

Sustained Benefit of a Community and Professional Intervention to Increase Acute Stroke Therapy

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Background: The ultimate test of an educational intervention is the sustainability of the effect after the intervention ceases.

Methods: The TLL Temple Foundation Stroke Project was a quasi-experimental study aimed at increasing Food and Drug Administration–approved acute stroke therapy in a nonurban community in east Texas. During the intensive community and professional intervention (phase 2), significantly more patients with acute stroke received intravenous tissue plasminogen activator (tPA) compared with the preintervention period (phase 1). In the comparison community, no change was noted. We present the results of tPA treatment in the 6 months after the intervention ended (phase 3).

Results: Two hundred thirty-eight patients had a validated stroke during phase 3. Among patients who experienced an ischemic stroke, 11.2% in the intervention group received intravenous tPA compared with 2.2% in

phase 1 ($P=.007$). In the comparison group, 1.4% received intravenous tPA in phase 3 compared with 0.7% in phase 1 ($P>.99$). Among eligible candidates for treatment, 69.2% were treated in phase 3 in the intervention community compared with 13.6% in phase 1 ($P=.002$). In the comparison group, 20.0% were treated in phase 3 compared with 6.7% in phase 1 ($P=.45$). There was 1 protocol violation among the 9 patients treated in the intervention community in phase 3.

Conclusions: There was a sustained benefit of the intervention in increasing tPA treatments in the intervention community even after cessation of the educational effort. Treatments in the control community remained few through all 3 phases of the study. A carefully planned multilevel intervention can improve community stroke treatments even in a nonurban community.

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THE EARLY SUCCESS of a community-based professional and public education project to increase delivery of acute stroke therapy in nonurban east Texas was previously reported.¹ Each year, 731 000 people experience a stroke in the United States.² Intravenous (IV) alteplase remains the only Food and Drug Administration–approved drug to treat stroke, but it must be given within a short 3-hour window. Industry and Medicare estimates suggest that only 1% to 2% of patients who experience ischemic stroke receive this treatment in the United States.³ Because ischemic neurons die in a time-dependent fashion, it is likely that new thrombolytic and neuroprotective treatments will also have a short time window for maximal efficacy.

One fourth of the United States' population resides in nonurban communities.⁴ These locations may be the most dif-

ficult places to deliver acute stroke therapy because of the distance from the hospital, the lack of medical center sophistication, and the need to overcome obstacles to disseminate information about stroke in a large sparsely populated area.^{1,5,6} Treatment of stroke in the United States involves internal medicine, emergency medicine, and family practice physicians, particularly in nonurban communities in which neurologists are few and stroke neurologists are absent.

We report herein the final phase of the TLL Temple Foundation Stroke Project. This phase was designed to determine if the beneficial effect of the intervention would be sustained after the active intervention was withdrawn. This may be considered the ultimate test for success of an intervention. As debate regarding stroke center certification begins,⁷ it is instructive to determine whether small nonurban hospitals can deliver acute stroke therapy.

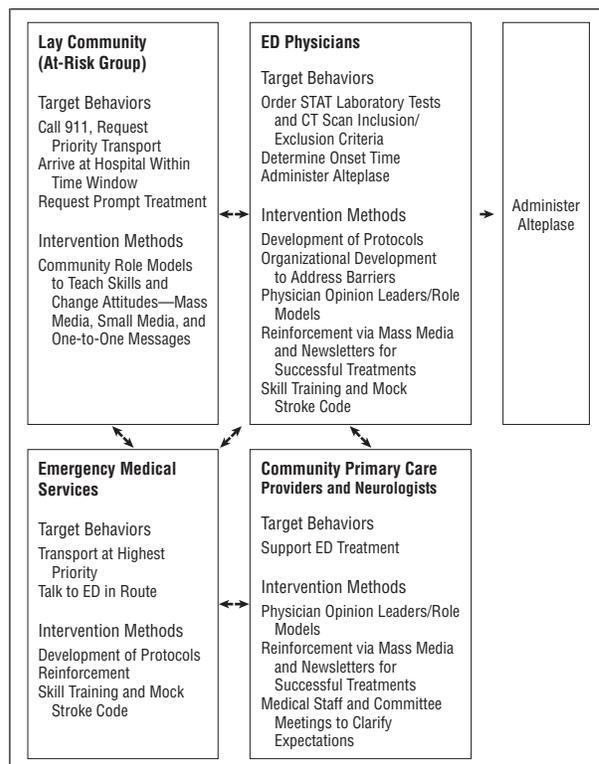
METHODS

The methods of the TLL Temple Foundation Stroke Project were previously reported.¹ Briefly, this quasi-experimental comparison group design within 2 communities⁸ was centered in east Texas. The intervention community contained Angelina, Nacogdoches, and Shelby counties. The sponsoring agency required that the intervention occur in this community. A comparison community (Jefferson and Orange counties) was chosen to match the demographics of the intervention community, and 5 comparison community hospitals were chosen to match the 5 intervention community hospitals. Active surveillance was used to capture all hospitalized stroke cases in the 10 hospitals. This method was similar to the one used in the World Health Organization MONICA study,⁹ and used previously validated stroke screening codes.¹⁰ Passive surveillance was also used to ensure complete case capture of any cases not identified by active surveillance. Cases were validated from source documentation by fellowship-trained stroke neurologists based on published criteria.⁹ An exhaustive system of quality assurance was used to ensure full case ascertainment and reliability of data abstraction. Patients were considered eligible candidates for IV alteplase treatment if they met the National Institute of Neurological Disorders and Stroke acute stroke study selection criteria.¹¹

The project was divided into 3 phases. The timing of the study phases was decided before data acquisition. Phase 1, from February 1, 1998, to October 31, 1998, was observational and provided baseline data for both communities. Phase 2, from January 1, 1999, to March 31, 2000, involved the educational component in the intervention community only. Data were collected during this period and were reported.¹ Phase 3, from April 1, 2000, to September 30, 2000, was observational and provided posteducational data in the intervention community and secular trend data in the comparison community. These data are produced herein.

The educational intervention was designed, based on the process of Intervention Mapping,¹² to create a multilevel program that delivered a community communication campaign combined with professional development and organizational change to increase access to acute stroke therapy in rural east Texas (**Figure**). The social environmental context of the person who experiences a stroke is critically important because many patients who experience stroke are aphasic, anosognosic, or parietic. It is frequently others who initiate a call to a medical professional for acute stroke care.⁵ Furthermore, once the call is made, the possibility of initiating stroke treatment depends not only on the behavior of the emergency department (ED) staff but also on the transport behavior of the emergency medical service and lack of interfering delay on the part of either primary care providers or neurologists who might be associated with the patient.¹³

The planning of this intervention included the analysis of the required behaviors of each segment of the community. Equally important, we focused on the interactions and potential interactions between the groups. For example, patients and bystanders interact with ED personnel and can convey expectations for urgent care. Primary care providers can delay the process by requiring to see a patient in the ED. We also analyzed the theoretical and empirical determinants of the behaviors of each segment. For example, for community laypersons to respond appropriately to stroke, they must have the knowledge and skills to identify signs of a stroke, know to call 911 without waiting, expect that quick action and prompt treatment will result in improved stroke outcomes, and perceive that the social norms in the community support assertively assisting someone with signs of stroke. Proposed determinants of the ED physicians' behavior included skills for the various components of the differential diagnosis, the establishment of on-



Schematic overview of the interaction of the community and professional interventions. CT indicates computed tomographic; ED, emergency department; and STAT, immediate.

set time, and the alteplase protocol. In addition, for EDs, there were organizational barriers, such as lack of protocols and standing orders and perceptions that other physicians (eg, primary care providers and neurologists) did not want the therapy given. Finally, reinforcement is an important determinant for the stroke-related behaviors of all the groups.

To target community members (including the medical care community), we created public service announcements for radio and television in English and Spanish. Community figures were used as role models to show calling 911 immediately for stroke symptoms, and to demonstrate that responding to stroke immediately can result in a better outcome. Community members were also encouraged to be assertive in asking the physician about tissue plasminogen activator (tPA) if taken to the ED for stroke symptoms, thereby providing a cue to act for physicians who were initially reluctant. Three local television statements ran the messages a total of 675 times. Radio public service announcements were broadcast 3376 times. Five full-size billboards in the intervention community were used for the intervention message. We conducted 488 training sessions to provide 634 subsequent trainers to disseminate the intervention message personally to 49 527 individuals in person. More than 60 000 brochures on stroke were used, and more than 5000 posters were displayed in the intervention community. Large employers, hospitals, pharmacists, health clinics, and places of worship were targeted.

To address physicians, the intervention relied on systems change in hospitals, change of perceived norms in the medical community, and reinforcement of behavior change through highlighting successes in news stories and providing newsletters to primary care providers, emergency physicians, and neurologists. This provided feedback regarding stroke treatment accomplishments. Multidisciplinary teams in hospitals developed ED protocols, solved problems related to responsibility for care, and scheduled continuing medical education and mock

Table 1. Demographic and Clinical Information for Patients Who Experienced Validated Stroke by Phase and Group*

Variable	Phase					
	1		2		3	
	Intervention Group (n = 218)	Comparison Group (n = 206)	Intervention Group (n = 400)	Comparison Group (n = 365)	Intervention Group (n = 130)	Comparison Group (n = 108)
Demographic characteristics						
Age, mean (SD), y	72.9 (13.7)	71.4 (12.9)	71.2 (13.9)	72.6 (12.4)	70.4 (15.7)	72.8 (15.1)
Female sex	57.5	61.8	56.7	58.1	56.9	56.5
Nonwhite race	23.4	34.0	20.8	28.0	25.4	31.5
High school graduate	58.9	56.2	57.3	66.8	68.6	62.1
No insurance	5.3	8.8	8.3	9.3	12.5	7.4
Risk factors						
Hypertension	71.7	79.5	71.1	77.6	75.4	87.5
Diabetes mellitus	30.4	30.3	29.2	32.3	27.1	48.2
Coronary artery disease	37.5	43.7	27.2	38.9	31.5	56.9
Atrial fibrillation	15.1	23.3	21.4	13.1	10.9	68.4
Current tobacco use	18.0	29.7	22.2	17.7	14.4	20.5
Previous stroke	39.0	40.5	37.6	41.4	44.1	65.2
Clinical data						
Blood pressure, mean (SD), mm Hg						
Systolic	161.4 (31.4)	162.1 (33.0)	162.7 (32.0)	164.9 (29.5)	159.0 (30.6)	158.1 (32.4)
Diastolic	84.7 (19.6)	83.8 (20.6)	85.1 (17.7)	82.7 (16.5)	84.5 (20.7)	76.2 (15.7)
Symptoms						
Motor	73.5	90.8	84.4	88.8	89.6	95.2
Sensory	43.7	40.6	47.9	48.0	38.8	65.9
Language	65.6	53.3	58.7	56.9	52.9	59.8
Visual	20.1	12.9	17.9	17.1	21.0	12.7
Neurologist examination	45.7	39.3	50.0	52.6	45.0	59.1

*Data are given as percentage of patients in each group unless otherwise indicated.

Table 2. Primary Outcome Measure of Proportion of Intravenous Alteplase Treatment for 2 Groups

Group	Phase*			P Value†
	1 (n = 424)	2 (n = 767)	3 (n = 238)	
Patients who experienced an ischemic stroke				
Intervention group	3/136 (2.2)	23/266 (8.6)	9/80 (11.2)	.007
Comparison group	1/141 (0.7)	2/233 (0.9)	1/70 (1.4)	>.99
Eligible candidates for treatment				
Intervention group	3/22 (13.6)	23/44 (52.3)	9/13 (69.2)	.002
Comparison group	1/15 (6.7)	2/36 (5.6)	1/5 (20.0)	.45

*Data are given as number of patients/total patients (percentage) for each group in each phase.

†The Fisher exact test was used for comparison of phases 1 and 3.

stroke codes for hospital and emergency medical services staff.

All treatment decisions were made by local physicians. We were not present or available for consultation for any individual treatment. The prespecified primary outcome measure was a change in treatment with IV alteplase in patients who experienced acute stroke from a presumed baseline of 1% to 6% in the intervention community. Similarly, we hypothesized that no increase in the use of acute stroke therapy would be observed in the comparison community.

Descriptive statistics for demographic variables, risk factors, clinical symptoms, proportion receiving IV alteplase treatment, and delay time to the ED were calculated by intervention and comparison groups and by phase. For continuous

variables, the mean and the SD were calculated. For dichotomized variables, the proportion was presented. For the outcome variables, we used the Fisher exact test to examine phase effect on dichotomized variables and analysis of variance to examine the continuous variables. This project was approved by The University of Texas at Houston Committee for the Protection of Human Subjects and by all participating hospitals. All participating subjects or their next of kin signed a written informed consent.

RESULTS

In phase 3, 2184 patients were screened. Of these patients, 1588 did not experience a cerebrovascular event. Of the remaining 596 patients, 219 were not county residents, 32 patients or their physicians refused participation, 41 were younger than 21 years, and 66 did not have sufficient documentation to validate the case as a stroke. This left 238 validated cerebrovascular events (transient ischemic attacks, completed ischemic strokes, intracerebral hemorrhages, or subarachnoid hemorrhages). Of these events, 150 were subsequently validated as a completed ischemic stroke. **Table 1** compares the demographic, risk factor, and clinical characteristics of the participants during the study's 3 phases.

Table 2 presents the study's primary outcome data. The proportion of patients who experienced an ischemic stroke and were treated with IV alteplase continued to increase in the intervention community hospitals in phase 3. No appreciable change was noted in the comparison community hospitals. **Table 3** provides the de-

Table 3. Delay Time to Hospital Arrival Information by Group and Study Phase

Group	Phase			P Value
	1	2	3	
Patients Who Experienced an Ischemic Stroke and Presented Within 2 h of Symptom Onset*				
Intervention group	28.1	31.7	28.6	.80
Comparison group	20.7	27.6	22.6	.45
Delay Time Analysis†				
Intervention group	9.1	4.5	8.7	.61
Comparison group	10.9	6.8	10.7	.90

*Data are given as percentage of patients unless otherwise indicated. The *P* value compares the percentage of patients presenting within 2 hours between phases 1 and 3.

†Data are given as median time (in hours) unless otherwise indicated. The *P* value compares log delay time data.

lay time to hospital arrival from the onset of stroke symptoms. There was no association of the intervention with delay time to hospital arrival or arrival within the critical 2-hour window¹⁴ needed for treatment to meet a 3-hour limit.

Among the treated patients in phase 3, 1 of 9 in the intervention group received treatment outside of National Institute of Neurological Disorders and Stroke protocol specifications. The 1 patient treated in a comparison community hospital was treated appropriately. **Table 4** provides the data on eligible candidates for IV alteplase treatment. During the study's 3 phases in the intervention community, internal hospital delay and physician reluctance to treat decreased while treatments increased. The comparison community did not experience a decrease in physician reluctance to treat eligible candidates.

COMMENT

This study demonstrates a sustained benefit from an educational intervention designed to increase Food and Drug Administration–approved acute stroke treatment. In the 6 months following cessation of the intervention, treatments continued to increase in the intervention community. During phase 3 of this project, 11.2% of patients who experienced an ischemic stroke received IV alteplase. This is a 10-fold increase from the national average.³ The non-urban location of this intervention is arguably the most difficult place for significant inroads to improving acute stroke therapy. While one quarter of the United States' population reside in nonurban locations, these areas require long driving distances to the hospital, have a paucity of specialist care, and have small unsophisticated hospitals unlikely to be the leaders in adopting new therapies.

The professional intervention was clearly successful. In this study, treatment of eligible candidates increased by 55.6% in the intervention community from phase 1 to phase 3. The defining characteristics of this intervention are that it tackled the problem from multiple perspectives and used a comprehensive analytic approach to proposing determinants of behaviors from all of the relevant segments of the community. It is tempting

Table 4. Barriers to Treatment Among Eligible Candidates for Intravenous Alteplase*

Study Phase	Hospital Delay	Physician Reluctance	Treated
Intervention Group			
1	27.3	59.1	13.6
2	15.9	31.8	52.3
3	7.7	23.1	69.2
Comparison Group			
1	13.3	80.0	6.7
2	5.6	88.9	5.6
3	0	80.0	20.0

*Data are given as percentage of patients.

to conclude that the physician professional intervention component was the most, or even only, successful part of the intervention. However, it is impossible to isolate the physician from the community context. Nevertheless, it is clear that physicians' skills improved. It is likely that efforts to increase self-efficacy and positive outcome expectations were most influential. Allowing local physician leaders to champion the message was highly relevant. While neurologists and emergency physicians acquiesced to treatment, it was the high-volume internal medicine and family practice physicians who changed hospital policy and encouraged treatment. Reinforcement through the media also probably played a significant role in physician behavior. The community intervention was highly visible and apparently valued in these relatively small communities by physicians and laypersons. Intervention efforts were seen by physicians, nurses, paramedics, and hospital administrators. These groups reported that this helped galvanize their resolve to provide acute stroke therapy.

We caution against the interpretation that the community components of the intervention were unnecessary because a change in delay time to hospital arrival was unaffected. The components of the intervention were interrelated (Figure), and some even targeted to the reciprocity between segments of the community. For example, it is difficult to quantify how important it was to have patients and family expressing urgency and asking for tPA in the emergency medical services transport situation and in the ED. The intervention specifically attempted to encourage patients and their family to ask for tPA in the ED. Many physicians told us that this motivated their decision to treat.

This study is limited by its quasi-experimental non-randomized design. The study sponsor required that the intervention be performed in its community. A comparison community was chosen, blinded to physician practice information or baseline variables. While all 5 intervention community hospitals were used in this study, data from only 5 of the comparison community hospitals were needed for sample size considerations. This study was not intended to examine outcome after IV alteplase treatment, but rather to examine if the use of Food and Drug Administration–approved acute stroke therapy could be increased appropriately in a nonurban environment. Indeed, the rate of protocol violations in the intervention community in phase 3 was less than that previously re-

ported.¹⁵ Many of our professional education efforts involved appropriate posttreatment care. No data were collected beyond the ED encounter. Fewer total cerebrovascular events were noted for phase 3 compared with phase 1 or 2, out of proportion for surveillance time. There is no clear explanation for this observation; surveillance procedures were the same in all 3 phases of the study.

The future of acute stroke therapy is likely to provide new therapies with short time windows for treatment because neurons die in a time-dependent fashion. While this project focused on IV tPA, it is likely applicable to acute stroke therapy in general. This project was performed in a nonurban community. Its applicability to urban environments warrants further study.

This study provides a framework to craft a health promotion campaign to increase acute stroke therapy. Stroke is the number 1 cause of adult disability and the number 3 cause of death in the United States. Efforts to improve outcome from stroke are likely to have an important public health impact.

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REFERENCES

1. Morgenstern LB, Staub L, Chan W, et al. Improving delivery of acute stroke therapy: the TLL Temple Foundation Stroke Project. *Stroke*. 2002;33:160-166.

2. Broderick J, Brott T, Kothari R, et al. The Greater Cincinnati, Northern Kentucky Stroke Study: preliminary first ever and total incidence rates of stroke among blacks. *Stroke*. 1998;29:415-442.
3. Nilasena DS, Kresowik TF, Wiblin RT, et al. Assessing patterns of tPA use in acute stroke [abstract]. *Stroke*. 2002;33:354.
4. US Bureau of the Census. Urban and rural population. Available at: <http://www.census.gov/population/censusdata/urpop0090.txt>. Accessed May 15, 2002.
5. Wein TH, Staub L, Felberg R, et al. Activation of emergency medical services for acute stroke in a non-urban population: the TLL Temple Foundation Stroke Project. *Stroke*. 2000;31:1925-1928.
6. Burgin WS, Staub L, Chan W, et al. Acute stroke care in non-urban emergency departments: the TLL Temple Foundation Stroke Project. *Neurology*. 2001;57:2006-2012.
7. Adams R, Acker J, Alberts M, et al. Recommendations for improving the quality of care through stroke centers and systems: an examination of stroke center identification options: multidisciplinary consensus recommendations from the Advisory Working Group on Stroke Center Identification Options of the American Stroke Association. *Stroke*. 2002;33:1-7.
8. Cook TD, Campbell DT. *Quasi-experimentation: Design and Analysis Issues for Field Settings*. Boston, Mass: Houghton Mifflin Co; 1979.
9. Tuomilehto J, Sarti C, Narva E, et al. The FINMONICA Stroke Register: community-based stroke registration and analysis of stroke incidence in Finland, 1983-1985. *Am J Epidemiol*. 1992;135:1259-1270.
10. Morgenstern LB, Wein TH, Smith MA, Moyé LA, Pandey DK, Labarthe DR. Comparison of stroke hospitalization rates among Mexican Americans and non Hispanic whites. *Neurology*. 2000;54:2000-2002.
11. Kwiatkowski TG, Libman R, Frankel M, et al. The NINDS rt-PA Stroke Study: sustained benefit at one year. *N Engl J Med*. 1999;340:1781-1787.
12. Bartholomew LK, Parcel GS, Kok G. Intervention Mapping: a process for designing theory- and evidence-based health education programs. *Health Educ Behav*. 1998;25:545-563.
13. Menon SC, Pandey DK, Morgenstern LB. Critical factors determining access to acute stroke care. *Neurology*. 1998;51:427-432.
14. National Institute of Neurological Disorders and Stroke. *Rapid Identification and Treatment of Acute Stroke: Proceedings of a National Symposium*. Bethesda, Md: National Institute of Neurological Disorders and Stroke; 1997. National Institutes of Health monograph.
15. Katzan IL, Furlan AJ, Lloyd LE, et al. Use of tissue-type plasminogen activator for acute ischemic stroke: the Cleveland area experience. *JAMA*. 2000;283:1151-1158.