

## CONCEPTS

## Health Policy

# Concept review of regionalized systems of acute care: Is regionalization the next frontier in sepsis care?

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## Abstract

Regionalization has become a buzzword in US health care policy. Regionalization, however, has varied meanings, and definitions have lacked contextual information important to understanding its role in improving care. This concept review is a comprehensive primer and summation of 8 common core components of the national models of regionalization informed by text-based analysis of the writing of involved organizations (professional, regulatory, and research) guided by semistructured interviews with organizational leaders. Further, this generalized model of regionalized care is applied to sepsis care, a novel discussion, drawing on existing small-scale applications. This discussion highlights the fit of regionalization principles to the sepsis care model and the actualized and perceived potential benefits. The principal aim of this concept review is to outline regionalization in the United States and provide a roadmap and novel discussion of regionalized care integration for sepsis care.

## KEYWORDS

delivery of health care, emergency service, hospital planning, integrated, intensive care units, regional medical programs, sepsis

## 1 | INTRODUCTION

Regionalization is the concept of organizing patients and healthcare practitioners into a system “to deliver the right resources to the right patient in the right place at the right time.”<sup>1</sup> The objective of this concept review was 3-fold: (1) to provide a comprehensive summation of the available literature and established models of regionalized acute care, (2) to identify the common core components of regionalized systems, and (3) to apply lessons about regional networks to sepsis care.

## 2 | DEFINING REGIONALIZATION

Regionalization is a geographic process of formal or informal health care policy that accentuates one or more of the following: the distribu-

tion of physicians, the distribution of equipment and facilities, and the control of patient movement within the system.<sup>2</sup>

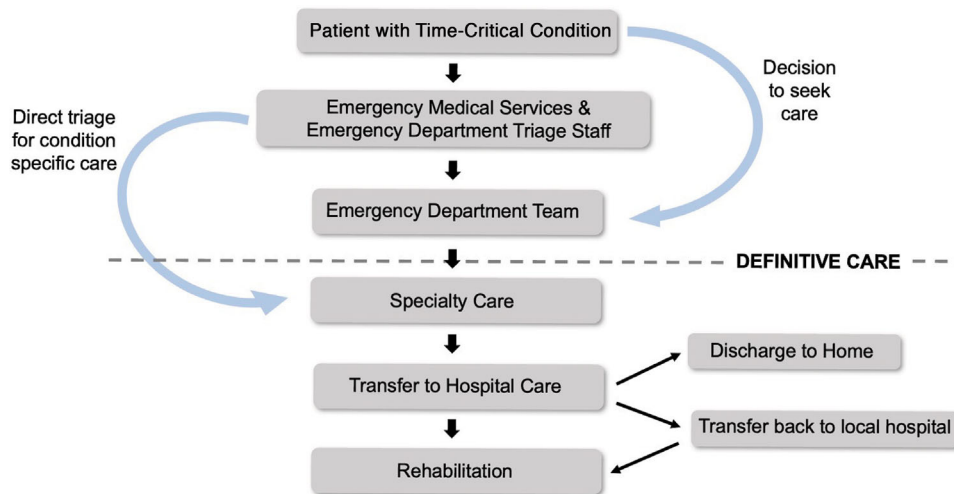
Regionalization is differentiated from “centralization.” Centralization is the consolidation of specialized services to higher-volume centers of care. In regionalization, systems are created to optimize the clinical capabilities of healthcare practitioners along the entire continuum of care for time-sensitive conditions (Figure 1).<sup>3</sup> Regionalization seeks to capitalize on the volume–outcome relationship: the observation that outcomes are better for specialized care delivered in centers that treat more patients.<sup>4,5</sup> A volume–outcome relationship has been demonstrated in trauma,<sup>6</sup> burn<sup>7</sup> stroke,<sup>8</sup> ST-elevation myocardial infarction (STEMI),<sup>9</sup> and neonatal ICU/obstetrics (NICU/OB)<sup>10,11</sup> care.

Regionalization within the United States has been limited historically because of a competitive, fee-for-service market-based system. Regionalization efforts instead have favored the formation of coalitions of private–public partnerships that share resources, coordinate

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**FIGURE 1** Flow diagram illustrating the standard sequencing of patient care for time-critical conditions

within the existing hierarchical network, and standardize care without direct restructuring of health care organizations.<sup>3,12</sup>

### 3 | ESTABLISHED SYSTEMS

The following provides brief summaries of the existing national models of regionalized care. Table 1 details each system more extensively.

1. Trauma: Trauma care has been the exemplar model of regionalization efforts, stemming from military experience with a tiered model of care<sup>13</sup> and the idea of the “golden hour.”<sup>14</sup> Initial work began in the 1950–1970s with the Committee on Fractures and other Traumas that eventually amalgamated into the American College of Surgeons Committee on Trauma (ACS-COT),<sup>15</sup> which published guidelines and initiated a national trauma verification program with over 1000 state-designated and 400 ACS-verified trauma centers. Over 70% of Americans now live within 45 minutes of a trauma center.<sup>3</sup>
2. Burn: Regionalized burn care has aligned closely with the trauma model, with the initial burn care guidelines being originally published in the Resources for Optimal Care of the Injured Patient.<sup>16</sup> In 1995, the American Burn Association (ABA) and the American College of Surgeons developed a verification process specific to regionalized burn care. Approximately 60% of acute burn patients are hospitalized at 1 of 123 self-designated burn centers—of which 65 are verified by the ABA and ACS.<sup>16,17</sup>
3. Neonatal Intensive Care/Obstetrics: Perinatal and neonatal ICU care has a history of regionalization dating back to the 1960s with the advent of neonatology as a subspecialty in pediatrics.<sup>18,19</sup> In 1976, the American Academy of Pediatrics and the American College of Obstetrics and Gynecology collaborated with the March of Dimes to publish guideline recommendations for perinatal care in “toward improving the outcomes of pregnancy,” which has been subsequently revised.<sup>20,21</sup> These guidelines have been imple-

mented in state perinatal health networks with ongoing federal and state funding.<sup>18</sup>

4. Stroke: In the mid-1990s, acute stroke therapy became time-sensitive with the advent of systemic thrombolysis<sup>22</sup> and now mechanical thrombectomy.<sup>23</sup> The Centers for Disease Control and Prevention developed initiatives that coincided with a series of developing guidelines by the National Stroke Association Stroke Center Network Program and Brain Attack Coalition that were further adapted by the Joint Commission into a program of stroke center verification with over 153 Comprehensive Stroke Centers, 1100 Primary Stroke Centers, and 45 Acute Stroke Ready Hospitals.<sup>8,24</sup>
5. ST-Elevation Myocardial Infarction: STEMI regionalized care started in 2004 when the American College of Cardiology/American Heart Association (ACA/AHA) established “door-to-balloon” time targets in STEMI.<sup>25</sup> In 2007, the Mission: Lifeline program was started to provide recognition and accelerate regionalization efforts.<sup>26</sup> The Joint Commission as of 2019 has offered 2 voluntary certifications for STEMI care.<sup>24</sup>

### 4 | STRUCTURAL ORGANIZATION OF REGIONALIZED SYSTEMS

The key principles behind regionalized systems are (1) standard selection, (2) infrastructure design and development, (3) data collection and surveillance, and (4) performance verification. Regionalization demands standardization through cooperation rather than competition.

Regionalization efforts vary significantly state to state and region to region, based on the level of organization, funding, professional leadership, and political prioritization. Regionalization efforts have followed a generalized, predictable pattern (Figure 2).

Professional organizations publish clinical guidelines of regionalized hierarchical systems.<sup>21,24,26,27,34</sup> These guidelines are adopted by governments, professional organizations, or third-party stakeholders for

**TABLE 1** Summation of national models of regionalization

| Trauma | Problem area addressed   | Leadership/criteria   | Generalized structure  | Differentiating factors   | Outcomes/database  |
|--------|--|---|--|---|--|
| Trauma | 24 hours in-house surgical coverage: specialty coverage—such as orthopedic surgery, neurosurgery, anesthesiology, emergency medicine, radiology, internal medicine, plastic surgery, oral and maxillofacial, pediatric and critical care, full lab and imaging diagnostic services, and operating room/postanesthesia care unit/ICU staff. | American College of Surgeons—Committee on Trauma (ACS-COT), <i>Resources for Optimal Care of the Injured Patient, 2014</i> . <sup>27</sup> Designation—State agency, generally follow ACS-COT standards, mandated through legislative or regulatory authority for levels of trauma care, requirements of participation, and associated penalties. Verification—voluntary, evaluation process done by ACS for level 1 and 2 centers according to adult/pediatric status, lasts for 3-year period.    | Tiered (Level I–V) according to capacity of care as by designation/verified criteria. EMS triage protocols to direct patient to most appropriate center of care—level Is for high-acuity surgical care, through level IV and V for smaller, local facilities providing rapid evaluation, essential stabilization and transfer up the chain.  | High-level trauma care is not profitable, <sup>28,29</sup> leading to minimal competition for providing trauma services outside of affluent urban areas. ACS verification process is active surgeon driven, self-imposed professional mandates leading to greater acceptance and level of participation. Proposed spinoff benefits for other time-sensitive, surgical emergencies: ruptured aortic aneurysms, etc. <sup>30</sup>  | From national data, risk-adjusted mortality from trauma was 7.6% in designated Level 1 trauma centers versus 9.5% in undesignated centers. <sup>31</sup> Another meta-analysis cited a 15% reduction in mortality after trauma system implementation. <sup>32</sup> National Trauma Data Bank <sup>27,33</sup> |
| Burn   | Specialized burn care is a low-volume, high-resource, high-expertise condition to treat. Burn teams, led by burn surgeons, involve multidisciplinary efforts that could not exist without regionalization of care and the consolidation of patients in a geographic catchment area to maximize volume-outcome relationship.                | American Burn Association. <i>American Burn Association—Burn Center Verification Review Program—Verification Criteria 2018</i> . <sup>34</sup> Voluntary, 3-year verification process principally evaluates survival, objective reviews of complications, emotional health and reintegration in society metrics. Additionally, the process verifies minimum guidelines for facility resources, volume, staffing, experience, continuing education, dedication to prevention, teaching and research. | Self-designated and American Burn Association verified burn centers: <ul style="list-style-type: none"> <li>• Specialized unit, with dedicated ICU beds</li> <li>• Transfer agreements for trauma care</li> <li>• Responsive surgeon and care team ratios to fit patient acuity</li> <li>• Rehabilitative services—occupational/physical therapy, social and psych</li> <li>• Sufficient number of yearly admissions (100 patients)</li> </ul> | Nurse staffing ratios and need for rehabilitation services unique to burn care—low turnover and high degree of multispecialty cooperation. Burn care given its resource-intensive nature has low profitability to a hospital <sup>35,36</sup> , but given a significant catchment area can remain independently viable, even turn a profit if surrounding institutions do not "skim" insured patients. <sup>37</sup> Spin off benefits for highly morbid conditions such as toxic epidermal necrolysis, necrotizing fasciitis and frostbite. <sup>38–41</sup> | Regionalization of burn care within the New York City metropolitan area was associated with care for patients in designated facilities in over 75% of the cases and a reduction in mortality by almost 50%. <sup>42</sup> National Burn Data Standard and National Burn Data Repository. <sup>34,43–45</sup>   |

(Continues)

TABLE 1 (Continued)

|                     | Problem area addressed   | Leadership/criteria  | Generalized structure  | Differentiating factors   | Outcomes/database   |
|---------------------|--|--|--|---|---|
| Stroke              | Stroke became an acute care condition with intravenous tPA, thrombectomy, and neurosurgical intervention results demonstrating time-sensitive benefits. System of care: IV tPA, computed tomography scanner, and stroke center—therapeutic, consultation, and interventional capabilities. Bypass to Primary Stroke Center/Comprehensive Stroke Center if < 15–20 minutes transport time. IV tPA at regional hospital if > 15–20 minutes transport time. | The Joint Commission (TJC)—Stroke Program with participation of the American Heart Association (AHA) and American Stroke Association. <i>Specifications Manual for Joint Commission National Quality Measures</i> . <sup>24</sup> Voluntary verification process through a Disease-Specific certification program.   | Four-tiered certification system: <ul style="list-style-type: none"> <li>Primary Stroke Center—stroke service/unit with tPA capabilities (2003)</li> <li>Comprehensive Stroke Center—telestroke service and complete surgical coverage (2012)</li> <li>Thrombectomy Stroke Center—provide thrombectomy for large vessel occlusions (2018)</li> <li>Acute Stroke Ready Hospital—primarily rural, tPA available and telestroke consult agreements (2018)</li> </ul>              | Stroke patients are primarily Medicare covered, <sup>46</sup> every hospital desires to treat stroke patients. <sup>3</sup> Telestroke is well-received and highly effective given that stroke consult is principally cognitive based and easy to conduct via phone/imaging review. Although stroke programs are well developed and yielding successful outcomes, the EMS bypass and triage protocols are not as robust nor effective as in the trauma system—lack of state mandates.   | Organized care data from Canada and Taiwan has been shown to reduce the following risks associated with stroke: death by 14%, death or institutionalized care by 18%, and death or dependency by 18%. <sup>8,47,48</sup> American Heart Association - Get Within the Guidelines Stroke (GWTG-S) <sup>49–53</sup>  |
| STEMI<br>PCI/Fibrin | Ongoing evidence has demonstrated a decreased chance of survival if either fibrinolysis or PCI is delayed >30 minutes. <sup>54</sup> Push to get patients to PCI/thrombolysis capable centers as expediently as possible (door to balloon/needle times of <90 minutes and <120 minutes for inter-hospital transfer patients).  | AHA and American College of Cardiology (ACC)—Mission Lifeline: Recognition Program. TJC—STEMI/Cardiac Program (Effective July 1, 2019). <i>American Heart Association Mission: Lifeline - Hospital Recognition Criteria v.3</i> . <sup>26</sup> Centers that meet certain time and guideline goals receive recognition on Gold, Silver, and Bronze levels respective to outcomes and compliance level. TJC program will feature 2 voluntary certifications for STEMI care. | Primary PCI centers meeting ACC/AHA guidelines: <ul style="list-style-type: none"> <li>Fellowship-trained interventional cardiologists</li> <li>Volume: 11 primary PCI procedures/year and 75 total PCI procedures per year</li> <li>± Cardiothoracic surgeons on staff or explicit transfer agreements for supportive care for patients with STEMI and complications—cardiac ICU</li> <li>Meet triage, time, and outcome goals according to established guidelines</li> </ul> | Cardiac PCI care is profitable and most general medical service hospitals rely upon cardiovascular care for financial viability. <ul style="list-style-type: none"> <li>Patients generally do not stay in hospital long (~24–48 hours post-op), leading to lower capitated payments</li> <li>System not as coordinated with significant “cooptation”—A mix between competition and cooperation, non-optimized system</li> </ul> Higher degree of EMS involvement with ambulance ECG and triage education for suspected STEMI. Certificate of Need laws play a significant role in establishing cardiac care facilities, minimizing procedure volume dilution. | Multiregional study in the United States indicated all process measures demonstrating coordination between EMS and hospitals had improved—first medical contact to ECG device use time of ≤90 minutes (hospital within ≤10 minutes), first medical contact to device time to catheterization laboratory activation of ≤20 minutes, and emergency department dwell time of ≤20 minutes. These improvements in treatment times corresponded with a significant reduction in mortality (in-hospital death 4.4%–2.3%; $P = 0.001$ ) that was not apparent in hospitals not participating in the project during the same time period. <sup>54</sup> American Heart Association—Coronary Artery Disease (GWGT-CAD) databases, <sup>49–53</sup> the Cardiac Arrest Registry to Enhance Survival (CARES). <sup>55</sup> |

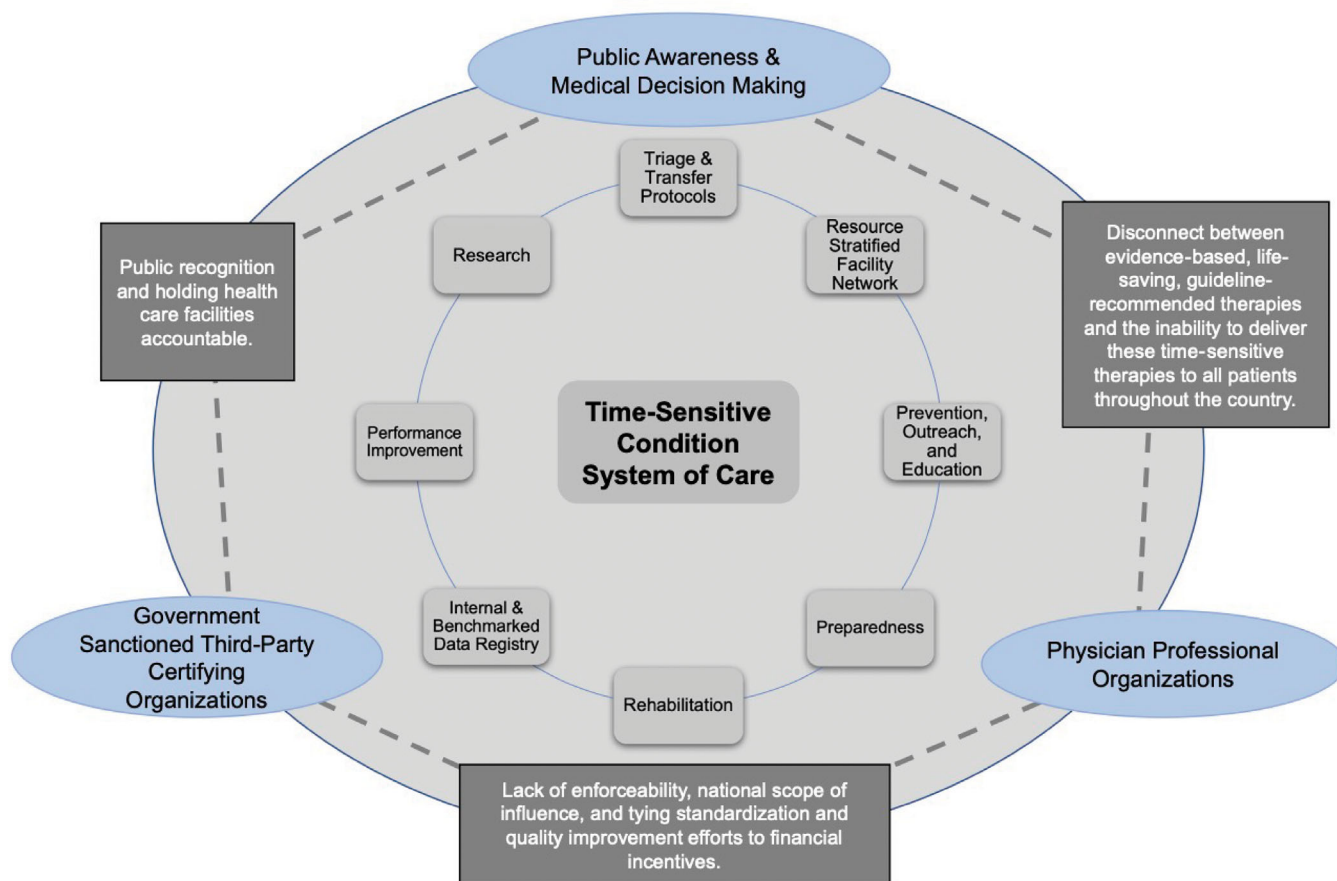
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TABLE 1 (Continued)

| Problem area addressed       | Leadership/criteria  | Generalized structure   | Differentiating factors   | Outcomes/database  |
|------------------------------|--|---|---|--|
| Neonatal ICU/obstetrics (OB) | American Academy of Pediatrics <i>Levels of Neonatal Care—American Academy of Pediatrics Policy Statement</i> (21), 21.<br>Recommendations for levels of perinatal care established in consortium with the March of Dimes through "Toward Improving the Outcome of Pregnancy."<br>These recommendations have been adopted by state perinatal programs and networks. Federal grant money available for system. Varies state to state regarding level of integration and verification. | Recommended levels of neonatal care:<br>Level 1—Well newborn nursery: neonatal resuscitation, stabilize and provide care for infants born 35–37 weeks.<br>Level 2—Special Care Nursery: Provide care for ≥32 weeks with neonatal specialists.<br>Level 3—Neonatal ICU: Provide care <32 weeks with pediatric subspecialists.<br>Level 4—Regional Neonatal ICU: all the above in addition to pediatric surgical subspecialists | Long-standing federal and state grant support. <sup>18</sup><br>Guidelines interpreted broadly and verification generally limited. No national verifying agency. Varies state to state.<br>Neonatal ICU care has seen increasing level of profitability, with more hospital facilities interested in providing intensivist care. <sup>56–58</sup><br>Obstetric labor and delivery in comparison has progressively decreased in profitability, with small hospitals and facilities facing ceasing their services nationwide. <sup>59</sup> | One meta-analysis demonstrated significantly worse outcomes for very low-birth rate and very preterm infants born at level 1 and 2 centers compared to higher levels. <sup>60</sup> Several studies that have looked at it from a state-level perspective have found significant benefit for premature infants <sup>10,11</sup> and have additionally identified that deregionalization trends have negatively affected care outcomes. <sup>61–64</sup><br>Vermont-Oxford database for neonatal ICU/OB care. <sup>65</sup> |

Abbreviations: ABA, American Burn Association; CT, computed tomography; EMS, emergency medical services; PCI, percutaneous coronary intervention; STEM1, ST-segment-elevation myocardial infarction; tPA, tissue plasminogen activator.





**FIGURE 2** Pictorial representation of the structural generalization of regionalized systems of acute care. The interior of the figure is composed of the identified 8 core components of regionalized systems that function concurrently. The circles in the outer triangle are the 3 constituents and description of the role and structure they provide relative to one another (the text on the lines between the circles) in systems of care. The figure demonstrates the multipart and party efforts that sustain the national models of regionalized care

verification in participating facilities. The funding for these efforts is largely sourced from fees paid by participating health care facilities for verification. Health care facilities participate for public recognition as evidence of verified efforts to improve clinical outcomes.<sup>3</sup> In some states, government agencies base accreditation on participation with varying degrees of legal, financial, and resource support.<sup>3,21,24,26,27,34</sup> Common to each of the systems, the guidelines and framework can be generalized to 8 core components that are discussed next.

## 5 | COMPONENTS OF REGIONALIZED SYSTEMS

### 5.1 | Triage and transfer

Delivering timely specialized acute care requires practical and evidence-based prehospital triage and interhospital transfer protocols. The time from symptom onset to arrival at an emergency department is often a source of delay, and this time can cause significant morbidity and mortality.<sup>3,66-68</sup> Regionalized triage protocols must consider time, geography, and hospital capabilities in selection. By allowing emergency medical systems (EMS) agencies to bypass local

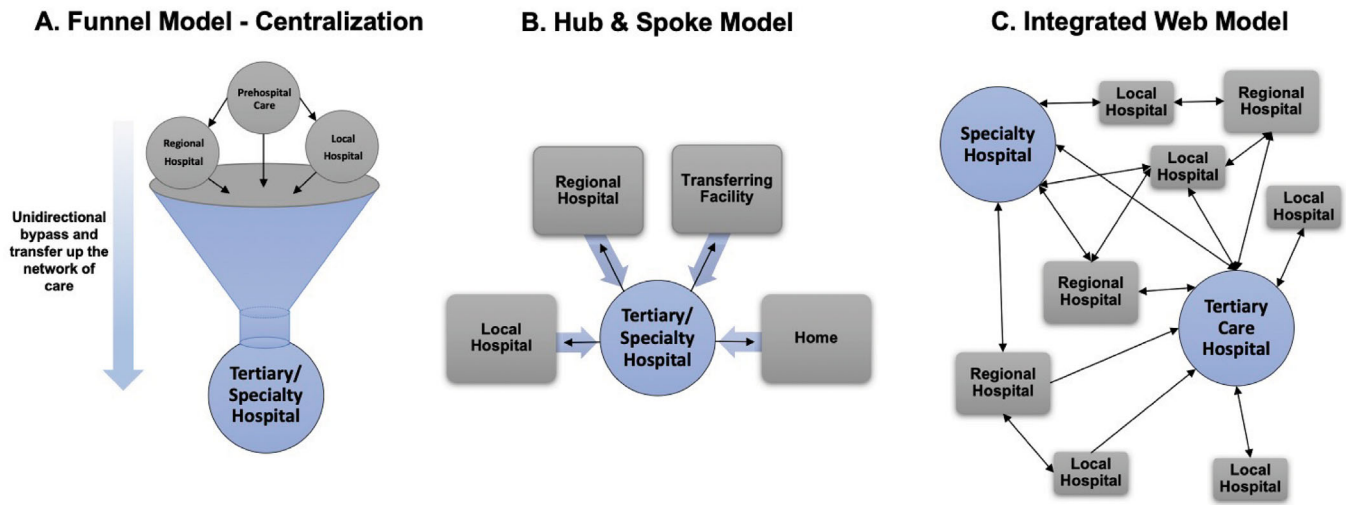
hospitals without advanced specialty capabilities, outcome benefits can be most pronounced—the evidence is particularly strong in stroke and STEMI care.<sup>54,49,66,67</sup>

Standardized severity assessment scales have been one approach to formalizing patient assessment. The Revised Trauma Score<sup>69,70</sup> and Rapid Arterial Occlusions Evaluation scores<sup>71</sup> have been used to identify patients for regionalized triage. Although these assessment scales have limitations, they provide a standard language for prehospital professionals to use to guide destination selection.

Advanced technology can augment prehospital triage. Notable applications have been the use of 12-lead ECG machines by EMS personnel<sup>54</sup> and telemedicine triage. In some instances, a tablet computer allows doctors to speak with patients and EMS healthcare practitioners remotely to select the most appropriate destination.<sup>72</sup>

### 5.2 | Resource stratified-facility network

Regional systems function in a multidirectional tiered hierarchy with the goal of matching clinical resources to patient needs (Table 1). Systems often adhere to characteristic models (Figure 3).<sup>3,11,73</sup> In



**FIGURE 3** These 3 characteristic models, which have been discussed in the literature, demonstrate the degree of integration and organization within regionalized networks of care. Arrows indicate patient flow. The “integrated web” model has emerged as the desired conception of a regionalized and integrated system of care

practice, most networks have relied solely on resource-focused stratification of existing facilities. The creation of a regionalized system of care poses several challenges: identifying the ideal geospatial organization of an ad hoc system and the state-by-state management of the system through designation/certification/verification processes.

1. Geographic Information Systems (GIS): GIS approaches have been applied to optimizing regionalized systems. These analyses propose locations for additional care facilities, typically in areas with rural or minority populations.<sup>74–81</sup> The ACS-COT conducted and developed a Needs Based Assessment of Trauma Systems Tool for evaluating trauma service areas. The tool was designed to aid in trauma system planning and has been tested with mixed success in Tennessee and California.<sup>82–84</sup>
2. State designation, certificates of need, and verification: The tiered structure of a regionalized system is often established by state policy. Facilities may be designated by the state or regional authorities. Thirty-five states have Certificates of Need regulations, which artificially limit competition in providing specialized services to improve outcomes, which has been implemented with mixed success.<sup>85</sup>

Alternatively, outside agencies (ACS-COT, The Joint Commission) may verify that facilities meet the criteria for specialty-specific designation. Continuous verification ensures that the appropriate resource infrastructure remains in place and functional.<sup>21,24,26,27,34</sup>

### 5.3 | Prevention, outreach, and education

The educational aims of regionalized systems affect the entire continuum of care. Professional organizations and national programs take the lead in organizing and preparing public and professional educational programming. Regional and local hubs contribute to training the

public in bystander response and methods for activating the acute care system (ACS-COT’s Stop the Bleed program,<sup>86</sup> AHA’s FAST stroke symptom recognition<sup>87</sup> and cardiopulmonary resuscitation training<sup>88</sup>). These programs view public response as the first step in reducing EMS response times and improving patient outcome.<sup>87,89</sup>

Incorporating standardized disease-specific training for health-care practitioners has been shown to have considerable impact.<sup>90</sup> In the trauma and cardiac care systems, this standardization has been achieved through basic life support and advanced life support classes offered as part of regional care systems.<sup>91</sup>

At the hospital and facility level, the verification process of every regionalized system requires some type of standardized training: advanced trauma life support,<sup>92</sup> advanced cardiac life support,<sup>93</sup> pediatric advanced life support,<sup>94</sup> and neonatal resuscitation program.<sup>95</sup> Tertiary care centers play the principal role in organizing these programs as required by verification criteria, which provides an organized dissemination pathway.

### 5.4 | Preparedness

Regionalized systems play a vital role in disaster preparedness and mass-casualty incidents evidenced in trauma,<sup>96–98</sup> burn,<sup>99–101</sup> and pediatric care.<sup>102</sup> By conducting resource assessments across the network and negotiating cooperative plans for surge events, regionalized systems can be well positioned to support the distribution of resources and care capacity that enable a rapid and organized disaster response.<sup>3</sup>

### 5.5 | Rehabilitation

Rehabilitation is a critical component of recovery for patients with acute care conditions—trauma,<sup>103</sup> burn<sup>104</sup> stroke,<sup>105</sup> STEMI,<sup>106</sup> and NICU/OB.<sup>107,108</sup> The outcomes currently tracked for acute

care conditions are generally restricted to process measures and outcomes.<sup>3,103,109</sup> This neglects the many patients left with disabilities and reduced quality of life, and regional care networks allow for assessment of longer term outcomes.

## 5.6 | Internal and benchmarked data registry

Regionalization networks sponsor national or local patient registries. Internal, hospital-based, clinical data registries aggregate data to identify variations in care for quality improvement and have proven effective when paired with rigorous performance improvement (PI) processes.<sup>110</sup>

Each system has established its own respective registry listed in Table 1. These registries standardize data collection by case acquisition, case definition, and coding conventions. By requiring registry compliance in the verification process, the proportion of capturing eligible cases is increased, the value of these information systems is amplified, and systemwide performance goals can be evaluated.

Unfortunately, these data systems are fragmented. They often include only paying facilities, lack linkage to EMS agencies and transferring hospitals,<sup>111</sup> and use proprietary software that limit public data access.<sup>112-114</sup> Additional issues include sustainability because of the resources needed to continually collect data,<sup>110</sup> incomplete data,<sup>111</sup> and control for covariates.<sup>33,115</sup>

## 5.7 | Performance improvement

Regionalization standardizes PI processes. Site visits offer an opportunity to review the PI process, ensuring that a process exists to identify cases for review and demonstrate institutional commitment to improvement.<sup>27</sup> The site review process functions both to independently evaluate system standards and to cross-pollinate best practices. Each of the national models has established quality improvement programs, such as ACS's Trauma Quality Improvement Program.<sup>115-117</sup>

## 5.8 | Research

Using data from benchmarked data registries, each of the systems has analyzed metrics assessing a system's outcomes and the appropriateness of patient transfer within the system—through reporting of over and undertriage rates.<sup>118</sup> Published studies supporting the benefit of each of the regionalized approaches to acute care are presented in Table 1.

## 6 | THE CASE FOR REGIONALIZING SEPSIS CARE

Systems of care drive local and regional processes, and examples of regionalization systems for other acute care conditions provide a template for how these networks can improve quality of care and outcomes. Sepsis is one example of an acute care condition for which

regional care should be considered, and several small-scale examples of regional sepsis networks have been developed.<sup>119-122</sup> Is regionalization the next frontier in sepsis quality?

### 6.1 | Need for a sepsis regionalization network

The experience of other regional networks define criteria for diseases that can be effectively regionalized. First, regional care networks are developed for diseases that require specialized care for which triage and transfer protocols are vital to optimizing outcomes. In many cases, this is evidenced by (1) specialized technology or training (in a resource-stratified network) or a (2) strong volume-outcome relationship for a time-sensitive condition in which patient choice may be impaired. Second, networks function best when they incorporate prehospital healthcare practitioners because of the importance of prehospital decision-making in care or triage. They may also require rehabilitation as part of the continuum of care with condition-specific considerations. Third, conditions that require significant public outreach for prevention, education, and preparedness activities are particularly amenable to regionalization. These networks may support registry-based data collection, research activities, and local or regional standardization and protocol development.

Does sepsis meet these standards? Sepsis care follows a robust volume-outcome relationship,<sup>123,124</sup> with care in high-volume facilities having the best outcomes. Previous work has shown not only that interhospital transfer is associated with higher mortality<sup>125-129</sup> but also that rural bypass puts patients at increased risk of death.<sup>130</sup> Timely care is associated with improved clinical outcome,<sup>131,132</sup> and the conditions under which patients require sepsis care impair their ability to choose their setting for care (eg, vulnerable population). Delays in sepsis recognition, early resuscitation, and transfer continue to put patients at risk.<sup>133</sup> In fact, if care in top-performing hospitals were available in lower performing centers, an estimated 20,000 US sepsis deaths could be prevented. Although sepsis care does not require advanced technology, it does require staffing and procedural resources—notably critical care and in some cases interventional radiology or surgery for source control—that are not routinely available in all hospitals.<sup>134</sup> Critical care services for advanced organ failure support for sepsis, however, often exist within other regionalized networks, such as trauma and stroke systems.

Prehospital care is common in sepsis, and some data suggest that prehospital recognition and management may influence outcomes.<sup>135</sup> Finally, sepsis care is currently poorly standardized (especially beyond initial resuscitation), with significant controversy surrounding the importance of a protocolized approach.<sup>136-138</sup> Standardizing training and outreach activities may be one strategy to expand the focus of sepsis quality improvement from one of process-based accountability (eg, SEP-1 measure) to one of sustained process improvement.

Financial barriers to sepsis regionalization may include a less lucrative sepsis payer mix, fewer sepsis-associated procedures, and billing complications amid variance in clinical protocols.<sup>139,140</sup> This consideration has been recognized in stroke regionalization but has been overcome in many settings to optimize patient outcomes.



## 6.2 | Attributes of a sepsis regional care network

Comparative analysis of regionalization networks reveals that the administrative structure and funding of these networks comes through 1 of 2 pathways: professional organizations or accrediting bodies. In many cases, these networks are driven by specialty groups who have a mission of improving access to relevant specialty care. A similar structure could be developed through a collaboration of critical care societies.

Ad hoc regional sepsis networks exist, in that critically ill patients may be triaged to more capable hospitals. Unfortunately, those triage networks have not yet been optimized, and overtriage and undertriage still plague sepsis network development.<sup>141–146</sup> These networks could be built on a hierarchical structure of patient-focused and facility-focused criteria that can better distribute patients among inpatient resources. In an era of resource constraints, increased regionalization, and overcrowding in tertiary care centers, formalizing risk stratification<sup>147–150</sup> to match patient needs seems a viable approach to sepsis process improvement efforts.

Such a network may play an outsized role in regional process improvement. Historically, sepsis quality measures have been narrowly focused. In contrast to the comprehensive multispecialty process-based approach of trauma, stroke, burn, and STEMI networks, sepsis quality has been defined by adherence with a narrow set of objective early activities. Although that approach has focused efforts in ED and ICU resuscitation care, it has neglected the importance of multispecialty involvement in robust comprehensive process improvement activities, public education and outreach, and care pathways that extend beyond the first 6 hours of care. Incorporating a more global approach to sepsis management allows for more rapid dissemination of knowledge and incorporation of local factors in the development of sepsis activities. The structure of formal sepsis care networks has the capacity to significantly improve clinical outcomes, even absent innovation in diagnostics or treatment.

One regional quality improvement initiative has illustrated the utility of a regional approach to sepsis. The Kansas Sepsis Project is a collaborative based at the University of Kansas, and it has distributed a model of pragmatic care and quality improvement through midsized health systems in Kansas.<sup>119,120</sup> By connecting small hospitals with regional centers and engaging in shared process improvement, the Kansas Sepsis Project has effectively provided a structure for rural hospitals to provide high-quality care in a standardized care environment, with criteria for screening and interhospital transfer. Early data suggest effectiveness of the program, but reports of efficacy have not yet been published.

## 7 | CONCLUSIONS

Regionalization of care is conceptually straightforward. Between the volume–outcome relationship and the number of conditions that have time-sensitive care interventions that need resource-appropriate care,

there are evidence-based arguments that regionalized care should be established for many conditions. Trauma, burn, ischemic stroke, STEMI, and NICU/OB care have seen improvements in outcomes associated with regionalization. Cardiac arrest, critical care, and sepsis may benefit as well.

Regionalization is part of the modernization of medicine. Regionalization will gain importance as health care transitions to a model of population health, coinciding with increasing government involvement<sup>151</sup> and anticompetitive policies, where systemwide efficiencies will allow avenues for different strategies of investment to improve outcomes. Public health agencies, payers, and regional governments have a stake in the outcomes of acute care regionalization. The challenge is coordinating silos of appropriately specialized disease-focused care into a regionally coordinated superstructure of acute care that optimizes patient outcomes throughout the United States. Understanding the framework, processes, and comparative differences behind regionalized systems will be valuable to improving existing systems and establishing new ones.

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### ETHICAL APPROVAL AND CONSENT TO PARTICIPATE

This study was determined to not constitute human subjects research by the University of Iowa institutional review board and thus approval was waived. This manuscript does not contain any individual person's data.

### CONFLICT OF INTERESTS

No financial or non-financial competing interests for either author.

### DATA AVAILABILITY STATEMENT

As listed per work cited. Digital recordings of interviews where permission to record was provided are available upon request.

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## SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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