia has been cited as a barrier that prevents titration of appropriate medications to adequate levels.8

The need to improve stroke prevention care is especially pressing among minority populations.9 The incidence of stroke among blacks and Hispanics is higher than in non-Hispanic whites.1 The prevalence of stroke among Latinos in Los Angeles County is elevated, reflecting an excessive burden of risk factors.10 The awareness and control of risk factors are poor among black and Hispanic stroke survivors.11

A systematic review showed that minorities are less likely to receive appropriate stroke preventive services.9 However,
Conceptual Model

Medical care for chronic diseases, including stroke, is suboptimal.13 To address this problem, the chronic care model (CCM) has been proposed as a guide to design interventions to improve complex care for patients with chronic disease.14 The 6 CCM components are self-management support, clinical information systems, delivery system redesign, decision support, healthcare organization, and community resources. Most CCM-based interventions have shown improvement of a care process or outcome measure and reduction of healthcare costs as a result.14,15

Group clinics for patients with a shared disease are based on the CCM component of delivery system redesign. Group clinics (also called cluster visits or chronic care clinics) contain elements of both a support group and a subspecialty clinic. Studies on group clinics have reported positive health outcomes and reduced costs.16–18 Group clinics have been implemented in care venues serving the uninsured.19 Group clinics may be particularly effective when patients share a social connection, such as patients with the same ethnicity.20

Coordination of patient care in an increasingly complex healthcare system is also based on the CCM component of delivery system redesign. Analyses of this component frequently show significantly improved access to care and decreased hospitalizations.21 Another CCM component consists of supporting patient self-management to improve self-efficacy, the confidence in one’s ability to behave in a way that produces the desired outcome.22,23 A systematic review of self-management programs among patients with diabetes, asthma, and hypertension found improvements in relevant physiologic outcomes.23

In this study, we have crafted an outpatient care intervention called SUSTAIN (Systemic Use of STroke Averting Interventions) that uniquely adapts the principles of a successful in-hospital stroke prevention program3 along with CCM components. Specific components in this intervention include group clinics, patient self-management, and care coordination and delivery of stroke prevention care by a trained, licensed, independent care provider, either a nurse practitioner or physician assistant. The target population is persons admitted to Los Angeles County (LAC) hospitals with a recent ischemic cerebrovascular event (stroke or TIA). On the basis of an analytic size of 268 patients, we will evaluate the efficacy of SUSTAIN in controlling blood pressure (BP) in a randomized, controlled trial (RCT). Finally, we will also conduct a cost analysis of SUSTAIN from the perspective of the LAC Department of Health Services. “Safety net” institutions may not have the resources to support care programs on the basis of health improvements alone; they also need to justify such programs on the basis of costs. Unless a care program is shown to have cost savings or be cost-neutral, scarce resources for supporting a new care program come at the expense of supporting another care program.

Methods

Setting, Population, and Subjects

The setting of this study is all 4 county hospitals that anchor care for patients in the LAC public healthcare system, which serves the largest, most ethnically diverse county in the United States. This system serves >10 million residents and provides health care to 700 000 people every year. According to LAC administrative databases, >50% of patients use a language other than English as their primary language, and 63% of outpatients are uninsured (Jeff Guterman, personal communication, 2010). Institutional review board approval was obtained at each of the 4 county hospitals.

Potential subjects are identified through outpatient clinics, admission diagnosis logs, and the stroke inpatient clinical pathways implemented at LAC. The inpatient clinical pathways prompt inpatient physicians to obtain verbal consent for the research assistant (RA) to meet with the patient and, if consent is obtained, to notify the research team. The RA determines whether the patient meets eligibility criteria for enrollment. If patients decline participation in the RCT, the RA requests permission to record their demographic information for generating enrollment propensity weights. Inclusion criteria include a TIA or ischemic stroke within the past 90 days and a systolic blood pressure (SBP) >120 mm Hg. Participants must be English-speaking or Spanish-speaking. Persons with hemorrhagic stroke are excluded because their high short-term mortality rate would lead to high attrition rates.24 Patients are excluded when the research team believes that they will be unable to actively participate in group clinic settings, such as persons with severe global disability. Persons with language (aphasia) or cognitive difficulties are eligible as long as they can communicate that they understand the study during the informed-consent process.

For eligible subjects who consent to the study, the RA administers the baseline survey. After administering the baseline survey, the RA uses a centralized call number to obtain the randomization assignment for the subject. A statistical programmer, who has no contact with subjects, keeps randomizations lists that were generated before the RCT began and will inform the RA about the assignment of the subject during the telephone call. These lists have an allocation ratio of 1:1 and a block size of 4 and are stratified by site and preferred language of the subject. To ensure that subjects randomized to the usual-care arm receive some attention about stroke, they are given the American Heart Association brochure “Controlling Your Risk Factors: Our Guide to Reducing Your Risk of Heart Attack and Stroke.” We anticipate that the impact of this type of passive education is small.

Subjects randomized to the intervention arm of SUSTAIN are offered the same usual care that is offered to subjects randomized to the control arm of SUSTAIN, as well as the usual care that is offered to patients not participating in the RCT. Usual care for a patient with a recent stroke or TIA in LAC consists of at least 1 scheduled appointment to the outpatient neurology clinic, followed by a plan to rapidly transition care to a primary care provider. Patients without an existing primary care provider are given instructions on how to obtain one affiliated with LAC.

Intervention Staffing

The intervention care managers are bilingual nurse practitioners or physician assistants. An RA assists each care manager in implementing the intervention by scheduling patients for regular and group visits and preparing for such visits. A SUSTAIN task force reviews the design of the intervention, recommends local adaptations to facilitate implementation at each site, and assesses the extent of implementation. It includes the site principal investigators at each of the 4 county hospitals and representatives from 3 community organizations whose missions match our research team’s goals of reducing the risk of stroke in underserved minority communities of Los Angeles: the American Heart Association, Partners in Care Foundation, and Healthy African-American Families.
Group Clinics
Each subject randomized to SUSTAIN is scheduled to attend group clinics at 2, 5, and 10 months after enrollment (see Figure 1). Separate group clinics are scheduled for subjects who speak English or Spanish. The first group clinic consists of education about stroke warning signs, stroke risk factors, medications, and community resources. The second group clinic consists of strategies to enhance self-management of their disease, such as adopting healthy lifestyle habits in diet and physical activity. At the third group clinic, the care manager reinforces content presented at prior group clinics. After each group clinic, there are brief one-on-one sessions with the care manager to individualize and reinforce content presented in the group session and solve problems with subjects facing unique challenges in adhering to recommendations.

Individual Clinic and Scheduled Phone Calls to Coordinate Care
Subjects in the SUSTAIN intervention are also scheduled to a regular clinic with the care manager at 1 and 7 months after enrollment (see Figure 1). These sessions reinforce content discussed at SUSTAIN group sessions and will help coordinate outpatient stroke care delivery. In addition, the care manager schedules telephone care-coordination calls starting 1 week after hospital discharge and between group clinics and individualized visits. Protocols on care coordination are followed when a problem is identified, such as a missed appointment or prescription refill.

Self-Management Tools
During individualized sessions, subjects are given a customized report card on their current versus optimal control of key stroke risk factors. Subjects review the report card and are instructed to bring a blank report card to future primary care provider visits so that these clinicians can be actively engaged in delivering stroke preventive services.

Subjects are provided BP monitors (Omron HEM-711 DLX) for use at home. This model has been validated according to international BP protocols. In focus groups that we conducted of persons with recent stroke or TIA in this population, participants preferred this model over others because it had a preformed cuff, making it easier to use. Subjects are trained on how to use this equipment, and the care manager follows home BP measurements at telephone calls and individual visits.

Table. Data Collected to Evaluate SUSTAIN

<table>
<thead>
<tr>
<th>Outcome Measures</th>
<th>Data Collected</th>
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<tbody>
<tr>
<td>Primary outcome SBP</td>
<td>SBP</td>
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<tr>
<td>Secondary outcomes LDL level</td>
<td>LDL level</td>
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<tr>
<td></td>
<td>Smoking status</td>
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<td></td>
<td>Physical activity level</td>
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<td></td>
<td>Healthcare costs</td>
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<td></td>
<td>Medical history</td>
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<td></td>
<td>Stroke severity (NIH Stroke Scale)</td>
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<td></td>
<td>(modified Rankin scale)</td>
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<tr>
<td></td>
<td>Patient perceptions of quality of stroke preventive care</td>
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<tr>
<td></td>
<td>Knowledge about stroke signs and risk factors</td>
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<tr>
<td></td>
<td>Medication adherence</td>
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<tr>
<td></td>
<td>Competing needs, access to care, chaos, social support</td>
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<tr>
<td></td>
<td>Depression screener</td>
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<td></td>
<td>Short-form 6-D</td>
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<td></td>
<td>Healthcare utilization (eg, hospitalizations)</td>
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</table>

NIH indicates National Institutes of Health.
Assessment of patient perceptions of stroke care quality was adapted from the Consumer Assessment of Health Plans Study. Self-report medication adherence is assessed through recommended scales and barriers to adherence are assessed through the Morisky scale. Medication adherence is also assessed through county databases containing pharmacy refill information. Other potential mediators include access to care, depression, competing needs, social support, and life chaos. We also collect sociodemographic data, insurance status, and measures of acculturation. Subjects are paid up to $115 for collection of outcome measures across all time points.

To perform cost analyses, we will first assess the direct costs of SUSTAIN by calculating the start-up costs (including time for the principal investigator to train SUSTAIN staff and the training time required by the staff to become proficient in carrying out their duties) and maintenance costs (including time for the care manager and RA to execute the intervention care management activities, clinic room charges, printing of materials, and telephone costs for care coordination). Associated costs based on utilization of county resources by subjects will be determined by a survey and a query of the county administrative database. Utilization includes the total number of hospital days, emergency department visits, outpatient visits, and prescription medications and laboratory tests relevant to stroke. The most well-known national guideline on BP control defines a normal SBP as ≤110 mm Hg. In addition, a large RCT has found clinical benefit for an SBP ≤115 mm Hg. Even after excluding persons with an SBP >120 mm Hg, we still anticipate that 964 hospitalized patients with a stroke or TIA will be eligible for this study during the enrollment period, a number considerably larger than the target enrollment of 410 patients. We will also be enrolling patients from the outpatient clinic.

Sample Size and Statistical Power
Our sample size calculation and power analyses are based on the primary outcome of SBP, the premier modifiable risk factor for stroke. The most well-known national guideline on BP control defines a normal SBP as <120 mm Hg. Large meta-analyses of observational studies and RCTs have found clinical benefit for having an SBP as low as 115 mm Hg. In addition, a large RCT of SBP lowering for secondary stroke prevention found similar health benefits for persons with baseline hypertension and for persons with baseline normotension. Based on available data from 1 of the 4 hospitals from which the data collection will be conducted, the mean and standard deviation of SBP for persons with stroke with an SBP >120 mm Hg are 148 and 20, respectively (Bruce Ovbiagele, personal communication, 2007). With a type I error of 0.05, a type II error of 0.1 (or power of 90%), and a 2-sided test, 132 subjects in each treatment arm (or 264 subjects in total) will enable detection of a difference of 8 mm Hg in SBP, which corresponds to an effect size of 0.5 between the 2 treatment arms. This difference of 8 mm Hg in SBP between the 2 treatments is smaller than the 10 mm Hg threshold cited in the guideline, and thus we have sufficient statistical power with the estimated sample size to detect clinical benefit. An alternative outcome measure to SBP is recurrent stroke, but our sample size is not large enough to detect differences in recurrent stroke during 12 months of follow-up.

Enrollment Sample Size
Although we will facilitate the retention of subjects in the RCT as much as possible, the retention rates in disadvantaged populations are likely lower than in other settings. In addition, we need to account for attrition due to mortality. The 1-year all-cause mortality rate after stroke is 15% to 20% for persons age 45 to 69 years and 20% to 25% for persons age 70 years and older. With a conservative estimate of a 65% retention rate to account for these factors, the target number for enrollment is 410.

We plan to enroll study participants for 24 months. Based on discharge diagnoses of stroke and TIA in the 4 LAC hospitals in 2007, we estimate that there will be 1608 admissions for stroke or TIA in the 24-month enrollment period (see Figure 2). Based on available data from 1 of the 4 hospitals, we estimate that approximately two thirds of all patients with new stroke or TIA will have an SBP >120 mm Hg. Even after excluding persons with an SBP <120 mm Hg, we still anticipate that 964 hospitalized patients with a stroke or TIA will be eligible for this study during the enrollment period, a number considerably larger than the target enrollment of 410 patients. We will also be enrolling patients from the outpatient clinic.

Analysis
The distributions of baseline characteristics between the SUSTAIN intervention and usual-care groups will be compared. Continuous measures will be compared with the 2-group t test, and ordinal or nonnormalitarian, continuous variables will be compared with the Wilcoxon rank-sum test. Nominal categorical variables will be compared with the \( \chi^2 \) test or Fisher’s exact test. Enrollment propensity weights will be used to analyze how the tendency to participate in the RCT impacts study outcomes. Enrollment weights based on a logistic-regression model will be calculated with demographic data collected from eligible nonparticipants. When needed, attrition weights will be determined from logistic-regression models with demographic data from participants who disenrolled from the study. These 2 weights will be combined to form an overall analytic weight, by using the inverse of the product of the probabilities of participation. Both the raw rate and the rate adjusted by the analytic weight will be compared between the SUSTAIN and usual-care arms.

Intention-to-treat analyses on all primary and secondary outcomes will be conducted with ordinal logistic or multiple linear-regression models. With outcome assessments collected at multiple times (baseline, 3 months, 8 months, and 12 months), repeated-measures mixed-effects models will be used to estimate population effects, as well as individual variation over time. The primary outcome of SBP will be analyzed as a continuous variable. In sensitivity analyses, it will also be analyzed as a dichotomous variable with 120 and 140 mm Hg as cutoffs. Intervention status will be a primary independent variable used in all models. We will compare study outcomes between the control and intervention groups both with and without adjusting for potential covariates associated with the outcome measure. To check the fidelity (uptake) of the SUSTAIN intervention, we will also analyze attendance at SUSTAIN clinics and the number of telephone coordination-of-care calls made during the 1-year care management follow-up. We do not expect differences in mortality rates between randomization arms during

<table>
<thead>
<tr>
<th>Target analytic sample of 268 subjects in SUSTAIN RCT</th>
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<tr>
<td>Patient meets inclusion criteria: recent ischemic stroke or TIA &gt; 40 years of age, SBP &gt;120 mm Hg Speaks English or Spanish Not severely disabled</td>
</tr>
<tr>
<td>Patient consents to participate in study</td>
</tr>
<tr>
<td>Baseline Data Collection: Interview, BP measurement, lipid level</td>
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<tr>
<td>RANDOMIZATION (1:1, stratified by site and preferred spoken language)</td>
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<tr>
<td>3 Month Data Collection: Interview, BP measurement, lipid level</td>
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<tr>
<td>8 Month Data Collection: Interview</td>
</tr>
<tr>
<td>12 Month Data Collection: Interview, BP measurement, lipid level</td>
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Figure 2. Enrollment of subjects and schedule for collecting evaluation data,

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the short time period that subjects are followed up in this study. However, if differential mortality rates between the 2 arms exist, we will analyze them in a manner similar to other missing data (determine whether it is missing at random or missing not at random, etc), and we will perform sensitivity analyses and imputation methods to determine whether missing outcomes data due to deaths change the results from unadjusted analysis.

We will examine the distribution of costs to determine whether the data need to be transformed and whether 2-part modeling is required to account for subjects with zero expenditures. The first cost analyses will compare the direct costs of SUSTAIN plus the associated costs for utilization among subjects in the intervention arm versus the associated costs of utilization among subjects in the usual-care arm during the 1-year period when subjects were enrolled in the RCT after randomization. The second cost analyses will extend the aforementioned analysis beyond the 1-year period to include all available data (potentially >3 years for the first subjects enrolled in the study). The third set of cost analyses will extend these analyses to include future costs based on the predicted risk of vascular events.

Significance, Sustainability, and Dissemination
SUSTAIN is designed to be implemented in resource-constrained settings for improving stroke prevention in vulnerable communities and reducing disparities in stroke care. It is designed to improve adherence to guideline-recommended care after hospital discharge to the outpatient setting by using CCM-based components in a nurse practitioner/physician assistant–coordinated approach.

We have proposed a series of analyses necessary for decision makers to determine whether to support the SUSTAIN intervention in LAC after the funding period. As part of the task force, the site principal investigators will have been involved in implementing the SUSTAIN program and are in a position to advocate for its continuation. In addition, the research team and the American Heart Association representative will update county administrators on developments throughout the award period. When we have completed this RCT, we plan to make the products from SUSTAIN available to the research and public health communities.

Limitations
In this study, we are randomizing patients instead of clusters, such as by site, because it is the most statistically efficient method for demonstrating efficacy and thus would require the smallest sample size. Cluster randomization is appropriate when the threat of contamination is high, but we believe that the threat of contamination is small in this study. Although a primary care provider could potentially manage subjects in both randomization arms of SUSTAIN, most of the care interventions in SUSTAIN will be conducted by the care manager, and this person will not be managing subjects randomized to usual care. In addition, given the large number of primary care providers, there will only be a few primary care providers who will also manage patients in both arms of the study.

Two recent UK care interventions, Stop Stroke and phase I of EXPRESS, did not show improvement in the delivery of stroke preventive services. The interventions in those 2 studies included issuing stroke care recommendations to primary care. However, in phase II of EXPRESS, treatments could be directly initiated by the implementation team, and this was shown to be effective. The SUSTAIN intervention consists of care managers who are not only supported by tools such as medication algorithms and tracking registries to form treatment recommendations but who also possess the clinical privileges to directly implement the BP guidelines and other risk factor recommendations.

Summary
Persons with a recent stroke or TIA are at increased risk of a future stroke. Their risk can be reduced through better control of modifiable risk factors, especially SBP. However, population studies show that management of stroke risk factors is inadequate and probably worse for minority populations. CCM is a guide to design interventions for improving outpatient care of chronic diseases, particularly diabetes. Although CCM-based interventions are supported by theory and data, an RCT needs to be conducted to determine whether it can be successfully implemented in a new population, persons with a recent stroke or TIA, in a setting only infrequently studied, a county safety net health system. An intervention shown to be efficacious and cost-efficient can potentially improve the health of all persons with a recent stroke or TIA and provide a blueprint for CCM-based interventions implemented in underserved populations.

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Disclosures
None.

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