GETAC Stroke Committee Meeting—November 18, 2006

PUBLIC COMMENTS:

Combined "Early Treatment Protocols For Rapid Transport" and "Requirements For Texas Stroke Center Designation" DRAFT documents.

1. I have a concern about the recommendations made by the GETAC committee of automatically triaging all stroke patients to the highest level of care if within a 15 minute time frame. Not all stroke patients are needing neurointerventional procedures, and there are limited facilaites that provide neurointerventional or Comprehensive care. If a primary stroke center has the capability to administer IV tPA (which they should), sending the patient to a CSC because it is a higher level of care wastes needed time and the PSCs stay "out of Practice" or do not maintain competency in the process of timely administration of IV tPA.

2. According to The BAC recommendations, Research is considered an optional component of a CSC: "A hospital can clearly provide excellent care as a CSC and not be involved in any research. Therefore research is considered an optional component of a CSC" Therefore, I would suggest that the critieria for Texas stroke CSC be changed from: f. Educational and research programs to f. Educational and Expert resources

3. To go along with the BAC recommendations and the fact that JCAHO is not going to provide certification for CSCs in the future, I would like to recommend that there be a component in the list of criteria for CSC that includes outcomes and quality improvement plan ie (per BAC): pg 1608 under OTHER:1 .multidisciplinary QA committee meeting on a regular basis to monitor benchmarks and review complications 2. monitoring the outcomes of procedures performed 3. Data base registry for: LOS, treatmetns received, DC destination/status, incidence of complications (DVT, aspiration pneumonia, UTI)

4. Attached are the draft document sent out on 9/29/06 by Mr. Steve Janda. The documents were discussed in our RAC meeting last PM and some of the comments/concerns are added to those documents in red font. Our RAC wants to congratulate the GETAC Stroke committee on the progress they have made to date, but feel that these draft documents / rules need considerable more work. Our RAC will support your efforts to make stroke care optimal in Texas.

5. I'm very much interested in the draft document regarding early treatment protocols for rapid transport for stroke patients. Would you be addressing the criteria for implementation of air medical transfers? I am not aware of any stroke-specific criteria (modeled after the STEMI protocol) and would like to see something of this nature also developed. My institution is the flagship (comprehensive stroke center) for a system network and would utilize air medical transport. Also our community outreach activities of greater Houston area would benefit from air medical transport into the Texas Medical Center where three JCAHO primary stroke centers are located. 1.) Has the committee to develop a region-specific stroke plan been identified and in place? 2.) Would this be one committee for the state or would each region develop their own. I would be very interested in participating. 3.) What is the time-line for design and implementation of this plan? 4.) Is there a strategic plan to identify which region's plan is developed first? 5.) Is there a roll-out plan for the state? 6.) Are there any consequences for not following the plan? 7.) Who would have access to the registry?

6. What happens if we have a pediatric patient? Do we take them to Children's Hospital or the stroke center?

7. As Chair of RAC -- I have many concerns regarding the draft document presented. The RAC's original Mission was to establish a regional trauma plan for the injured patients in our RAC. The reason that I tell you that is that all the players in that organization are pre-hospital and hospital trauma care providers. It is important to remember that RAC members participate on a voluntary basis on top of their regular jobs. If I were to ask who in the RAC has an expertise in stroke care there would be few if any to raise their hand. Those players do not attend the RAC meetings. That would be our first goal before establishing. I do not feel the RAC's have the authority to categorize hospitals as stroke centers. This process would only work if it was through DSHS. There would also be many questions which would need clarification regarding the criteria.I applaude your efforts to move this project forward and the RAC's in the State will always step up to the plate when needed. Let us not set
a goal that we the RAC can not achieve. Involve us and work with us in this process and lets get the experts to the table.

8. The proposed model by BAC might be more appropriate for urban areas but it is not impossible in other scenarios. The poster child for this program is for example the St. Luke Hospital in Kansas City (Mid-America Brain and Spine Center) that has developed one of the busiest and more efficient networks covers a rural area.

There area models like the one implemented by the Medical College of Georgia that is based on teleradiolgy which allows to solve the problem of 24/7 interpretation available in each hospital. In this program the neurologist in the stroke center even was able to received a televised exam of the patient in real time and then could make the assessment and assume the responsibility of authorizing to start the TPA administration at the referring facility or in transit.

Absolutely the patients should not be taken to local hospitals by EMS. This is a waste time particularly in rural areas. This concept is the foundation of regionalization and it has been proven to work in other rural areas of the country for trauma and stroke.

Although it is true that IV TPA is the only FDA approved treatment in acute stroke, there are plenty of other innovative treatment options developed since the approval of TPA. Much of the research in this area for the last ten years has been dedicated to extend the window of opportunity. There are multiple trials on-going and many of them are use image-base selection criteria to guide the therapy and select the patients that can be safely treated up to 24 hs. The capability of participating in these trails in San Antonio will be unique to UTSCSA.

It is true that the only 4% of the acute stroke admissions receive TPA but for this particular reason the patients should be transfered to specialized centers that can provide other treatment options accepted beyond the 3 hs. The PROACT trial (NIH funded) demonstrated the advantage of using intra-arterial TPA up to 6hs. The MERCI retrieval device has been cleared by the FDA to remove clots up to 8 hs. Ongoing trials are exploring to extend the time limits.

The question about source for financing is a reasonable concern but to argue against the value of having a registry and collecting this data is contrary to every principle of evidence based medicine. These arguments would not be valid even a decade ago, nowadays they are an anachronism.

It appears that there are some facts that need to be acknowledged and circumvent but to dismiss such a valuable project will be an awful mistake that would deprive patients in the state of Texas of the best possible medical care. Details should not jeopardize a very important undertaking to improve the healthcare in the region.

Indeed some adaptation to the particular Texas geographic reality should be considered but operational organization used for the Trauma centers could be a great example to replicate.

9. In reviewing the draft document on "Early Treatment Protocols for Rapid Transport" I noticed that the draft recommends three levels. 2ii. gives levels 1 & 2 to comprehensive and primary Stroke Centers.

These are my recommendations:

Level I Comprehensive Stroke Center

1. Certified as a JCAHO Primary Stroke Center
2. Accomplished Phase 2 or 3 of GWTG
3. Enroll stroke survivors into Research Clinical Trials - expand the treatment hours to 9
   a. Ischemic Stroke
   b. Hemorrhagic Stroke
   c. Secondary Stroke Prevention
4. Neuro Interventional Radiologist available 24/7
5. Organized Outreach education provided to community, EMS and surrounding healthcare facilities
6. Annual Neuroscience seminar

Level 2 Primary Stroke Center

1. Certified as a JCAHO Primary Stroke Center
2. Using GWTG as their stroke registry
3. Treat AIS up to 6 hours (IV & IA tPA)
4. Neuro Interventional Radiologist available 24/7
5. Offer at least one community stroke education event
6. Offer at least one EMS stroke education event

Level 3 Stroke Support Facilities

1. Participate in data collection related to stroke as part of their PI program
2. Must have transfer agreements with a Level 1 or Level 2 Stroke Center
3. Provide Stroke Education for ED staff
   a. How to recognize an acute stroke
   b. Exclusions/Inclusions for treating AIS with TPA
   c. Administering tPA and associated complications
   d. NIHSS

10. The docunment "Early Treatment Protocols for Rapid Transport" leads one to think that the RACs will be responsible for implementing the new region-specific stroke plans. But, the "Requirements for Texas Stroke Center Designations" adds valuable insight, specifically that each hospital will be responsible for showing DSHS that they meet the requirements by a signed affidavit. That information helps a lot, but do we really think that will be effective? Why should hospitals not be required to go through a survey process like the trauma centers? What will be the penalty if they falsify the affidavit (other than removal of advertising)?

11. Most hospitals do not have neurology or neurosurgery on-call coverage 24/7, and few emergency physicians will administer TPA alone, without appropriate specialty back-up. Transfers to another facility will delay treatment beyond the 3-hour window. Protocols to establish a “standard of care” without such back-up, and state liability protection for the physicians administering TPA in the setting of acute non-hemorrhagic stroke, according to state protocols, should be part of the package, in my opinion.

12. Will there be criteria to stableize and transfer for level IV's, because that's what we do now. What would be different? Will this be essential criteria for designation?

13. The draft document needs a little work. It requires the implementation of a regional stroke plan by each RAC. That is not in the mission
statements of RACs. Furthermore, RACs do no have the manpower to designate facilities. They

do not currently designate trauma facilities either! The document includes patients up to 8 hours out, yet it requires no more than 15 min delay for transfer to the highest level stroke center. If the highest level center has a neuroradiologist that can affect patient care for up to 8 hours, why go to a center that can't do anything after 3 hours? These comments are ment to be constructive, and I fully agree with involvement of the RACs---up to a point.

14. The document, in defining the components of a regional plan, itemizes the need to address the patient within 8 hours of the onset of signs and symptoms, with the time frame to be altered as new therapies are available. The most current treatment regimen from the American Heart Association involves the use of fibrinolytic (or “clot buster”) drugs that are effective when used in patients within 3 hours of the onset of signs and symptoms. Should the consideration within the regional plan, therefore, be in addressing the patient within that time frame? Thanks for this opportunity to comment.

15. 1. The wording on instruct paramedics should be ALLOW. The paramedic should be allowed some discretion. 2. The 15 minute thing is way too short. There are cases that going to the appropriate stroke center may take more that 15 extra minutes. 3. We do not need a registry and more bureaucracy. This should not be a complicated on expensive process on an already financially burdened health care system

16. I think the concept of stroke center designation is absolutely essential!! There are certain centers who have a neurosurgical/intensivist team of surgeons, neurologists, and neuro-radiologists who are capable of delivering state of the art stroke care....better than what we in the community can deliver. I would like everyone to consider bypassing closer hospitals in their territory to go to a stroke or tertiary care center even if the transport time exceeds 15- 20 minutes. If time is of an essence, then aeromedical transport could be indicated.

17. What good does it do to write such a statement when you have hospitals and EMS services that do not and will not comply with it.

18. When is it anticipated that JCAHO will have their review process in place for Comprehensive Stroke Center Certification? If a JCAHO Primary Stroke Center chooses to pursue Comprehensive stroke center Desgination without JCAHO, is this considered a certification or designation? If indeed the criteria is already set forth by the BAC and published in the Stroke 2006 issue for Comprehensive Stroke Centers, who oversees if criteria and outcomes are indeed being followed?

19. i have one concern that keeps getting bypassed in whatever topic comes up it seems-frontier/rural ems. i am a hospital based ems-critical care access-our er has three beds-we stabilize and transport a large number of folks. we have the ability, by protocol, to transport folks from the scene directly to any hospital if necessary or requested. however, we often cannot meet timelines set by "national standard". we need the issue of not being able to meet time guidelines addressed and suggest what is the "next" best route to take...we keep hearing that since we cant transport a patient within certain guildelines, we are screwed and so is our patient. those patients and their needs must be addressed. yes, i understand all too well that their outcome may not be as "good" as someone that is 15 minutes away from a stroke center. our situation is ----- medical center-level 3, is 63 miles away. ---------- level 1's, i believe, are 117 miles away. by the time we pick up a patient, bring to our hospital, stabilize, arrange transfer to one of these hospitals-WHICH TAKES UP TO A DAY FOR ACCEPTANCE (ESPECIALLY =====) OUR PATIENT IS MAKING FUNERAL ARRAINGEMENTS. yes, we have helicopters all over the place-1 is 15 min out, 1 is 20 minutes out, 2 are 25 minutes out and 2 are 50 minutes out...IF THEY ARE AVAILABLE..we are making plans to simply ground everyone we can or have to, by upgrading our units to specility care....but there is no guidelines to help us equip our trucks with needed equipment for stroke. please remember, we are small and have very limited funds to spend on such. that makes it even harder. but, there are numerous small ems services around our area

that will fall between the cracks because frontier/rural ems will be forgotten in the process. i realize that we may not be the shining gem in this process and outcome but we can and want to porvide care for our stroke patients just as much as ANY big city ems or hospital. i thank you for tackling this task...it is long overdue.

20. I am encouraged by the wording below. It was my greatest fear that the protocols would cause tremendous delays in care initiation by EMS staff attempting to get patients to a definitive care program. In the past I have seen great harm come to patients when delays were caused by protocols that bypassed a closer facility where it was appropriate to initiate care. "There should be no more than a 15 minute delay caused by taking a patient to the next highest level of stroke care."

21. I think we need to be very careful with this issue. The idea of a Stroke Center revolves around the controversial issue of thrombolytics for acute cerebral infarction. Since there still remains a large amount of disagreement on this topic, I am very loath to create a standard of care by creating a system parallel to the trauma system for stroke.