Regionalization of emergency medical care has gained supporters and captured the interest of many in the emergency medical care field over the last few years. It is a complex issue, from both a clinical and a political perspective. The desired end result of improved patient care is difficult to achieve, and it is one that too often becomes lost in all the political arguments that surround the issue.1

In its landmark 2006 report, the Institute of Medicine promoted regionalization as a means of improving patient outcomes and reducing costs.2 A regionalized system of specialty referral centers (SRCs) can and does improve patient outcomes. Research performed over the course of several decades within the United States has yielded solid evidence that regionalized systems of care for trauma patients significantly improve patient outcomes.3–13 Early studies also demonstrate outcome improvements for ST-elevation myocardial infarction (STEMI) patients in some systems14–16 but perhaps not all.17

This latter point deserves more detailed discussion later in the chapter. The establishment of a regional system of care does not, in and of itself, have any definitive impact on patient outcomes. The design of the system is vital to its success, and that success is highly dependent upon the ability of the designers to examine the entire system of emergency patient care. As in the old saying, “a chain is only as strong as its weakest link,” the design of a regional system needs to focus on every aspect of the patient’s quite complicated journey through the emergency medical care system, identify the “weak links,” and target them for improvement.

Regionalization is threatening to many stakeholders, and the political arguments surrounding regionalization efforts are sometimes quite difficult for the planner to counteract. There are many barriers, but the two most common are organizational silos and resistance to change. “Organizational silos” is a term that came into popular use in the early 2000s. It signifies an organization that is focused inward, on its own needs, and is vertically focused only on its goals within itself. An organizational silo has little interaction with other organizations, and the perspectives within such an organization are, by definition, inwardly focused. A prime example of such an EMS organization would be a dispatch center run by a reluctant sheriff’s office. The organization does not consider itself part of the medical care team and considers its job done when an ambulance dispatch call is transmitted to responders.

Most of our providers do not understand the intricacies of the entire emergency medical care system, even though they work in it every day. They tend to operate within their organizational silos, and any attempt to integrate their work with other providers must begin by breaking down those barriers.

THE EMERGENCY MEDICAL CARE SYSTEM

The emergency medical care system (EMCS) is broader than the typically accepted definition of an EMS system. The EMCS encompasses the entire
care pathway the patient must traverse in his or her complicated journey during an emergency call activation within the United States system model. That is, the EMCS encompasses all the components of care as exemplified by the EMCS Circle (see Figure 50.1). In contradistinction, we typically speak of an EMS system as only the out-of-hospital component of the patient’s care.

Components of the system vary widely in their capabilities. There are areas of the country where emergency telephone service still utilizes a seven-digit number, emergency medical dispatch training is unknown, and the caller is told, “Someone will be right there” but is then disconnected. The local ground and air response is also quite variable in both skill levels and experience. Even in more urban areas, hospitals may vary significantly in their capability to care for severely ill or injured patients. These patients may require a high level of care that is unavailable at the local level to optimize outcomes. The early identification and “care mapping” for this type of patient forms the basis for an integrated EMCS system design and regionalization of medical care.

An understanding of the importance of the EMCS to the entire patient care experience is crucial to successful regionalized system design. Too often, healthcare providers utilize “silo thinking” and only concentrate on their part within this complicated system. For example, in-hospital clinicians conceptualize well those processes that occur within the hospital walls, but they often fail to understand the difficulties involved in identifying, treating, and transporting the patient in the out-of-hospital environment. Out-of-hospital practitioners often lack knowledge of the complexities within a modern hospital and the inherent difficulties in making hospital systems work cooperatively. Few consider the difficult job that telecommunicators face as the “first first responders.” EMS medical directors are perfectly positioned to bridge these many disciplines and to educate others on the entire spectrum necessary for system design and improvement. The importance of someone in that position with the broad perspective cannot be overstated.

Although progress has been made in developing truly comprehensive EMCS systems during the past 25 years, success in efforts to regionalize facilities through categorization and designation has varied. Only when all participants are able to truly focus on the goal of improved patient care can the necessary system improvements begin to occur.

Let us examine an example of what occurs daily in many modern systems.
The dispatcher in a seven-digit call center setting receives a call for emergency medical help. The caller tells the dispatcher that a child is choking and turning blue. The dispatcher, whose administration refuses to implement pre-arrival instructions, replies “I’m sending someone right now,” and immediately dispatches a first responder unit and a transport ambulance. The activation interval is two minutes, the first responder “out of chute” time is two minutes, and the total response time is seven minutes. A one-minute patient access interval makes a total of 10 minutes from the initiation of the call to the initiation of care.

The child is pulseless and apneic, but initial resuscitative efforts return a weak pulse. The transport ambulance arrives, and after a 20-minute scene time, their protocol is to transport to the nearest facility. The transport interval is 15 minutes. The nearest facility is a low-volume ED that rarely cares for pediatric patients, and there is quite a bit of initial confusion about management. A lack of pediatric-specific equipment at the hospital delays definitive airway care and IV establishment for the hypotensive, minimally responsive child. A decision to transfer to a pediatric regional referral center is made. Elapsed time from arrival at this facility to the call for transfer is 40 minutes.

The pediatric tertiary center insists on sending its own transport team for the child. This requires gathering the team and a one-hour response time ensues, followed by a 45-minute scene time at the local hospital, and a 50-minute transport time back to the tertiary center. The child is admitted to the tertiary care center’s pediatric intensive care unit, exhibits signs of hypoxic encephalopathy, and dies three weeks later. Everyone shakes their heads and says, “What a shame it is.” Quality improvement processes occur, and each entity, from the dispatch agency to the transport team, concludes that it did the best it could have done. After all, no one could have driven faster, dispatched help faster, or bagged the child better, and the transport team agreed that they did not have a viable patient to work with in the first place. It was all unavoidable and most unfortunate.

This, of course, is little solace to the child’s family who realize it was 10 minutes after their call before their child was ventilated, that it took four hours to get to the tertiary facility, and that if the original ambulance had turned right instead of left at one crucial intersection, it could have driven their daughter directly to the tertiary center in only 30 minutes.

How could regionalization have helped this child? A system of looking at the entire spectrum of care provided to this patient rather than the individual components of care is important. These “silos” have continually hampered our perspective and our patient care. A process that examines every piece of care within the context of the whole, identifies deficiencies, and proactively plans for maximizing that care on a regional basis is required. As noted above, the designation of SRCs is but a part of building a truly integrated emergency medical care system.

The ability to broaden one’s horizons and focus on the bigger picture is daunting for many. Because the U.S. healthcare system is designed so that several agencies with diverse ownership care for the patient, it is much safer to remain in organizational silos. Different political agendas or boundaries foil a full focus on the needs of the patient, subjugating them to the needs of the various organizations. No one pays attention to the sum of the whole except the hapless and helpless patient.

DEFINITIONS

Regionalization is the formation of a coordinated statewide or regional system of care that combines out-of-hospital components and in-hospital emergency components with public health components. This may involve designation of SRCs, but this designation process is only a small part of the overall system that must be crafted for a successful outcome. The goal is to facilitate improved patient care and encourage overall economy by concentrating costly resources within the region and coordinating that care to focus on patient outcomes.

Categorization is review against standards to classify facility capabilities. Categorization is encouraged before facility designation should occur.

Designation is the formal selection for patient referral and transfer by an organizing body that has been given governmental authority to do so. Typically, there is a minimum set of standards that a facility must meet to become designated as a specialty receiving center.

The Time-Critical Diagnosis (TCD) System is the concept that a coordinated, integrated EMCS can utilize to treat those diagnoses that are truly time-critical. Clear evidence demonstrates that severe trauma, acute ischemic stroke (AIS), and STEMI outcomes can be improved by specialty care at regional referral centers.
designated by an accrediting body. The TCD concept seeks to avoid the creation of three separate systems (stroke, trauma, and STEMI) within a state or region. It is far more appropriate and cost-effective to coordinate the three arms of the systems under a common banner of Time-Critical Diagnosis (TCD). This allows resource sharing and coordination at many different levels and decreases duplication. Once formed, the combined TCD body has a significantly more powerful position in the political arena than do individual efforts.

HISTORICAL BACKGROUND
In the past 70 years, the U.S. military made most of the advances in the care of the critically injured patient despite the fact that civilian accidental injuries occurred at an alarming rate.\textsuperscript{19,20} Care of the severely injured progressively improved through World War II and both the Korean and Vietnam conflicts, mainly by stressing rapid transport to specialty centers capable of providing the levels of care necessary for the patient. Lessons learned were slow to translate into the civilian sector, however.

In 1961, a “shock-trauma” unit was established at the University of Maryland to study shock in humans, followed by the first civilian trauma unit at Cook County hospital in Chicago in 1966. This first trauma unit began promoting the concept of regionalization of trauma care in the civilian sector.

The publication of the farsighted \textit{Accidental Death and Disability: The Neglected Disease of Modern Society} in 1966\textsuperscript{19} was the seminal event for what has become the regionalization concept and modern civilian trauma care. The report detailed the problems within the medical care system of the day that contributed to the high mortality due to trauma in the U.S. A few selected quotes from the report seem ironic today, 42 years later:

- “The general public is insensitive to the magnitude of the problem of accidental death and disability.” (page 5)
- “Local political authorities have neglected their responsibility to provide optimal emergency medical services.” (page 6)
- “Emergency departments of hospitals are overcrowded, some are archaic, and there are no systematic surveys on which to base requirements for space, equipment, or staffing for present, let alone future, needs.” (page 6)

- “Fundamental research in shock and trauma is inadequately supported.” (page 6)
- “Under medical leadership, national forums should be conducted at the highest levels on all subjects important to total emergency care from the time of receipt of an injury through rehabilitation.” (page 6)
- “Very few communities provide sufficient financial support for adequate ambulance services.” (page 13)

It is tempting to focus on all of the problems inherent in our emergency system today, and the fact that we continue to see many of the same problems forty years later, but in actuality the system is much improved overall from 1966. Congress did pay some attention to the report and attempted to address some of the perceived shortcomings by directing funding into the Department of Transportation (see Chapter 1, “History”). Late in the 1960s and early into the 1970s, the conceptual design of a “systems approach” to trauma and emergency medical care began to emerge in some areas of the country. The initial programs were targeted to specific types of patients such as cardiac, trauma, burns, and spinal cord injuries. Illinois founded the first regionalized system in 1971.\textsuperscript{21} The Emergency Medical Services Act of 1973 funded a nationwide shift from funeral home-based ambulances to a professional system of response and transport. A major goal of the grant program was regional EMS systems development on a national scale.\textsuperscript{24}

CATEGORIZATION AND DESIGNATION
It quickly became apparent that a system of categorization of hospital capabilities was needed so that other healthcare providers, both out-of-hospital and transferring emergency departments, would be better informed about where to refer patients. For example, the categorization of a burn center according to established standards allowed other healthcare providers to refer patients without the need to visit and examine the center themselves. Categorization provided the SRC some minimum standards it had to meet, and the process eventually raised standards on a national level.

The need for standards for SRCs is well supported. Trauma centers need to have specialty teams ready to perform necessary interventions up to and
including major surgery. Stroke and STEMI centers must be able to administer appropriate therapy to promote restoration of blood flow promptly. All require immediate imaging capability, immediate specialist review, and high-level coordination of on-site clinical expertise and processes. Additionally, all require ongoing, careful quality improvement efforts aimed at relentlessly improving their processes.

Formal designation of facilities by an authorized body tended to follow in some areas. The designation process ensured that the categorization was correct and that minimum standards were being met. In states that did not mandate those minimum standards, care was found to be mediocre when compared to a formal process, but it was also found that any attempt at organization was better than no system at all.3-13,40,41

Regionalization accomplished through designation requires changes on the part of providers, and if an authorized lead agency is not already identified, it also requires enactment of state or municipal laws. For example, in New York State in 1998, facilities in half of the EMS regions were categorized based on guidelines established by the State EMS Council without formal state authority.20 Since there was no legal authority to designate facilities, the process relied on voluntary participation that was uneven in some regions and nonexistent in others.23

Without an authorized lead agency to carry out the process, the risk of legal challenges increases, since designation often creates de facto monopolies by restricting the number of facilities allowed to participate and by requiring that certain standards of care be met prior to participation.24,25 In the absence of explicit authority, the designation process may be impeded by physicians, hospitals, or other special interest groups.

Initially, system planners did not adequately address the need for explicit authority to designate trauma centers, and this shortfall was compounded by the lack of federal funding for upgrading hospital facilities. Individual hospitals were expected to make costly improvements on a voluntary basis.18 Since it was assumed that designation of trauma centers would promote the development of regionalized EMCS systems, attempts were often made in the 1970s to organize EMCS systems around trauma center development.26

When federal EMS systems funding effectively ended in 1982, program initiatives and necessary legislative changes became the responsibility of individual states. Those responsible for developing or managing EMS systems found that in the absence of both federal money and legal authority, plans for regionalization through facility designation usually failed.

Under these circumstances, local efforts were sometimes unfocused. Without federal or state leadership, the effort fell to the local organizations that had variable success at setting aside institutional concerns and “silos” to advance the goal of patient care. This approach produced false starts and unbalanced results stemming from the failure to upgrade general emergency care capabilities and an over-concentration on trauma care. When the federal support for trauma system development collapsed in the 1990s, often so did the EMCS system development. Many of the SRC problems were caused by the relaxation of the originally strict criteria recommended by the American College of Surgeons (ACS) and the premature development of Level II trauma center designations. The competition for designation as Level II centers among smaller community hospitals, and the resulting litigation, effectively halted development of the designations process altogether in many areas.27

Concern regarding adverse economic effects—mainly the loss of patients—by those institutions not designated occasionally resulted in resistance by hospital administrators and physicians to both categorization and designation. In fact, fewer than 10% of all trauma patients actually require trauma center care; therefore, the actual loss of patients from non-designated hospitals was minimal.18 These same concerns are evident more than two decades later in the discussions about categorization and designation for acute ischemic stroke and STEMI.

Lead agencies with appropriate empowerment are important, since they may plan, implement, and operate without serious legal challenge.28-30 EMCS systems development is much more difficult when there is fragmentation of authority or no authority for facility designations, regionalization, and overall system design. A branch of government with legislative authority to designate is the best-suited to serve as the lead agency.

This may assume many different forms besides an actual government unit. For example, Colorado and Pennsylvania utilize independent foundations for trauma center designation. The effectiveness of such an approach has not yet been fully determined, however, and should be observed carefully by system medical directors in other states. Whatever format is chosen, there must be a clearly defined body that has responsibility and authority to ensure an effective system.
Unauthorized designations expose agencies to antitrust liability. Explicit statutory authority affords the greatest protection against exposure to risk of liability for violation of the Sherman Act when limitations are made on the number of medical facilities used by a system. In Huron Valley Hospital Inc. v. City of Pontiac, the court held that, “[State] regulatory actions within the gambit of valid legislation...are exempted from the antitrust laws under the ‘state action’ defense.” Proper authorization to designate granted to an agency that enforces state policies through activities closely supervised by state officials would not violate antitrust laws. However, “anything short of properly constituted authority may run afoul of federal law. To avoid such antitrust problems, the proper authority must perform hospital designation.”

Though the law is unsettled nationally, it would appear that, in the absence of definitive court decisions or express legislative authority, governmental agencies with “implied” powers may be considered to be outside of the scope of the antitrust laws.

The recent development of effective stroke and STEMI acute therapy again raises these same issues within new and different groups. A few states have already developed classification standards for these categories of care. Some hospitals have “self-designated” themselves as “stroke centers” or “cardiac centers” without objective review against established criteria. This is very similar to the formative days of the trauma system where hospitals rushed to self-designate as “trauma centers.” Self-designation did not produce the expected clinical outcome improvements with trauma, and it is likely the same process will repeat itself for stroke and STEMI centers.

**PUBLIC LAW 101-590**

The concept of regionalization and its ability to improve patient care is not new. The enactment in November 1990 of the Trauma Care Systems Planning and Development Act (PL 101-590) provided for the establishment of a federal trauma systems program. This act was intended to assist the local and regional planning efforts for trauma system development by breaking down some of the barriers to effective organization that were noted during the 1980s. However, the 1990 Act, which was supposed to provide grants to states for planning, implementing, and developing comprehensive trauma systems, was not funded when enacted. In November 1991, funding that finally was authorized to implement a new federal trauma systems program for 1992 totaled only $5 million. This amount was well below earlier projections, which were as high as $75 million.

PL 101-590 had two primary goals. First, it was designed to remove the barriers and rectify the problems that in many parts of the country prevented timely and efficient development of a comprehensive EMCS. Second, it provided incentives, including grants, to states and localities to establish coordinated regionalized trauma care systems that would enable severely injured individuals to receive timely and highly specialized care at designated trauma centers. The trauma care system concept was premised on the belief that victims of severe trauma require special care and, as a consequence, they were to be transported to designated trauma centers, bypassing closer emergency departments. At that time, the only systems that were proven to improve patient outcomes were for trauma. Modern therapy for stroke and STEMI would not be broadly available or utilized for another decade, and the need for a regionalized system for these other time-critical diagnoses was not yet evident.

Passage of PL 101-590 ratified the widely held belief that regionalized trauma systems reduced death and disability from trauma. Regionalized trauma care systems were models of healthcare delivery that could coordinate and integrate prehospital services and hospital resources to assure that optimal care was provided to traumatically injured patients. The 1990 legislation specified that such systems must identify and designate trauma centers with specialized physicians and equipment immediately available on a 24-hour basis. Also required were methods to identify severe trauma victims in the prehospital phase and to ensure that all major trauma victims were transported to trauma centers.

PL 101-590 addressed the issue of authority, effectively diminishing the threat of legal challenges to development and implementation of designation schemes. However, while the threshold issue of legal authority to designate was resolved, the financial burden caused by the large numbers of uninsured or indigent patients brought to designated facilities, along with inadequate reimbursement rates, still presented a great barrier to regionalization.

A May 1990 Senate committee report addressing the Emergency Medical Services and Trauma Care Improvement Act revealed that since 1987, many urban trauma systems were threatened by total collapse because of financial losses. The committee report also
discussed the findings of a 1989 review conducted by the Office of Technology Assessment (OTA) on rural EMS and trauma care needs that noted that not all states had developed EMS systems extending into rural areas. The report detailed the fact that rural EMS systems lacked adequate numbers of trained personnel, universal coverage by a communications network, and overall systems development. Serious injuries, according to the report, posed special problems to rural communities: “Injury-related morbidity and mortality are often higher than in urban areas because of the time delays in reaching trauma victims on isolated roads, homes, or farms. The chance of a severely injured individual dying in a rural area is three to four times higher than in urban areas.” The OTA report concluded that “EMS systems that integrate all levels of hospital care within a state promote regionalization and are likely to improve rural trauma patient outcomes.”

PL 101-590 provided grants to states for development, implementation, and monitoring of statewide trauma systems. The trauma care component included the designation of trauma care regions and centers.

In 1992, 26 states were awarded grants adjusted to population and geographical size. The grant program requirements included submission by the state of yearly trauma system plans that took into account guidelines developed by the ACS Committee on Trauma, the American College of Emergency Physicians, and the American Academy of Pediatrics. While the law specifically provided that grant funds could be used to reimburse designated trauma centers for uncompensated care, the first round of awards did not allow for the funding of uncompensated care.

The law authorized the Secretary of Health and Human Services to:

1. establish an information clearinghouse to disseminate information on the experience of state and local agencies with respect to trauma care system development and operation;
2. establish an Advisory Council on Trauma Care Systems to conduct needs assessments on a country-wide basis; and
3. establish funding for research and programs that seek to improve rural EMS.

By early 1993, progress was being made in each of those areas.

After more than 25 years of advocacy to enact legislation that would fully address trauma program concerns such as authority, standards, and national coordination, the passage and funding of PL 101-590 was enthusiastically greeted by most of the healthcare establishment. Unfortunately, enthusiasm has been greatly tempered by an economically constrained environment in which this legislative action has been able to attract only token funding. Advocates of trauma care systems (and now, stroke and STEMI systems) are inevitably left with the impression that the 1990 law was meant more to tantalize than to fulfill.

Funding for this trauma program was lost in the mid-1990s. Funding authorization returned in 2001, and again in 2007 with passage of H.R. 727-Trauma Care Systems Planning and Development Act amendments, but the level of funding to be provided is unclear. The bill, as signed by the president, allocates $12 million in FY 2008, $10 million in FY 2009, and $8 million for each of FY 2010–2012 years. Unfortunately, the need for this type of system development is often poorly understood at all levels, the appropriation process fails to support the bill’s intentions, and funding remains elusive.

SIMULTANEOUS PROCESSING

A key concept in the design of any regionalized system is that of simultaneous processing. This is contrasted to the traditional means of providing emergency medical care by sequential processing. Think for a moment of the traditional emergency call:

- someone calls 9-1-1;
- an ambulance responds;
- an assessment is made and treatment started;
- the patient is transported to the ED, admission information is gathered, and the assessment is repeated;
- after the ED examination, diagnostic tests are done;
- a provisional diagnosis is made, and a treatment plan is developed;
- specialty consultants are called to the ED, if needed; and
- admission or discharge occurs.

Assessment and care are performed in a sequential fashion of “First A, then B, then C.” If a transfer from one hospital ED to another must occur, as is often the case with seriously ill and/or injured, time-critical patients, this sequential process has even more steps added.
Early in the development of trauma systems and trauma care, it was noted that this sequential process resulted in excessive delays for severely injured patients whose care was of a time-critical nature. In the earliest days, trauma teams were activated only after the patient had been examined in the ED, but out-of-hospital assessment and classification of injury severity (field trauma classification) made it possible to move care forward and have the trauma team respond at the same time as the patient was being brought to the ED—an early example of simultaneous processing.

Moving care forward means that personnel are performing a task that typically was only performed by a higher-level healthcare provider. As in the above example, paramedics began calling “trauma alerts,” an activity that was previously only in the purview of physicians. Significant time savings resulted in the symptom-onset to definitive care time frame, and today that concept expands into field activation of stroke teams and cardiac catheterization labs. It is a key component of simultaneous processing (see Figure 50.2).

Today, instead of cardiac catheterization labs being activated only by cardiologists, we have progressed through ED physicians and (now) to field personnel performing those activations. This allows the simultaneous activities of catheterization lab (or stroke team) response while the patient is being transported to the hospital. The design of any regionalization system must account for this important concept to decrease the time elapsed from symptom onset to definitive care. In the future, with the assistance of programs such as Advanced Automatic Crash Notification (AACN) and Helicopter Early Launch Programs (HELP), we will begin to see simultaneous processing come under the purview of the modern 9-1-1 telecommunications center.

OUTCOMES

In the second paragraph of this chapter, we alluded to the improved outcomes that might be realized with regionalization. At present, three major diagnoses are considered “time-critical” emergencies: severe trauma, AIS, and STEMI. Time from symptom onset to definitive care can be directly related to patient outcome, and early identification and/or field triage to an appropriate (though not necessarily closest) facility, combined with rapid, standardized treatment, can dramatically affect morbidity and mortality. That is, we can affect outcomes by planning for the “right care, at the right place, in the right time.” Other diagnoses are sure to follow as we learn more about how to maximize efforts and outcomes within integrated systems.

Matching patients to the appropriate resources poses unique challenges, especially with time-critical conditions. Emergency call-takers, initial responders, ambulance services, air medical resources, community hospitals, and regional referral centers must all cooperate smoothly, handing the patient off with speed and efficiency to achieve the best possible outcomes. They must provide pre-arrival instructions, assess patient needs, administer appropriate and proven interventions rapidly and effectively, determine the appropriate destination facility, select expeditious

FIGURE 50.2 Sequential v. Simultaneous Process. (Copyright William Jermyn, DO; used with permission.)
transportation, notify appropriate specialists and intervention teams, and ensure they are prepared for the patient. Quality improvement processes must be coordinated for all aspects of patient care, and they must ensure effective feedback and necessary improvements.

Achieving that level of integration is a formidable task, however. Despite their apparent common goal of helping the patient obtain good care, each of these entities has different motivations, responsibilities, and focus, not all of which are consistent with a highly coordinated response:

- Call takers may not be part of a 9-1-1 system, or may be primarily engaged in other public safety work and not trained or certified in emergency medical dispatch (EMD). They may even be prohibited from providing pre-arrival instructions.
- Initial responders such as law enforcement and fire service agencies may be tax-based community resources, focused on rapid, limited intervention, and a quick return to service.
- Ambulance reimbursement on a “per run” basis and crew anxiety increase pressure to transport the patient to the nearest available community hospital and return to readiness as soon as possible.
- Air ambulance providers with high fixed costs may be encouraged to perform little screening for appropriate use of their expensive assets, potentially depriving other, truly time-critical, patients of their speed when needed.
- Community hospitals often express concern that failure to do a complete work-up on a patient before transfer may be a violation of the Emergency Treatment and Active Labor Act (EMTALA), even if the patient’s initial presentation clearly demonstrates needs beyond the facility’s capacity.
- Regional referral centers frequently complain that patients who can be cared for appropriately at community hospitals are transferred to the referral centers anyway.

TRAUMA

Early in the trauma system development process, researchers began to ask how to measure the outcomes of a patient population that was treated within a trauma system compared to those treated outside of a trauma system. At the time, there were no electronic patient registries. They developed a tool that was not as rigorous as a randomized, controlled study, but as good as anyone could achieve with the measuring tools of the times. A panel of surgeons, blinded to the hospital and system, reviewed cases and determined if deaths were preventable, probably preventable, or not preventable.

These panels routinely found that care in trauma systems with a rigid SRC designation process was best. This system design, using outside site review team verification, was compared with both “no system” and a “self-designation” system, where a hospital performed the review process upon itself according to various published standards. Patient outcomes were found to be best with the outside review, in between with “self-designation,” and worse with “no system.”

These differences were sometimes quite dramatic. For example, the classic study by West, Trunkey, and Lim compared the San Francisco area, which had a formal trauma system, with Orange County, CA, which had no trauma system. They found that only 1 of 92 deaths were deemed potentially preventable in the San Francisco system. In distinct contrast, 11 of 30 Orange County deaths were deemed clearly preventable and another 11 of 30 were deemed potentially preventable. They estimated that a formal system in Orange County could result in as much as a 73% decrease in non-central nervous system (CNS) related deaths and a 28% decrease in CNS-related deaths. In a follow-up, Cales studied the same Orange County area several years later, both before and after a regionalized trauma system implementation. He found that potentially preventable deaths fell from 34% to 15%, a 44% relative decrease that occurred even after the original publication and the national attention that focused upon the area.

Formal, rigorous, outside site review processes can improve the performance of hospitals already designated as trauma centers. Rural institutions that choose to designate themselves as Level III facilities have improved outcomes, even after transferring the patient. At all levels, it has become accepted knowledge in the United States that a regionalized system of care for the trauma victim is desirable. The overall reduction in preventable mortality is probably in the 50% range and the reduction in delays to disposition falls from 54% to 7%. The question becomes: Does the same logic apply to other time-critical diseases, and can we realize the same improvements in care?
STROKE

The mortality benefits of a formal stroke system have yet to be explicitly defined. These systems are new and the research is ongoing at this time. There are several studies that hint at improved outcomes for patients with AIS and for hemorrhagic stroke (which comprises about 20% of all strokes and has a 25% decrease in mortality when treated within a designated stroke center\textsuperscript{45,46}).

By inference, organized stroke systems should improve mortality. The use of thrombolytics for AIS is becoming less controversial, and the mortality benefit of this therapy has become more accepted, especially for the subset of patients treated within 90 minutes from symptom onset.\textsuperscript{47,48} There are more data that demonstrate that adherence to rigorous administration criteria can minimize complications and gain the mortality benefits delineated in the original study.\textsuperscript{49,50}

Subacute care within stroke units is better provided within designated and dedicated centers, decreasing both stroke progression and complications.\textsuperscript{51} Finally, a regionalized system can significantly improve the number of patients who receive acute interventions for stroke.\textsuperscript{52} Combined, these elements can reasonably be expected to decrease mortality and morbidity once entire systems are able to gather enough data to study the optimal system design.

ST-SEGMENT ELEVATION MYOCARDIAL INFARCTION

Systems of care that deal with STEMI have shown some significant decreases in in-hospital mortality and morbidity. One study failed to demonstrate any mortality improvement,\textsuperscript{17} but this may have been more of a function of the system design than any other factor. The time improvements were modest at best, and the authors agreed that the study was underpowered to detect any mortality decreases with these time savings.

In contrast, system designs that integrate all aspects of the EMCS have demonstrated significant savings in symptom-onset to definitive-care times, mortality, and morbidity. Gross et al. demonstrated a 76% relative reduction in overall in-hospital mortality (actual reduction of 6.5% compared to “NRMI-like” hospitals with a system that focused on early identification of STEMI patients and effecting rapid transfer for PCI therapy in a three-county regional system; “NRMI-like” hospitals was a category used in 2004 in the former National Registry for Myocardial Infarction database that compared “like” hospitals of similar size and capabilities).

Even more enlightening was the subgroup analysis based on initial destination of the patient. The subgroup of patients taken to an outside facility first, for “stabilization,” and then transferred had an average of 79 minutes added to their symptom-onset to definitive-care times. Their overall in-hospital mortality was 4.3%, while the in-hospital mortality for those patients who were taken directly to the PCI center (i.e., field triaged to the regional center) or walked into the PCI hospital was 0%.\textsuperscript{14} Lest one think this was an outlier study, these data and relative mortality decreases have been confirmed in a completely independent system in Ottawa, where the overall mortality was found to be quite similar at 1.9%.\textsuperscript{15,16}

These studies demonstrate significant savings in times, mortality, and morbidity that mirror those seen in the early days of the trauma system development. But we face political battles as difficult as those when we began the struggle for trauma systems. These battles are worth fighting when our patients’ lives are at stake.

PAYER/FUNDING ISSUES

Funding, not surprisingly, is a key factor. Trauma has a poor history of reimbursement, but cardiac care is fairly well reimbursed under the current U.S. system for hospitals. This may foster competition for such designations. Transporting agencies will need to be fairly reimbursed for their work within systems and longer transport costs. Indeed, the capabilities of each and every component within the Circle will have to be examined and fully funded to allow for the high efficiency necessary for such a complicated system to properly function.

Current reimbursement patterns by governmental and private payers often discourage system development and sustenance. Payers currently reimburse under the assumption that assessment and “stabilization” should be done at the closest facility, and that the patient should be transferred to a higher level of care when appropriate. This, in effect, discourages field triage to a more distant facility. Under the old paradigm of destination decisions being made only by physicians, this model had utility.
In the new paradigm of Time-Critical Diagnoses, “stabilization” at facilities without the capacity for definitive care only translates into delay and worsening of outcomes. From the Gross et al. study, we know that when a patient is stopped at an outside facility for “stabilization,” an average of 79 minutes are added to the patient’s eventual definitive care. Notably, this was in a system that sought to decrease the time required to transfer by several means, including a “one-call system.” In this day of EMTALA requirements, this figure seems reasonable.

Furthermore, when they studied the subgroups, those patients who were delayed for “stabilization” had a 4.3% in-house mortality versus 0% for those who walked into, or were field triaged directly to, the PCI center. These data argue forcefully against any delays in definitive care, and payers should re-examine their standards to accommodate the advances and concepts of regionalization.

WHAT DOES AN OPTIMAL SYSTEM LOOK LIKE?

The short answer is that we don’t know the final answer yet. The regionalization concept is a “work in progress,” and improvements are being made constantly. There are, however, some key concepts and tenets that we can enumerate today:

• Care needs to be “moved forward” and providers must be able to step out of their traditional roles and perform at a higher level than they would have done a decade ago. This does not necessarily mean technically challenging treatment. Instead, it means making a correct diagnosis quickly, making a correct triage and destination decision quickly, and being able to activate the appropriate receiving personnel. Out-of-hospital personnel must be better trained to recognize and make appropriate destination decisions.

• Importantly, medical directors for out-of-hospital personnel will have to guard against “mission creep.” That is, they will have to ensure that their personnel appropriately identify stroke and STEMI candidates without extending the field triage decisions to other patients who do not fall under the Time-Critical Diagnosis system (overtriage). In the trauma system, we have encouraged overtriage, and there have been few consequences when these inappropriate decisions were made. However, the fiscal impact to hospitals losing significant numbers of chest pain or “weak/dizzy” patients who do not qualify as STEMI or stroke patients will generate and maintain their political resistance to an integrated system. This stresses the need for accurate, reliable out-of-hospital diagnostic systems, such as 12-lead ECGs and prehospital stroke scales.

• It will be important for EMS medical directors to monitor their systems for inappropriate overtriage and to minimize those instances through education based upon quality-improvement benchmarks. A functional quality management system will become even more important and will need to “drive” the continuing medical educational programs for all members of the EMCS team. This necessitates an integration of all members into a coordinated quality management process.

• An aggressive data collection process that encompasses all components of the Circle is necessary. This data collection process allows analysis and effective quality improvement of the entire system so that “weak links” in the chain may be identified and improved.

• Clear protocols are needed at every level of the Circle to allow for early identification, moving care forward, simultaneous processing, and field triage of the patient to the correct destination.

• Incorporation of the traditional public health roles of public education and prevention as integral parts of the overall system is critical. This necessitates a working relationship with non-traditional partners but brings an entirely new audience to our daily work.

• Designation of SRCs should be done in a structured, formal fashion using outside review teams.

• A protected quality improvement process, free from concerns of discovery by plaintiffs’ attorneys, is critical for meaningful evaluation activities to occur. These activities need to include all components of the Circle, so that deficiencies can be identified and resolved in a non-confrontational manner.

• A designated overarching agency needs to be identified, with the necessary legal authority to oversee the political and administrative processes needed for a regional system to succeed.

• An oversight committee should allow for the input of expert stakeholders and encourage their
participation in the design and refinement of the system’s processes. Common subcommittees should include, but not be limited to, medical oversight, funding, public education, prevention, quality improvement, individual clinical committees (9-1-1, EMS, stroke, STEMI, trauma), and legislative.

- Organizational silos need to be acknowledged and resolved. Leadership focused on improving patient outcomes through decreasing the time from symptom onset to definitive care is the key to bridging the gaps between provider groups.

**SUMMARY**

The concept of regionalization of care will continue to grow. The data are compelling both for the trauma system and selected STEMI system designs. Regional referral centers will continue to promote themselves and their programs. Overtriage must be monitored carefully to protect smaller hospitals and systems lest they be harmed financially.

EMS medical directors are uniquely positioned to be able to coordinate all aspects of the Circle and to understand the disparate viewpoints of all the participants. We have the choice of actively participating in the design or not.

The analogy of the new homeowner with a freshly prepared plot of dirt comes to mind. That plot is going to grow something whether we actively manage it or not. We can sit back, do nothing, choose not to participate, and there will likely be a weed patch. If we actively manage the plot, sow seed, water, and tend it, we may grow a lush, green garden, where the fruits of our labors are measured in the lives of patients that would not have otherwise survived. The choice is ours.

**REFERENCES**

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