Time Critical Diagnosis System

Recommendations to Advance Emergency Medical Care for Stroke and STEMI in Missouri

Missouri Time Critical Diagnosis System Task Force

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Report Information

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Description: This report examines and supports the need for a systems approach to time critical diagnosis and care for acute ischemic stroke and ST-Elevation Myocardial Infarction (STEMI) similar to that for trauma emergency care. Recommendations, rationale, supporting evidence and suggested actions from the TCD System Task Force are described. These recommendations provide the strategic directions for the coming years to guide promulgation of new regulations and establishment of processes, procedures, protocol and resources that will advance emergency medical care for Missourians that suffer a stroke or STEMI.

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Preface

Missouri's Time Critical Diagnosis System History

Emergency Medical Services (EMS) and trauma care reform have been policy priorities for Missouri since 2003. The Missouri Foundation for Health (MFH) and Missouri Department of Health and Senior Services (DHSS) were integrally involved in planning efforts for this reform. The planning began with facilitated discussions with the EMS and trauma community that included emergency room physicians, trauma nurses, state health officials and other health care professionals. Early in the process, DHSS engaged its State Advisory Council (SAC) on EMS to compile a white paper that detailed problems with the EMS system and examined possible solutions. Dr. Bill Jermyn, then Chair of the SAC, joined the planning effort. He brought decades of emergency medical experience to inform the early planning and became the state's preeminent EMS reform champion.

Efforts continued in 2004 when hundreds of Missouri's emergency care professionals, as well as legislators and other public policy leaders, were assembled to discuss the planning process. The group asked the SAC and Dr. Jermyn to take the lead. MFH hosted a second statewide summit where participants more narrowly defined the strategic planning process. The plans were compiled, and in 2005, MFH provided funding to DHSS to create a leadership position to advance the plan. DHSS established the Medical Director of Emergency Medical Care Services position with this funding and Dr. Jermyn accepted the position at that time. Through the leadership of Dr. Jermyn and Dr. Lynthia Andrews, SAC Chair, a Time Critical Diagnosis (TCD) committee was created in 2007. Efforts were invested to improve communication on the importance of EMS reform to legislators, health officials and the general public and the 360^0/365 Emergency Medical Care System website, symbol and logo was created to brand the initiative-*Right Care, Right Place, Right Time*.

DHSS and MFH provided ongoing support and leadership, and new funding for the effort was received from the Centers for Disease Control and Prevention through the DHSS Heart Disease and Stroke Prevention Program. The framework established for trauma care was determined appropriate to address stroke and ST-elevation myocardial infarction (STEMI). This overarching framework was the beginning of the TCD system. DHSS Director Jane Drummond called for the formation of a Steering Committee and Task Force to compile recommendations for the TCD system to address stroke and STEMI in an integrated fashion with trauma care in 2007.

This report represents the culmination of the Task Force's impressive work to determine next steps for the TCD system to address stroke and STEMI. These will be implemented over the next several years. Missouri's EMS leaders have played a critical role in this history and their persistence, hard work and dedication will continue to advance care for patients with "time critical" diagnoses.

This report is dedicated to the commitment, vision and passion of John William (Bill) Jermyn, DO, FACEP.

February 14, 1951 – May 15, 2008

"It is the right thing to do for Missouri. Let's get 'er done!"

That was our charge, our mission. But it was Dr. Bill Jermyn's vision.

Dr. Jermyn often said those words to our team. It was his call to action. And it soon became ours. Anyone who ever heard him utter his mantra, felt the impact.

Dr. Jermyn had an innate sense for innovation, a gift for leadership, and a rare ability to unify diverse voices around a common goal. He was driven by doing the right thing, even when it was unpopular or thought impossible. Through his determination and perseverance he united the Time Critical Diagnosis Task Force on a common mission.

This report is a testament and eulogy to Dr. Jermyn, an acknowledgement that one person's dedication and vision stands to make a difference for Missouri. He wasn't alone in the pursuit. He knew he needed partners for that, and he found them—the Governor, the Missouri Foundation for Health, the Missouri Department of Health and Senior Services, the State Advisory Council on Emergency Medical Services, The Vandiver Group, Inc., the Time Critical Diagnosis Task Force and, ultimately, the Missouri General Assembly, which passed the first legislation of its kind in the country (House Bill 1790) one day after he died.

I am no great chemist; I am no great person. I have accomplished no great deeds. I am only a trail blazer. I have tried to point the way. Others, the great of earth, shall probably come along, read these signs, and do the work…I am the trail blazer.

George Washington Carver

Dr. Jermyn led, and we had rigorous intellectual discourse and difficult debates, the kind born of deep conviction. But at the end of the day, we were better for it; and consensus grew due to the merit of his vision and our focus on doing the right thing in Missouri to improve patient care.

Dr. Jermyn and our team of dedicated, thoughtful professionals redefined patient-centered emergency medical care for stroke and STEMI for Missouri that we believe will make a difference and might spark other states to follow suit. Many will benefit from his vision.

This report will guide next steps in Missouri to take us closer to the vision—stroke and heart attack victims accessing appropriate care in a timely manner, recovering sooner with fewer problems and living longer.

Congratulations, Missouri. And thank you, Dr. Bill Jermyn.

We're getting 'er done.

TIME CRITICAL DIAGNOSIS SYSTEM

Recommendations to Advance Emergency Medical Care for Stroke and STEMI in Missouri

Time Critical Diagnosis System Task Force for Stroke and STEMI

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Acknowledgements

Appreciation is extended to the following individuals and the organizations they represented for contributing time, expertise and resources to serve as a member of the Time Critical Diagnosis Task Force for Stroke and STEMI. The result of their collective efforts is reflected in this state-of-the-art report that will effectively guide Missouri's emergency medical care efforts for years to come.

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Abbreviations and Acronyms

AHA	American Heart Association
AMI	Acute Myocardial Infarction
CDC	Centers for Disease Control and Prevention
CSC	Comprehensive Stroke Center
DANAMI-2	Danish Multicenter Randomized Trial on Thrombolytic Therapy Versus Acute Coronary Angioplasty in Acute Myocardial Infarction
DHSS	Missouri Department of Health and Senior Services
DPS	Missouri Department of Public Safety
ECG	Electrocardiogram
EMD	Emergency Medical Dispatch
EMS	Emergency Medical Service
FAST	Face - Arm - Speech -Time (Stroke Heroes Act FAST public education stroke symptom and action campaign in Massachusetts)
HELP	Helicopter Early Launch Program
MFH	Missouri Foundation for Health
MI	Myocardial Infraction
PAI	Pre-Arrival Instructions
PCI	Percutaneous Coronary Intervention
PPCI	Primary Percutaneous Coronary Intervention
PSC	Primary Stroke Center
RACE	Reperfusion in Acute Myocardial in Carolina Emergency Departments
STEMI	ST elevation myocardial infraction
TCD	Time Critical Diagnosis
rt-PA or t-PA	Recombinant tissue plasminogen activator

Executive Summary

Executive Summary

The Missouri Department of Health and Senior Services (DHSS) and the Missouri Foundation for Health committed to work in concert with partners to expand Missouri's emergency medical system in order to improve care for those who suffer from **stroke** and **ST-elevation myocardial infarction (STEMI)**. This expansion for stroke and STEMI care follows the methodology of trauma system development. Over 100 medical experts, leaders and emergency medical care providers from across the state came together to participate in the Time Critical Diagnosis (TCD) System Task Force to formulate recommendations for Missouri's system expansion. A number of issues made the Task Force's mission critically important. Heart disease, including STEMI, is the leading cause of death, and stroke is the third leading cause of death in Missouri; delayed treatment increases a patient's risk for death and disability; the trauma system model has been shown to improve patient outcomes; and improved outcomes for stroke and STEMI patients have been demonstrated in other states and regions using similar advanced approaches for stroke and STEMI care.

Stroke - *Sudden brain dysfunction due to a disturbance of cerebral circulation. The resulting impairments include but are not limited to paralysis, slurred speech, and/or vision loss. Ischemic strokes account for over 80 percent of all strokes and are typically caused by the obstruction of a cerebral blood vessel. Hemorrhagic strokes account for the remaining 20 percent of strokes and are typically caused by rupture of a cerebral artery. This report focuses on ischemic stroke.*

ST-Elevation Myocardial Infarction (STEMI) - *A myocardial infarction for which the ECG shows ST-segment elevation, usually in association with an acutely blocked coronary artery. A STEMI is one type of heart attack that is a potentially lethal condition for which specific therapies, administered rapidly, reduce mortality and disability. The more time that passes before blood flow is restored, the more damage that is done to the heart muscle.*

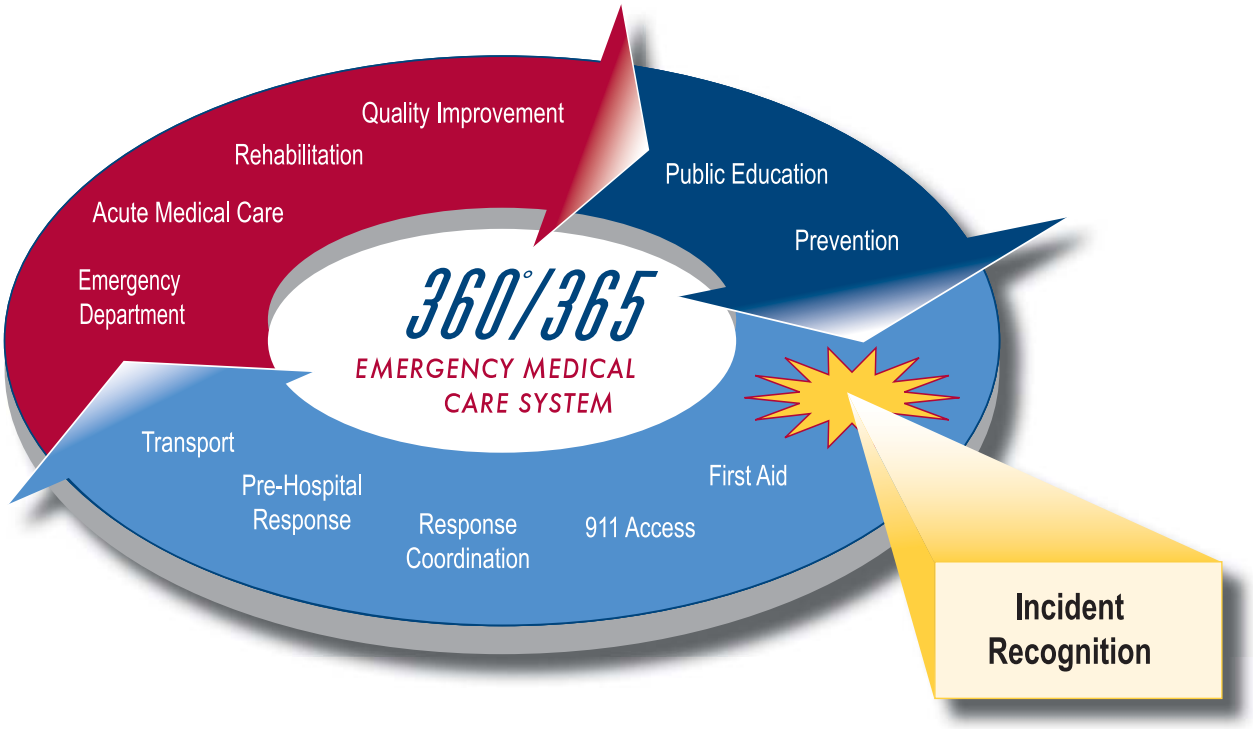
The Task Force has compiled the recommendations in this report as a first step toward achievement of the following goal: Improve health outcomes by establishing a TCD system for Missourians who have a stroke or STEMI. These recommendations focus on how a functional system can be created in Missouri to improve the transport, diagnosis and treatment for stroke and STEMI patients. The recommendations put forth an approach to the diagnosis and care of stroke and STEMI patients that integrates these two 'newer' time critical diagnoses with the established trauma care model. The unique and distinct issues inherent to stroke, STEMI and trauma care are each addressed while integrating common processes and approaches in order to improve the effectiveness of the entire system.

The TCD system provides a comprehensive statewide infrastructure with an inclusive approach towards emergency medical care for Missouri. The TCD system offers significant advantages. First, its approach to emergency medical care of STEMI and stroke focuses on timely assessment and transport to a facility that can provide definitive care within the comprehensive system network. Secondly, it gives the TCD system an intrinsic ability to grow and integrate approaches for currently unrecognized time critical conditions in the future beyond

today's accepted diagnoses and care practices for STEMI, stroke and trauma. In addition, the TCD system protocols, practices and infrastructure will evolve as future insights, technology and new practices dictate for continuing improvement in outcomes.

The TCD system represents a continuum of patient care, beginning with public education about prevention efforts, recognition of signs and symptoms and the importance of immediately seeking care. It then circles through the continuum of system components to emphasize evidence-based and best practices for incident recognition, first aid, 911 access, response coordination, pre-hospital response, transport, emergency department care, acute medical care, and rehabilitation. Finally, and equally important, it incorporates quality improvement processes throughout the system. The recommendations in this report address all but the prevention and rehabilitation elements in the continuum model shown below. (Figure 1).

Time Critical Diagnosis Continuum of Care (Figure 1)



System design for stroke and STEMI is inherently complex and poses challenges. Challenges include: assurance that the system supports the technical and evolving nature of care for stroke and STEMI; understanding and respect for the broad range of experiences, expertise, and perspectives of out-of-hospital and hospital providers represented within the TCD system; consideration of the distribution of, access to, and differing capacities of emergency medical service agencies and hospitals, all of which are influenced by regional, geographic and economic factors; and the competing interests of autonomous agencies working within an integrated system that may naturally create conflict. In spite of these challenges, the task force members united on the common ground that a system approach results in better health outcomes. To that end, the task force recommends the following for the **Time Critical Diagnosis System** to advance care for those patients with stroke and STEMI in Missouri:

Time Critical Diagnosis (TCD) System - *A coordinated, integrated group providing emergency medical care services using regionalization concepts to treat those diagnoses that are truly time critical. At this time there is clear evidence that severe trauma, acute ischemic stroke and STEMI outcomes can be improved by regionalized care incorporating specialty referral centers that are designated by an accrediting body. These conditions require quick assessment, diagnosis and treatment. The system focuses on timely recognition, assessment and transport to a facility that can provide definitive care within the comprehensive care network. Within the TCD concept, it is more intuitive to coordinate the three arms of the system under one banner rather than have three separate systems. This allows resource sharing and coordination at many different levels that decreases duplication and costs.*

OUT-OF-HOSPITAL SYSTEM COMPONENTS

A. 911-Emergency Medical Dispatch (EMD) and Response Coordination

1. The TCD system has a comprehensive 911 system for EMD that focuses on patient care.
2. The TCD system holds the local EMS agency accountable for the provision of EMD and Pre-Arrival Instructions (PAI) to the caller.

B. Pre-Hospital Response and Transport

3. The TCD system out-of-hospital providers have equipment and technology that is up to date, compatible and links between EMS and hospital services, and supports accurate patient assessment and recognition of stroke and STEMI symptoms.
4. The triage and assessment processes within the TCD system establish consistent state triage protocols and assessment tools that meet core standards and allow modification of state protocols and tools at a regional level to accommodate unique needs and variables within that area as long as core standards are met.
5. The TCD system supports early activation of hospital services, such as the cardiac catheterization laboratory or stroke team, from the field or as soon as personnel (field or hospital emergency department) identifies a patient with a stroke or STEMI.
6. The transport protocols within the TCD system strive to minimize time from symptom onset to definitive care; make transport determination at time of dispatch or first patient contact to minimize out-of-hospital time; determine type of transport (air or land) required based on the: a) condition of the patient, b) location of patient in relation to care facility that can provide definitive care, and c) local conditions (e.g., weather, terrain); employ all resources (e.g., mutual aid, air agreements) so most appropriate unit responds; and develop a process for early launch of helicopter service when needed.

7. The TCD system supports direct admission of stroke and STEMI patients to the hospital for provision of necessary services.

HOSPITAL SYSTEM COMPONENTS

C. Hospital Care for STEMI Patients

8. The TCD system designates different levels of hospital STEMI care and establishes regulations based on agreed-upon state criteria with attention to variables detailed in this report.

D. Hospital Care for Stroke Patients

9. The TCD system designates three different levels of stroke hospital care and establishes state regulations based on agreed-upon criteria addressing the variables detailed in this report for:
    i. Comprehensive Stroke Centers,
    ii. Primary Stroke Centers, and
    iii. Secondary Stroke Centers.
10. The TCD system evaluates incorporation of telemedicine into care of stroke patients for rural areas or regions without a designated stroke center.

E. Small and Rural Hospitals

11. The TCD system defines and maintains the role of small hospitals.

SYSTEM WIDE

F. Quality Improvement

12. The TCD system includes a statewide registry specific for STEMI and stroke with required reporting from out-of-hospital and hospital agencies within the TCD system.
13. DHSS creates and coordinates a congruent registry, database platform, and reporting process that does not cause redundancies or undue hardships on reporting agencies.
14. The TCD system uses nationally recognized data elements to define reporting requirements where available and practical.
15. The data management system supports the processes for quality improvement of the continuum of services and care, as well as patient outcomes for all out-of-hospital (dispatch, response coordination, EMS, transport) and hospital agencies within the TCD system.

G. Professional Education

16. The TCD system supports training and continuing education for out-of-hospital providers (EMD, EMS, transport personnel) to obtain needed competencies and improve current practices for stroke and STEMI care.
17. The TCD system supports training and continuing education of physicians and hospital staff to obtain needed competencies and improve current practices for stroke and STEMI care.

18. The TCD system updates training and continuing education regularly to incorporate changes made due to quality improvements, changes in evidence-based approaches and best practices, or improve areas of weak performance as indicated by quality improvement measures.

H. Public Education

19. The TCD system supports coordinated public education to inform patients about signs and symptoms, the importance of calling 911, the type of care needed, and facilities equipped to provide that care.

I. Payer

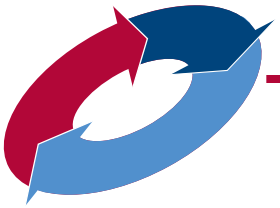
20. The TCD partners identify payment issues and problems that impact recommended care and desired outcomes for stroke and STEMI patients within the TCD system and begin discussions with health care plans and other key stakeholders to resolve.

J. System Administration

21. DHSS provides administrative oversight for the TCD system.
22. DHSS establishes an advisory body to guide TCD system implementation and oversight.
23. DHSS promulgates regulations to implement TCD system requirements.
24. DHSS leads efforts to evaluate the TCD system implementation and impact on desired outcomes.
25. DHSS assesses system components, compiles plans to address gaps where needed and seeks support to fill gaps in a collaborative manner with TCD system partners.

There is much work to be done to implement these recommendations and, as the task force has already done, the broad cross-section of partners and stakeholders also need to unite on the same common ground. Improving stroke and STEMI outcomes for Missourians through the TCD system is a unifying principle that supports the partners' respective missions and makes compelling the need to implement these recommendations. A collective investment of time, resources and commitment to systems development and integration from the agencies involved is essential. This investment, coupled with the innovations of the TCD system, will advance emergency medical care for Missourians. Moreover, it will serve as an example for the nation in progressive approaches to emergency medical care of time critical diagnoses.

Purpose and Process



Purpose and Process

The Task Force has compiled the recommendations in this report as a first step toward achievement of the following goal: Improve health outcomes by establishing a TCD system for Missourians who have a stroke or ST-elevation myocardial infarction (STEMI). These recommendations focus on how a functional system can be created in Missouri to improve the transport, diagnosis and treatment for stroke and STEMI patients. The recommendations put forth an approach to the diagnosis and care of stroke and STEMI patients that integrates these two 'newer' time critical diagnoses with the established trauma care model. The unique and distinct issues inherent to stroke, STEMI and trauma care are each addressed while integrating common processes and approaches in order to improve the effectiveness of the entire system.

> **"Goal: Improve health outcomes by establishing a TCD system for Missourians who have a stroke or ST-elevation myocardial infarction (STEMI)"**

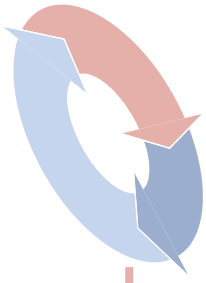
The TCD Task Force was composed of over 100 experts, clinicians, emergency health care providers and others representing emergency medical services, hospitals, statewide agencies and professional associations that constitute the comprehensive continuum of care and services for those impacted by stroke or STEMI. Meetings were open forums and participation was encouraged and sought from all interested parties. The Task Force met six times in structured and facilitated meetings to gain an understanding of the current and emerging practices for stroke and STEMI care, outline Missouri's current approaches, identify ideal approaches, review issues from various perspectives (e.g., patient, pre-hospital and hospital providers) and compile recommendations for each of the 10 system elements they identified. Task Force members also invested time outside of the meetings to research and discuss options for the recommendations.

Task Force members agreed to use the guiding principles shown below to focus discussion and ultimately craft the recommendations based on their purpose and common philosophy.

The Task Force presents the recommendations within this report to the Missouri Department of Health and Senior Services Director for consideration and further action. Rationale and evidence is provided for the recommendations where available. In addition, considerations for action steps to guide implementation have been included in this report. These were drawn from the TCD Task Force's discussions and the DHSS' past experiences and should be periodically updated based on implementation priorities and available supports. The recommendations for administration (page 35) detail infrastructure needs and key administrative actions the task force believes will advance Missouri's TCD system.

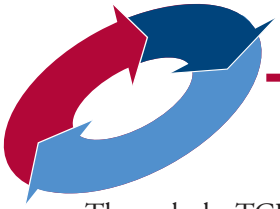
Guiding Principles

- Patient-centered care and improving patient care are the number one priorities.
- High-quality care should be safe, effective and timely.
- The system appropriately incorporates each component to create a functioning, cohesive system.
- A role for local community hospitals is maintained to assure critical access to health care.
- Missouri's system design decisions are supported by the evidence.
- Stakeholder consensus is achieved on the system's infrastructure.
- System design supports a population-based approach.
- System design supports increased operational efficiencies.
- Health outcomes and system implementation have a feasible evaluation mechanism to track impact of the changes.



Purpose and Process

Background



Background

Through the TCD system, STEMI and stroke care pathways are integrated with the well-established model for care of the trauma patient. Accordingly, the emergency medical care system becomes an expandable umbrella system for emergency medical conditions that currently encompasses trauma, STEMI, and stroke. As such, victims of STEMI and stroke in Missouri will benefit from more efficient and effective processes for receiving the appropriate care in a timely fashion from the most appropriate source. The TCD system will evolve to accommodate future advances in technology and treatment for these and other conditions that warrant time critical care and diagnosis.

Magnitude of Stroke and STEMI

To begin, stroke (both ischemic and hemorrhagic) is the third leading cause of death and a major cause of disability in the United States and Missouri. There were a total of 3,243 deaths due to stroke among Missouri residents reported in 2006.[1] Due to its higher stroke death rate (55.8 per 100,000), Missouri ranked low (40 out of 52) compared to other jurisdictions (includes District of Columbia and Puerto Rico) in 2004 for age-adjusted stroke death rate (51.1 per 100,000 total United States average).[2] On a national scale, roughly 780,000 people experience a new or recurrent stroke each year.[2] Of this group, approximately 23 percent will die, 15 percent to 30 percent will be permanently disabled, and 20 percent will require institutionalization during the first three months post-stroke.[2, 3] An estimated 87 percent of all strokes are of the ischemic type.[2]

Historically, rural populations have faced unique challenges in access to timely definitive stroke care.[4] Although intravenous **thrombolysis (lytic therapy)** is the only approved therapy for acute ischemic stroke, less than 5 percent of patients receive it.[5, 6, 7]

Both nationally and in Missouri, heart disease, including the burden from STEMI, is the leading cause of death.[8] In Missouri, 26.9 percent of deaths in 2006 were due to heart disease.[1] Missouri ranks even lower (45 out of 52) in 2004 age-adjusted coronary heart disease death rates (Missouri - 169.5 per 100,000 compared to total United States average - 150.2 per 100,000) compared to stroke death rates by state,[2] which underscores the seriousness of this problem in this state. There were a total of 14,647 heart disease deaths reported for Missouri residents

Lytic Therapy (fibrinolysis/ thrombolysis) - *"Clot buster" drug therapy used to dissolve clots blocking flow in a blood vessel. It refers to drugs used for that purpose, including recombinant tissue plasminogen activator. This type of therapy can be used in the treatment of acute ischemic stroke and acute myocardial infarction.*

Myocardial Infarction - *A myocardial infarction or heart attack is death of or damage to part of the heart muscle due to an insufficient blood supply. Heart attacks occur when one of the coronary arteries that supply blood to the heart muscle is blocked. Blockage is usually caused from a buildup of plaque (deposits of fat-like substances) due to atherosclerosis. If a plaque deposit tears or ruptures, a blood clot may form and block the artery, causing a heart attack.*

Reperfusion - *The process of restoring normal blood flow to an organ or tissue that has had its blood supply cut off, such as after a myocardial infarction.*

Door-to-needle time - *The time from arrival at the hospital door to initiation of lytic therapy to restore blood flow in an obstructed blood vessel.*

Door-to-balloon time - *The time from arrival at the hospital door to PCI balloon inflation for restoring blood flow in an obstructed coronary artery in the cardiac catheterization lab. This term is commonly abbreviated as D2B.*

Percutaneous Coronary Intervention (PCI) - *Procedure used to open or widen narrowed or blocked blood vessels to restore blood flow supplying the heart. PCI can reduce symptoms of chest pain or reduce damage done to the heart by a heart attack. Usually, the blood vessels are accessed through the skin over the leg or arm arteries. A small balloon on a catheter is delivered through the system of blood vessels into the area of blockage in the heart and then inflated to open the blocked artery. Devices such as a stent or scaffold may be subsequently deployed at the blockage site to help keep the area from closing up again.*

in 2006.[1] In 2008, an estimated 770,000 Americans will have a new coronary attack, and about 430,000 will have a recurrent attack. It is estimated that an additional 175,000 silent first **myocardial infarctions (MI)** occur each year.[2]

In parallel to stroke, rural populations also face challenges in access to timely definitive STEMI care. According to studies around the nation, currently roughly 30 percent of eligible STEMI patients do not receive **reperfusion**, or artery-opening therapy, and of those that do, fewer than 50 percent of patients have **door-to-needle time** for fibrinolysis within 30 minutes and fewer than 40 percent of patients have **door-to-balloon time** within the recommended 90 minutes for **Percutaneous Coronary Intervention (PCI)**, the preferred therapy for STEMI. [9, 10, 11]

Time Critical Nature of Stroke, STEMI, and Trauma

As with the management of the trauma patient, management of the stroke and STEMI patient is also time-dependent. The shorter the time between signs and symptoms to definitive care, the better the outcomes.

Stroke

Fundamental to the TCD concept for acute ischemic stroke is the principle that prompt treatment leads to improved outcomes. Acute ischemic stroke accounts for 87 percent[2] of all strokes and is the focus of this report. At the present time, research has clearly shown that prompt treatment for acute ischemic stroke reduces disability. Intravenous thrombolysis with **recombinant tissue plasminogen activator (t-PA)** is the only Food and Drug Administration-approved therapy for acute ischemic stroke. However, only a very small percent of ischemic stroke victims get definitive care and treatment within the recommended time of 180 minutes. In fact, Schumacher et al.[5] found a mean thrombolysis rate of only 1.12 percent in their retrospective, observational cohort of 366,194 hospitalizations for ischemic stroke management. One of the key explanations for this finding was patient arrival at the hospital beyond 180 minutes of stroke onset, in addition to mild or rapidly improving symptoms.[5, 6, 7]

Why is treatment of acute ischemic stroke time critical? Evidence shows that patients treated with t-PA within the first 90 minutes of the accepted 180 minute window from stroke onset have increased odds of improvement at 24 hours and improved three-month outcomes.[12] These benefits of complete or nearly complete neurological recovery were also found to be similar at one year after stroke.[13] On the other hand, patients treated after 90 minutes from symptom onset have poorer outcomes and a graded response to t-PA with reduced recovery. Essentially there is less benefit and more hemorrhages with delayed treatment even if treatment

still falls within the current window of 180 minutes.[12] Accordingly, the earlier patients are treated with t-PA, the higher the odds of a good outcome.[12, 14] Based on these models, it is crucial that patients be treated as quickly as possible even within the currently accepted time frame of 180 minutes (or three hours) in order to improve outcomes.[14]

While current research mainly underscores the time critical nature of diagnosis and treatment for acute ischemic stroke, the focus of this report, future research may also support a time critical aspect to the diagnosis and management of hemorrhagic stroke. As such, the TCD System recognizes this evolving nature of medicine and supports any advances in management for hemorrhagic stroke, as well as other time critical conditions that will require timely diagnosis and treatment.

Recombinant Tissue Plasminogen Activator (t-PA, also known as rt-PA) - *A thrombolytic (clot-dissolving) agent the goal of which is to destroy the thrombus (or clot) within the blood vessel by stimulating fibrinolysis (clot breakdown) to allow restoration of blood flow.*

STEMI

Similar to stroke, STEMI is also time critical in nature. Fundamental to the TCD concept for STEMI is the principle that reducing time to treatment improves outcomes. For example, research has demonstrated that time from onset of STEMI symptoms to treatment affects outcomes at one year.[15] In fact, each 30-minute delay has been found to be associated with reduced heart function at discharge, increased relative risk for mortality at one year and an overall increase in one-year mortality of 7.5 percent.[15] In addition, **symptom-onset-to-treatment time** greater than four hours has been found to be an independent predictor of one-year mortality; thus, symptom-onset-to-treatment time is an important factor related to mortality.[15, 16]

Symptom onset-to-treatment time - *The time from symptom onset to initiation of therapy to restore blood flow in an obstructed blood vessel.*

Additionally, door-to-balloon times also significantly impact risks for death. According to the National Registry of Myocardial Infarction-2 study, there is a direct relation between shorter door-to-balloon (or cardiac catheterization) times and lower adjusted risks of mortality.[17] In fact, some studies have found that in-hospital mortality is strongly associated with time to primary PCI from presentation at the hospital, or door-to-balloon time regardless of time from symptom onset to presentation or baseline risk of mortality. This emphasizes the importance of also shortening door-to-balloon times for all patients.[18] Moreover an analysis of four trials of primary PCI for STEMI that looked at clinical outcomes at 30 days, stratified by door-to-balloon times, found lower rates for death and major adverse cardiovascular events for door-to-balloon times less than 90 minutes.[19] Long-term survival is clearly impacted by delays in door-to-balloon times in high risk patients and in patients presenting early after symptom onset.[20]

Given the direct relationship between treatment delays for STEMI and higher morbidity and mortality rates, it is imperative that the TCD system focus on reducing the time to treatment from both the time of symptom onset and patient arrival at hospital in order to reduce death and disability for STEMI patients.

Trauma

Finally, the organized trauma systems approach to the severely injured trauma patient made way for huge strides in the advancement of care for the trauma population, improving morbidity and mortality. Studies of outcomes following trauma system implementation demonstrated a 50 percent reduction in preventable death rate, a decrease in delays to disposition from 54 percent to 7 percent, and a decrease in cases of sub-optimal care from 32 percent to 3 percent. [21, 22]

Trauma center designation and accreditation through a formal system (i.e., meeting criteria for designated levels of care) was shown to improve patient and hospital outcomes compared to a voluntary system; similarly, development of a formal regional system was shown to improve regional outcomes. [23, 24, 25] In fact, regional trauma systems with designated centers have been found to use resources more efficiently with cost savings realized through decreased length of stay, decreased intensive care unit length of stay, and overall decreased hospital costs. [23, 24, 25] Notably, the Institute of Medicine recommends development of geographically organized and interconnected systems of care. [26]

The trauma system development experience indicates that it has been one of acceptance over time; as the benefits were seen, such as a relationship between trauma system implementation and reduced mortality, there was acceptance of the idea that hospitals with extensive experience with injured patients can offer more appropriate care than those receiving occasional trauma patients. [27, 28, 29] Importantly, a latent period occurred before the reduction in mortality was seen. This latent period suggests a need for a maturation period during which the system stakeholders optimize protocols, inter-hospital transfer agreements, quality improvement processes, and other components. [27, 28, 29]

> **“The history of trauma system development provides the long-term experience and results that corroborate the benefits of an organized, systemic approach in the management of a time critical diagnosis.”**

In summary, ample evidence attests to the time critical nature of both stroke and STEMI. The history of trauma system development provides the long-term experience and results that corroborate the benefits of an organized, systematic approach in the management of a time critical diagnosis. Accordingly, the TCD system enables timely, appropriate care of the stroke and

STEMI patient populations by adapting the methodology and model for trauma care, the historical time critical entity with proven outcomes.

Other States' Stroke and STEMI Initiatives and Impact

Several states have initiatives in place for stroke, STEMI, or both. In terms of advances in stroke care, North Carolina, New York, Massachusetts, New Jersey, Illinois, Texas, Alabama, and Florida are among those states with programs in various stages of development for improving stroke care. Like the TCD system for Missouri, these programs borrow the basic tenant of timely triage of the patient to the appropriate level of care from the trauma care system.

Studies of regionalized stroke systems have shown some key benefits that include improved access to neurologists, especially for rural areas.[30] In addition, data show decreased time from symptom onset to emergency room arrival, improved door to treatment time, improved paramedic diagnostic capability, and increased use of t-PA especially among community hospitals with the establishment of stroke centers.[31] Though long-term data beyond one year are not yet available, the medical community anticipates reduced stroke mortality and disability in the long-term with implementation of these systems of care. For rural communities or areas without stroke centers in particular, regional network models and telemedicine availability have demonstrated safe and improved t-PA usage for stroke and access to stroke care expertise.[4, 32] The regional network model can realistically be used to provide region-specific care as part of a larger state-based model.

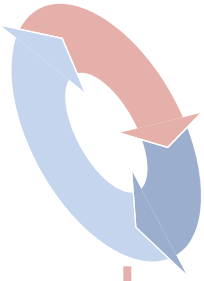
In the same vein, many states have initiatives directed at improving STEMI care. Among these states are Maryland, Massachusetts, North Carolina, Pennsylvania, Georgia (Atlanta), Oregon (Portland), Minnesota, California, Florida, Texas, and Michigan. Like stroke, these systems have also been modeled on the trauma system concept. Notably, studies of regionalized systems of STEMI care have also shown benefits. For example, in the Reperfusion in Acute Myocardial Infarction in North Carolina Emergency Departments (RACE) study, the system approach for STEMI resulted in a decrease in the proportion of patients not receiving reperfusion or artery-opening therapy, an increase in the proportion of patients receiving primary PCI and improved reperfusion times.[33] Additionally, the DANAMI-2 (Danish Multicenter Randomized Trial on Thrombolytic Therapy Versus Acute Coronary Angioplasty in Acute Myocardial Infarction) study was actually terminated early due to a 40 percent lower incidence of recurrent myocardial infarction, disabling stroke, or death at 30 days in patients transferred to a primary PCI center from a referral center for PCI compared to those that were not transferred and instead underwent only fibrinolysis. [17, 34]

Similarly, the experience of the Abbott Northwestern Hospital System for inter-hospital triage of STEMI patients found that patients transferred from community centers to regional PCI centers via well-defined methodology had outcomes similar to those taken directly to a PCI center.[35] Essentially combining the Abbot experience with that of the Mayo Clinic, investigators argue that establishment of a system is feasible, that the transport of STEMI patients in the acute phase can be safely done, that standardized protocols are important, that coordinated transport plans play an important role, and that there is a need for public education of the importance of early access into the system.[9]

When considering timely application of PCI, studies have shown that the strategies with the strongest evidence for shorter door-to-balloon treatment times include the effective use of pre-hospital **electrocardiogram (ECG)**, the use of a single call system, activation of catheterization laboratory by emergency medicine physicians, policies for catheterization team arrival, clinical pathway implementation, and performance data monitoring and feedback.[36] Likewise, in efforts to move care forward, both Gross et al.[37] and LeMay et al.[38] found that paramedic diagnosis of STEMI and direct activation of and triage to primary PCI was associated with a greater percentage of patients achieving less than 90- minute door-to-balloon times, higher rates of PCI, and lower in-hospital mortality. As such, several locations, such as Boston, have moved ECG interpretation and cardiac catheterization lab activation forward to the pre-hospital providers. For Missouri, the TCD system embraces the adoption of established and emerging best practice options for STEMI response and care to improve outcomes.

Electrocardiogram (ECG) - *A recorded tracing of the electrical activity of the heart. The heart rate, heartbeat regularity, size and chamber position, presence of any prior heart attack, current injury and the effects of drugs or devices i.e., pacemaker can be determined. An abnormal ECG pattern is seen during a heart attack because damaged areas of the heart muscle do not conduct electricity properly.*

In summary, the experiences and results from numerous other states demonstrate both the feasibility of and actual and potential benefits from a systematized approach to stroke and STEMI care similar to that for trauma patients. The TCD system, however, further advances the concept and goes one step further to create an umbrella system for the evolving care of the stroke, STEMI, trauma, and other TCD patients in the future. Currently, though other states are working on an organized trauma system-type approach for STEMI and/or stroke, no state has approached them on such an integrated systems level as represented by the Missouri TCD system.



Background

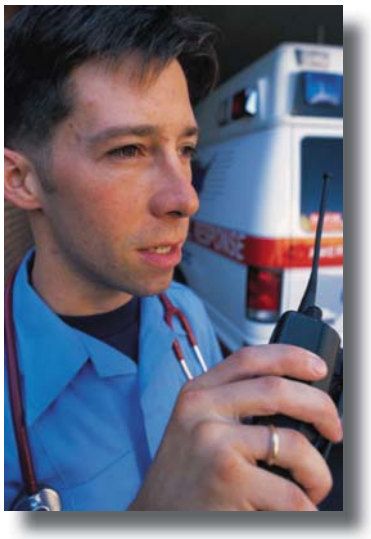
Recommendations

Time Critical Diagnosis System Recommendations

Advancing Emergency Medical Care for Stroke and STEMI

Out-of-Hospital System Components

911-Emergency Medical Dispatch (EMD) and Response Coordination



Emergency medical services operate at the intersection of health care, public health and public safety and therefore have overlapping roles and responsibilities. This can lead to fragmentation in delivery of 911 services when the local agency that performs this service (including fire, police, emergency management and emergency medical services) have different authority, training, equipment, reporting procedures, staffing, oversight and jurisdictional lines.[39]

It is critical that there be rapid and appropriate EMD and Pre-Arrival Instructions (PAI) when a call is received regarding a patient that is having a stroke or STEMI. A comprehensive and coordinated 911 system supports a timely and appropriate acute medical response. As such, EMS agencies are better staffed to provide appropriate EMD and PAI for calls regarding suspected cases of stroke or STEMI.

Recommendations:

1. The TCD system has a comprehensive 911 system for EMD that focuses on patient care. The Missouri Department of Public Safety (DPS) and DHSS should work together to lead this development with shared goals and criteria.
2. The TCD system holds the local EMS agency accountable for the provision of EMD and PAI to the caller. Specifically, the authority and responsibility for medical 911 dispatches should be vested with the local EMS agency. This accountability should be a part of the comprehensive 911 system that is collaboratively designed by DPS and DHSS.

Suggested Actions:

- DHSS and DPS meet to determine resources and process to create a comprehensive 911 system for EMD for Missouri.
- DHSS and DPS jointly establish a work group to compile recommendations for a comprehensive 911 system for EMD.
- DPS evaluates the proportion of jurisdictions where EMS agencies, compared to non-EMS agencies, are accountable for the provision of EMD and PAI.
- In areas where EMD and PAI are provided by non-EMS agencies, the work group identifies barriers and issues to transfer this authority to EMS agency.
- Incorporate solutions to these barriers and issues in comprehensive 911 recommendations and plan for EMD.
- Review current EMD and PAI protocol for stroke and STEMI patients; update, if needed; and determine training needs.

Supporting Evidence:

- "Activation of the 911 system by patients or other members of the public is strongly supported because it speeds the treatment of stroke. 911 dispatchers should make stroke a priority dispatch." [13]
- Research in North Carolina[40] finds that: "the development of [a] statewide telecommunication training program to improve knowledge and care for suspected stroke or MI is needed in North Carolina. Dispatching for stroke and MI could be enhanced by requiring all communication centers to be EMD-certified and by creating consistent and standard dispatching practices across the state, using triage algorithms. Implementing these changes could improve rapid response and care for acute stroke and MI patients." Although all suggestions may not be applicable to Missouri, they emphasize the need to restructure 911 and EMD to accommodate the time critical nature of stroke and STEMI.
- The National Heart Attack Alert Program Coordinating Committee via the Access to Care Subcommittee (1995)[41]:
  - Found that "[t]he impact of well-trained, medically managed EMDs on the early care of potential acute MI patients is believed to be beneficial. However, standards for emergency medical dispatching vary widely across the nation."
  - Made "a number of recommendations regarding the use of medical dispatch protocols, provision of dispatch life support, EMD training, EMD certification, and EMD quality control and improvement processes."
  - Made further recommendations that "cover the 'chain of survival' concept, universal and enhanced 911, emergency medical dispatching, ground ambulance specifications, automated external defibrillators, advanced life support coverage, medical direction, 12-lead electrocardiograms, and prehospital thrombolysis."

- According to JV Dunford, "Along with other essential personnel that make up the fabric of the public safety net, emergency medical dispatchers have now become essential to the provision of time-critical skills and compassion for perceived medical emergency."[42]

Pre-Hospital Response and Transport

Similar to the management of the trauma patient, the systems approach for stroke and STEMI patients is transitioning from thinking in terms of hospital door-to-treatment times to minimizing time from actual event onset to treatment.[16] As such, pre-hospital response and transport play a crucial role in identifying the time-critical patients and delivering them to the appropriate care in the quickest time possible. Accordingly, the TCD system strives to create an efficient process for patient identification, triage, and transport.

Recommendations:

1. The TCD system out-of-hospital providers have equipment and technology that:
    a. Is up to date and compatible between EMS and hospital,
    b. Links effectively between pre-hospital and hospital levels, and
    c. Supports accurate patient assessment and recognition of stroke and STEMI symptoms (e.g., 12-lead ECG capability, use of new equipment that supports accurate and timely triage and assessment).
2. The triage and assessment processes with the TCD system:
    a. Establish consistent state triage protocols and assessment tools that meets core standards, and
    b. Allow modification of state protocols and tools at a regional level to accommodate unique needs or variables within that area as long as core standards are met.
3. The TCD system supports early activation of hospital services, such as the catheterization laboratory or stroke team, from the field or as soon as personnel (field or emergency department) identifies a patient with stroke or STEMI.
4. The transport protocols within the TCD system:
    a. Strive to minimize time from symptom onset to definitive care;
    b. Make transport determination at time of dispatch or first patient contact to minimize out-of-hospital time;
    c. Determine type of transport (air or land) required based on the:

i. Condition of the patient, (e.g, time elapsed from time of symptom onset or when patient was last known well),
ii. Location of patient in relation to care facility that can provide definitive care, and
iii. Local conditions (e.g., weather, terrain).

d. Employ all resources (e.g., mutual aid, air agreements) so most appropriate unit responds and develop a process for early launch of helicopter service when needed (i.e., Helicopter Early Launch Program [HELP]).

5. The TCD system supports direct admission of stroke and STEMI patients to the hospital for provision of necessary services for definitive care (e.g., catheterization laboratory services for STEMI patients, administration of thrombolytic therapy for patients with acute ischemic stroke).

Suggested Actions:

- DHSS convenes and facilitates an out-of-hospital TCD work group to compile, adopt or adapt triage protocols and assessment tools in order to rapidly and accurately identify stroke and STEMI patients.
- The work group assesses equipment needs and provides guidelines on appropriate equipment for both out-of-hospital and hospital agencies to support and transmit or communicate this assessment to hospital.
- The work group writes general transport protocols and algorithms for minimizing the time between onset of symptoms and transport to facility that can provide definitive care.
- The work group identifies issues that impact patient transport in the state and compiles general guidelines for use by out-of-hospital and hospital agencies to address such issues as mutual aid agreements, air agreements and diversion policies that would impact agencies' abilities to provide timely transport to the appropriate facility.
- The work group reviews existing training and continuing education requirements for out-of-hospital agency staff and makes recommendations for changes, as needed, for stroke and STEMI patient care.

Supporting Evidence:

- It has been recommended "[t]hat EMS personnel begin the initial management of stroke in the field" using well-established guidelines, and "the development of stroke protocols to be used by EMS personnel is strongly encouraged."[13]
- "Patients should be transported rapidly for evaluation and treatment to the closest institution that provides emergency stroke care…In some instances, this may involve air evacuation.

EMS personnel should notify the receiving hospital's emergency department so that the appropriate resources may be mobilized."[13]

- According to Jollis et al., "Another barrier to rapid care for patients with STEMI arises from the lack of standardized protocols for treatment" and that "substantial improvement in time to mechanical reperfusion was associated with…the standardization of protocol-driven decision making algorithm."[43]
- Jollis et al. further state, "Obtaining pre-hospital electrocardiograms (ECG) for patients with symptoms of cardiac ischemia is associated with faster treatment" and "a reduction of at least 10 minutes in door-to-needle times in patients receiving fibrinolysis." [43]
- Jollis et al. also state that "[p]re-hospital ECG's can further affect rapid delivery of care if EMS personnel are trained to recognize ST-segment elevation and immediately activate the catheterization laboratory." [43]
- Strongly associated with reduced door-to-balloon times are early, one call activation of the catheterization laboratory [43, 44, 45] and transmission of ECG data from EMS personnel in the field. [44, 45]
- Jacobs et al. concluded: "To achieve the ideal system for EMS, a complete understanding of the technological and financial barriers to acquiring pre-hospital ECG's will need to be obtained because equipment costs and reliability of data transfer have been major barriers to widespread implementation." [9]

Hospital System Components

Replicating the trauma center designation process, the TCD system would create different levels of hospital-based care for both stroke and STEMI patients. The center designation criteria would be clearly established in state regulations. While the designation process for trauma, stroke and STEMI centers will have similarities, there are distinct differences for these three conditions, and the requirements will be accordingly modified to provide the respective care needed.

If they want to participate, hospitals voluntarily select which level of care they wish to provide. DHSS would approve center designation for hospitals that meet the criteria to be detailed in state regulations.

Trauma, stroke and STEMI care levels are independent designations. A hospital may choose one, two, three or none of the care level designations.

"Trauma, stroke and STEMI care levels are independent designations. A hospital may choose one, two, three or none of the care level designations."

Hospital Care for STEMI Patients

In keeping with the concept that those centers which care most frequently for trauma patients have the greatest expertise and ability to adapt to the rapidly advancing best practices for trauma care, the STEMI medical community likewise finds that the STEMI population is best served by designated centers and leveled care. At this time, there is no national certification process for health care providers to provide STEMI care.

Recommendation:

The TCD system designates different levels of hospital STEMI care and establishes state regulations based on agreed-upon criteria. Variables the STEMI center designation criteria should address include, but are not limited to:

i. Hospital equipment, technology and service capacity to support STEMI care (e.g., number of percutaneous coronary interventions (PCIs) conducted in a given time frame, availability of surgical backup);
ii. Ability to meet time and performance standards for delivery of specified services (e.g., door to catheterization [balloon] time);
iii. Diversion avoidance policy in regard to TCD patients;
iv. Time frame for availability of services (e.g., 24 hours a day for seven days a week);
v. Hospital protocol for a) pre-hospital and STEMI team communication, b) care and coordination, and c) when appropriate, rapid transfer from non-PCI facility to PCI facility;
vi. Institution involvement in clinical research related to heart disease or STEMI;
vii. Hospital capacity to support STEMI patient care and discharge transition back to care and oversight by their primary care physician in either home or referral setting;
viii. Ability to report data and maintain quality improvement process as required for given center designation; and
ix. Credentials and abilities of personnel to perform TCD protocol and provide care services.

Suggested Actions:

- DHSS convenes and facilitates a STEMI work group to identify center designation criteria and requirements for hospitals that address variables listed in the Hospital Care for STEMI Patients Recommendation.
- DHSS promulgates regulations on STEMI center designations based on the requirements identified by the work group.

- The work group advises DHSS on designation process and procedures.
- The work group identifies the best approach to inform hospitals and the health care community about the TCD system and designation process and helps, as needed, to improve understanding of system and designation process.
- The work group reviews current training and continuing education requirements for hospital staff and makes recommendations for changes, as needed for care of STEMI patients.

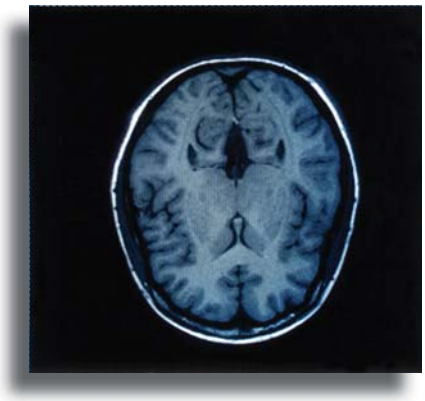
Supporting Evidence:

- Waters et al.[17] recommends:
  - "The designation of centralized Acute Myocardial Infarction (AMI) centers located within a reasonable distance from all referral community hospitals; centers should have proven expertise in performing primary PCI."
  - "The development of AMI teams at community hospitals that can accurately identify STEMI patients eligible for primary PCI, correctly administer preferred initial medications, and rapidly transfer patients directly to the AMI center."
  - "The central coordination and management of care at community and tertiary hospitals."
  - "The implementation of quality monitoring to continually assess processes of care and outcomes for patient transferred for primary PCI."
  - "The creation of clinical research networks to extend AMI research into community hospitals and provide a structure to prospectively evaluate transfer strategies and adjunctive pharmacologic regimens."
- Bradley et al.[36] found "[r]easonable evidence also exists for":
  - Establishing single-call systems for catheterization laboratory activation;
  - Setting expectations for catheterization lab team availability/response; and
  - Having organizational environments to lead cultural change related to STEMI care and improving door-to-balloon times.
- Jacobs et al.[9] summarized recommendations regarding development of systems of care for STEMI to include:
  - Standardized point-of-entry protocols;
  - Inclusive organization of "STEMI referral hospitals" and "STEMI receiving hospitals;"
  - Pre-hospital ECG diagnosis of STEMI, emergency department notification, and catheterization laboratory activation; and
  - Participation in national data collection and quality improvement programs.

- She further stated: "Establishment of regional systems of care that include pre-hospital EMS protocols and emergency inter-hospital transfer agreements between STEMI referral and receiving hospitals will improve access to primary PCI and thereby improve outcomes."

- LeMay et al.[38] found:
  - "Recommended guidelines for door-to-balloon times were achieved more often when patients were identified in the field by trained paramedics and transported directly to a designated center for primary PCI than when patients were evaluated by physicians in emergency departments."
  - "Patients with ST-segment elevation myocardial infarction who are triaged in the field by trained paramedics have significantly shorter door-to-balloon times than do patients who are first evaluated in the emergency department according to the usual standard of care."
  - "With the application of a city wide primary PCI program, in-hospital mortality during the first year of operation fell to less than 5%."

Hospital Care for Stroke Patients



In keeping with the concept that centers, which care most frequently for severe trauma and STEMI patients, have the greatest expertise and ability to adapt to the rapidly advancing best practices care, the stroke medical community likewise believes that the stroke population is best served by designated stroke centers and leveled care.

There is a national process for recognizing health care providers that meet established criteria and are certified as a Primary Stroke Centers (PSC).[46] This process is managed by The Joint Commission, which has certified 10 providers in Missouri as Primary Stroke Centers. Recommendations have also been made for Comprehensive Stroke Centers (CSC)[47] but there is not yet a national process for certification at this level.

Recommendations:

1. The TCD system designates three different levels of stroke hospital care and establishes regulations based on agreed-upon state criteria. The three levels of stroke care centers recommended are:

   Level I. Comprehensive Stroke Centers,
   Level II. Primary Stroke Centers, and
   Level III. Secondary Stroke Centers.

   Variables the center designation criteria and regulations should address include, but are not limited to:

i. Hospital equipment, technology and service capacity to support stroke care;
ii. Ability to meet time and performance standards for delivery of specified services (e.g., door-to-needle time for thrombolytic therapy);
iii. Time frame for availability of services (e.g., 24 hours a day for seven days a week);
iv. Diversion avoidance policy in regards to TCD patients;
v. Hospital protocol for 1) pre-hospital and stroke team communication, 2) care and coordination, and 3) when appropriate, rapid transfer from facility without stroke care capacity to facility with stroke care capacity;
vi. Hospital capacity to support stroke patient care and discharge transition back to care and oversight by their primary care physician in either home or referral setting;
vii. Institution involvement in clinical research related to stroke;
viii. Ability to report data and maintain quality improvement process as required by given center level designation; and
ix. Credentials and ability of personnel to perform TCD protocol and provide care services for stroke patients.

2. The TCD system evaluates the incorporation of telemedicine in care of stroke patients for rural areas or regions without a designated stroke center.

Suggested Actions:

- DHSS convenes and facilitates stroke work group to identify center designation criteria and requirements for hospitals that address those variables listed in first recommendation for Hospital Care for Stroke Patients.
- DHSS promulgates regulations on stroke center designations that incorporate those criteria and requirements.
- The work group advises DHSS on the designation process and procedures.
- The work group identifies a means to inform the hospital and health care community on the TCD system and designation process in a collaborative manner with appropriate partners.
- The work group reviews current training and continuing education requirements for hospital staff and makes recommendations for changes, as needed for care of stroke patients.
- The work group works with selected experts to compile a white paper or more specific recommendations on how to provide care to stroke patients in rural areas or regions that do not have designated stroke centers.
- The work group makes recommendations for how to incorporate and effectively use telemedicine as a tool within the TCD system to improve access to definitive care of stroke patients.

Supporting Evidence:

- The following guidelines have been made for the early management of adults with ischemic stroke: [13]
  - "The creation of a PSC (primary stroke center) is strongly recommended. The organization of such resources will depend on local variables."
  - "The design of several community-based PSC's that provide emergency care and that are closely associated with a CSC (comprehensive stroke center), which provides more extensive care, has considerable appeal. The development of CSC is recommended."
  - "Certification of stroke centers by an external body, such as JCAHO [Joint Commission on Accreditation of Healthcare Organizations, currently The Joint Commission] is encouraged."
  - "For patients with suspected stroke, EMS should bypass hospitals that do not have resources to treat stroke and go to the closest facility capable of treating acute stroke."
  - "Telemedicine can be an effective method to provide expert stroke care to patients in rural areas. Additional research and experience on the usefulness of telemedicine is encouraged."
- Schumacher et al.[5] found that high-volume stroke hospitals were more likely to treat patients with thrombolysis than those with lower volumes. In fact, "the odds for using thrombolysis decreased with decreasing mean annual number of stroke patients treated at a hospital." These findings support the need for designated, leveled centers of care for stroke patients.
- Results from two Minnesota stroke care surveys show the state's progress in EMS recognition of stroke as an emergency event.[48] However, the surveys also raise concerns about the differences in capacity and practice between small rural hospitals and large metropolitan hospitals for stroke care.

Small and Rural Hospitals

Rural communities in both Missouri and across the country are faced with a lack of access to specialists and trained clinicians on a 24 hours a day, seven days a week basis to provide timely definitive care. For example, Jacobs, et al., [9] found that both Illinois and North Carolina had significant variability in the availability of key diagnostic technologies, programs, and personnel for acute stroke assessment and treatment. Faced with these challenges, small hospitals have begun to organize EMS assessments and t-PA protocols to provide the best stroke care possible. In the same vein, Abbott Northwestern Hospital and the Mayo Clinic in Minnesota have demonstrated that regional systems for STEMI care that incorporate community, small, and rural hospitals are feasible. [9]

Rural and small hospitals provide quality and essential services in an accessible and cost-efficient manner for communities, particularly those in rural areas. A TCD system must recognize the role these hospitals play (generally those that are not designated as a stroke or STEMI center), use their services when appropriate for the timely provision of definitive care, and maintain the availability of their services for the community.

Recommendation:

The TCD system defines and maintains a role for small hospitals.

Suggested Actions:

- The advisory body and/or existing work groups:
  - Evaluate the impact of the center designation process and make modifications as appropriate on the transport protocol for EMS services in rural areas or areas where there are no designated centers.
  - Define role for small hospitals (non-designated centers) that may be by-passed and advocate the value they play in health care delivery system. Review protocols to be developed to make sure this role is not compromised.

Supporting Evidence:

- Okon et al.[4] maintain that a stroke network could enhance care and thus improve outcomes in rural and frontier regions.
- Henry et al.[35] conclude that rapid transfer of STEMI patients from a non-PCI center with as few as 10 beds to a PCI center that is up to 210 miles away was safe and effective using standardized protocols and an integrated transfer system.
- Jacobs et al.[9] conclude that "our goal should be nothing less than implementation of urban, suburban, and rural systems of care for patients with STEMI that allow the timely delivery of the appropriate life-saving therapies to all patients in all places." They also conclude that the Abbott Northwestern and Mayo Clinic experiences solidify the feasibility of establishing integrated systems of collaborative care that reduce barriers between different hospitals and groups of health care professionals.

SYSTEM WIDE

Quality Improvement

As with any system, data provides the foundation for continual evaluation and performance improvement and serves as a juggernaut for change within a system. Without the appropriate accommodations for data collection and compilation, a system lacks situational awareness. Once data is collected and compiled, those results require analysis and dissemination that ultimately bring improvement. Accordingly, the TCD Task Force makes specific recommendations regarding data collection, processing, dissemination, and use for quality improvement.

Tracking patient outcomes and services, beginning with 911 calls through hospital discharge, is a major step in building collaboration between out-of-hospital and hospital providers. Use of these data for quality improvement can strongly impact patient survival.[49] The links across the components of the TCD system for stroke and STEMI care provide important information for public health officials on how people in communities access health care and the problems they have using health care, as well as disparities between communities in how people seek and receive emergency care.

Recommendations:

1. The TCD system includes a statewide registry specific for STEMI and stroke with required reporting from out-of-hospital and hospital agencies within the system. Each involved system agency and designated STEMI and stroke center will report required data elements to the statewide registry in a manner that can be easily done. The statewide approach will not prohibit local organizations from using their own data for quality improvement purposes currently in place.
2. DHSS establishes and coordinates a congruent registry, database platform, and reporting process that do not create redundancies or undue hardships on TCD reporting agencies.
3. The TCD system uses nationally recognized data elements to define reporting requirements where available and practical.
4. The data management system supports the processes for quality improvement of the continuum of services and care, as well as patient outcomes for all out-of-hospital (dispatch, response coordination, EMS, transport) and hospital agencies within the TCD system.

Suggested Actions:

- DHSS convenes and facilitates a quality improvement work group to review such items as current national and state data management programs, stroke and STEMI registries, recommend data elements, quality improvement functions and

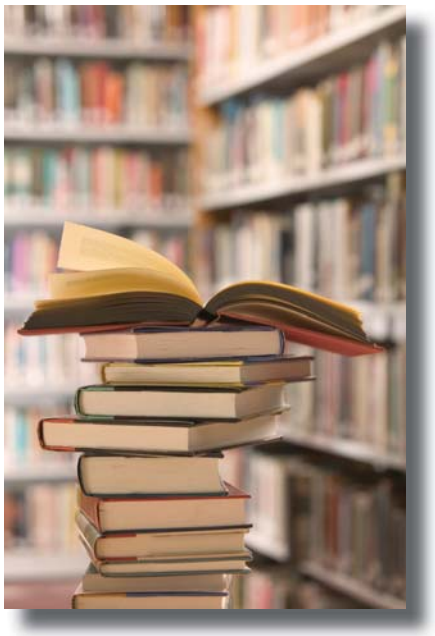
benchmark measures in order to identify what is to be incorporated into DHSS's system-wide data management program.

- DHSS creates a platform for the data management system based on the work group recommendations. DHSS strives to: a) build on current successful approaches to capture and link data across the system, b) ensure compatibility with data reporters, and c) establish realistic procedures that are not redundant with other reporting requirements.

Supporting Evidence:

- Jacobs et al. emphasize the importance of participation in national, regional, and hospital- and systems-based data collection and quality improvement programs.[9]
- According to Bradley et al., "The strongest evidence" supports "use of data monitoring and providing prompt data feedback" for improving STEMI care, making data monitoring systems an important strategy to advance STEMI care.[36]
- The Joint Commission's Primary Stroke Center Certification Program recognizes the centrality of and requirement for tracking outcomes and on-going quality improvement programs.[55]

Professional Education



As best practices and standards of care evolve, so too must the competencies of out-of-hospital and hospital providers. Therefore, the TCD system must emphasize the centrality of core competencies and continuing education to improving care and, subsequently, outcomes for Missourians. Accordingly, the Task Force makes the following recommendations.

Recommendations:

1. The TCD system supports training and continuing education for out-of-hospital providers (EMD, EMS, transport personnel) to meet competencies needed and improve current practices for stroke and STEMI care within the TCD system (e.g., training on use of equipment, assessment tools and current technology that allows rapid and reliable recognition of stroke and STEMI symptoms; training to improve provider knowledge of appropriate care facility and transport options to minimize out-of-hospital time from time of symptom onset to definitive care).
2. The TCD system supports training and continuing education of physicians and hospital staff to obtain needed competencies and improve current practices for stroke and STEMI care within the TCD system.
3. The TCD system updates training and continuing education regularly to incorporate changes made due to quality

improvements, changes in evidence-based approaches and best practices, or improve areas of weak performance as indicated by quality improvement measures.

Actions:

- DHSS compiles training and continuing education recommendations for EMD, pre-hospital and hospital staff with respective work groups.
- Identify approaches to provide training on use of new assessment tools, protocols, policy changes and other issues that support care of stroke and STEMI patients.
- Determine assessment process for staff skill and competency levels as needed.
- Implement a delivery plan to include, but not be limited to, the use of existing training networks, internet, sponsored speakers at conferences for pre-hospital and hospital staff, and coordination with professional associations.
- Determine approaches or review schedule for updating training and continuing education plans as evidence-based and best practices progress and based on results of quality improvement changes or areas where weaknesses exist.

Supporting Evidence:

- "To increase the number of patients who are treated, educational programs for physicians, hospital personnel, and EMS personnel also are recommended."[13]
- Jacobs et al.[9] stress the importance of on-going training and education for out-of-hospital and hospital staffs and physicians on STEMI care.

Public Education

Much work remains in improving the public's knowledge about the warning signs of heart attack and stroke, the need to call 911, and the understanding that EMS are the optimal means of accessing urgent medical care. Like Maine[49], New York[50] found that public knowledge about stroke symptoms is low. New York's survey results show that delay in calling 911 is one of the most important obstacles to positive stroke outcome. Reasons for delay are similar to reasons for delayed response to heart attacks. These reasons include the expectation that symptoms will occur in a dramatic manner, as depicted in the movies, rather than the more common onset of initially ambiguous but gradually increasing discomfort. Patients unrealistically judge their personal risk as low, are generally unaware of the benefits of using 911 over alternate transport and appear to need the permission of family or health care providers to act.[51] Other findings from New York indicate the need to educate patients during routine medical visits and other

teachable moments about the warning signs of stroke, the need for immediate medical attention, and the need to call EMS. Authors with the Massachusetts Heart Disease and Stroke Prevention Program indicate the Stroke Heroes Act FAST media and public awareness campaign shows promise for increasing stroke and 911 awareness.[52] Such efforts are important because no attempts to improve EMS and hospital emergency department systems of stroke care will improve patient outcomes unless people recognize the warning signs of stroke and heart attack and activate the system by calling 911.[53]

“...no attempts to improve EMS and hospital emergency department systems of stroke care will improve patient outcomes unless people recognize the warnings signs of stroke and heart attack and activate the system by calling 911.”

Recommendation:

The TCD system supports coordinated public education to inform patients about signs and symptoms, the importance of calling 911, the type of care needed, and facilities equipped to provide that care.

Actions:

- DHSS collaborates with stakeholders or convenes a public education work group of partner organizations that will use market research to identify best strategies and approaches to educate the public on creation of designated stroke and STEMI centers and when their services are appropriate.
- Identify campaign strategies, messages and approaches that unify and coordinate partner efforts to inform the public about signs and symptoms of stroke and STEMI and importance of calling 911.

Supporting Evidence:

- “To increase the number of patients who can be seen and treated within the first few hours after stroke, educational programs to increase public awareness of stroke are recommended.”[13]
- Jacobs, et al. conclude that the “ideal system [for STEMI] would promote culturally competent educational efforts with clear and consistent messages…”[9]

Payer

As emergency care for stroke and STEMI comes to mirror that of acute severe trauma, payment and reimbursement policies and procedures for stroke and STEMI will also need to parallel those of acute severe trauma. Payers for emergency transport and care of the severely injured trauma patient recognize the need for flexibility in location and provider(s) for care of the trauma patient based on the trauma system concept and structure. This flexibility must also extend to encompass the emergency transport and care of the stroke and STEMI patient.

Recommendation:

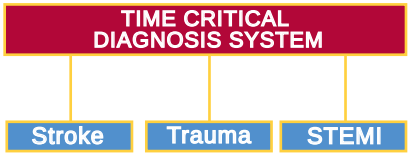
Identify payment issues and problems that impact recommended care and desired outcomes for stroke and STEMI patients and begin discussions with health care plans and other key stakeholders to resolve.

Actions:

- TCD partners conduct an exploratory meeting with representatives from both out-of-hospital and hospital agencies within the TCD system, private health plans, Medicare and Medicaid to determine a feasible way to evaluate costs of services for patients with stroke and STEMI, factors that impact costs, and current payment and reimbursement issues and problems.
- Collect data and information needed to evaluate the nature of problems. Develop strategies and actions to overcome those problems in order to support quality care at affordable prices.

Supporting Evidence:

- "Reimbursement issues may also hinder rapid transfer of patients from smaller community hospitals to larger PPCI [Primary PCI] hospitals…" [43]



System Administration

DHSS is authorized by the State of Missouri to provide oversight to the emergency medical system, designate hospitals as trauma centers when they meet the criteria for center designation, and promulgate rules in relation to emergency medical system components (Chapter 190, Missouri Revised Statutes). The 94th Missouri General Assembly recently passed legislation to expand that authority to include STEMI center and stroke center designations for those hospitals that meet criteria to be stipulated in rules.

There is a need for clear state center designation criteria and an independent process that involves broad participation of every component of emergency, stroke and STEMI care to advance and administer the TCD

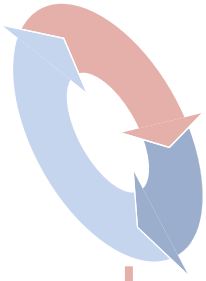
system. DHSS' recently expanded authority in relation to stroke and STEMI centers, combined with its existing role in the emergency medical care system, establishes it as the lead agency to advance Missouri's TCD system.

Recommendations:

1. DHSS provides administrative oversight for the TCD system.
2. DHSS establishes an advisory body to guide TCD system implementation and oversight.
3. DHSS promulgates regulations to implement TCD system requirements.
4. DHSS leads efforts to evaluate the TCD system implementation and impact on desired outcomes. DHSS staff with evaluation competencies will work with the quality improvement work group to define key outcomes, performance measures and benchmarks to be tracked on a statewide basis.
5. DHSS assesses system components after regulations and new system processes are adopted, determines gaps, compiles plan to address gaps in care within Missouri's TCD system, and seeks support to address in a collaborative manner with TCD system partners.

Actions:

- DHSS administration will evaluate resources and staffing needed to support expansion of the TCD system to address stroke and STEMI in a distinct yet similar process to that of trauma care.
- DHSS determines need for new budget decision items for FY 2010 (begins July 2009).
- DHSS compiles long-term plan to formalize oversight by January 2009.
- DHSS meets with key stakeholders and formulate plan for representation and structure of advisory body and officially appoint advisory body by March 2009.
- DHSS establishes TCD work groups (out-of-hospital, stroke, STEMI, quality improvement, and professional and public education as detailed in this report). The first priority is establishing those work groups that will advise DHSS on promulgation of regulations for the stroke and STEMI center designations.
- DHSS promulgates regulations according to statutory authority.
- DHSS establishes a process for representatives of hospitals, physicians and emergency medical services providers in a select community or region to compile and submit community-based or regional plans and approve those that meet recognized criteria.
- DHSS establishes means to evaluate implementation and impact of new TCD elements.




Evaluating
Progress

Evaluating Progress

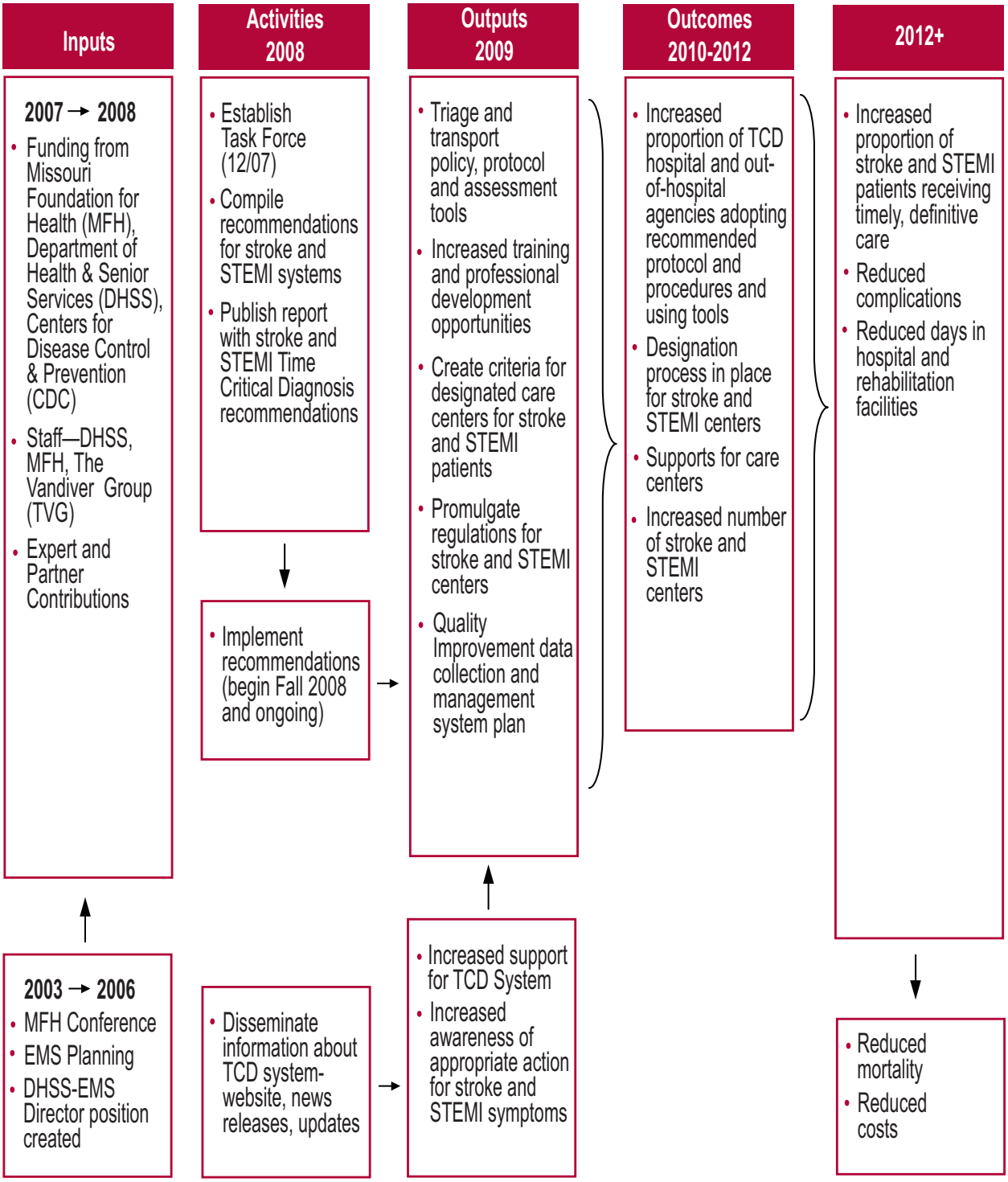
The recommendations proposed within this report are improvement strategies that focus on processes within the system. As such, DHSS will use process evaluation to track the progress of the system's development. As the system develops, new processes will be implemented, and benchmarks and quality improvement measures will be established along with standardized data collection means to evaluate the quality of care and long-term outcomes. Plotting the progress of each quality indicator over time will allow TCD partners to determine whether the system is moving in the right direction and potentially provide public metrics that could be used for quality assurance and determining where changes and improvements are needed. [9]

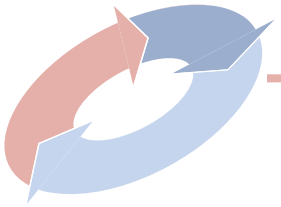
Implementation of system improvements must be monitored to ensure that these changes support desired outcomes. These outcomes will range from improved operational efficiencies and cost savings to improved patient outcomes. The quality improvement component and evaluation design must carefully monitor the impact of new procedures, protocols and care plans on clinical outcomes. It will also be important to assure that the system accommodates new treatment modalities and emerging therapies for stroke and STEMI care. [9]

Much excellent work has been done that can inform Missouri's evaluation plans. Performance measures have been developed for emergency medical services within stroke systems of care[54] and evaluation measures are emerging for system development of care for STEMI patients. [9]

The logic model that follows (figure 2) outlines the outcomes anticipated from implementation of the TCD system for stroke and STEMI care over the next decade in Missouri. Accomplishments that could occur within the next two years of this report include new policies, protocols and tools; increased training and professional development opportunities; promulgation of regulations that outline criteria for designating stroke and STEMI care centers; and a detailed plan for the quality improvement data collection system. With ongoing support, an increase in the number of EMS agencies adopting recommended protocols and practices could be expected along with a new process for hospitals that wish to be designated as a stroke and/or STEMI care center. This in turn will result in an increased proportion of patients receiving timely access to definitive care that ideally will reduce complications, days in the hospital and rehabilitation facilities, costs, disability, and death from stroke and STEMI in Missouri.

Logic Model for Stroke and STEMI TCD System Planning and Implementation (Figure 2)





Evaluating Progress

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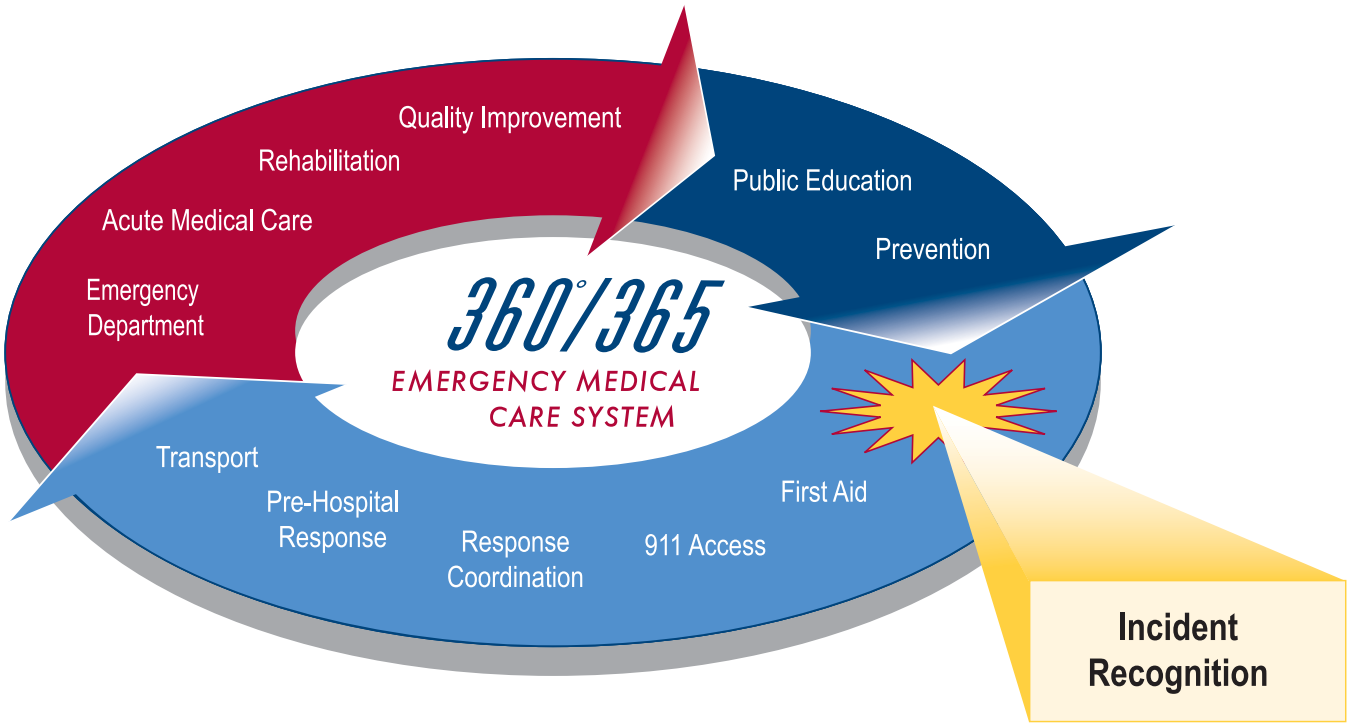
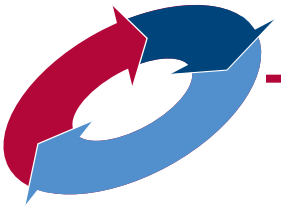
Appendix

The following figure is a diagram of the Time Critical Diagnosis (TCD) System, a coordinated, integrated group providing emergency medical care services using regionalization concepts to treat those diagnoses that are truly time critical. The 360^0 represents the complete circle of care... from initial first aid after an incident to the actions taken at the hospital to the steps to prevent the next incident from happening. The 365 represents every day of the year that the system goes through this cycle.



Notes



Notes

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