Regionalization of health care is a method of providing high-quality, cost-efficient health care to the largest number of patients. Within pediatric medicine, regionalization has been undertaken in 2 areas: neonatal intensive care and pediatric trauma care. The supporting literature for the regionalization of these areas demonstrates the range of studies within this field: studies of neonatal intensive care primarily compare different levels of hospitals, whereas studies of pediatric trauma care primarily compare the impact of institutionalizing a trauma system in a single geographic region. However, neither specialty has been completely regionalized, possibly because of methodologic deficiencies in the evidence base. Research with improved study designs, controlling for differences in illness severity between different hospitals; a systems approach to regionalization studies; and measurement of parental preferences will improve the understanding of the advantages and disadvantages of regionalizing pediatric medicine and will ultimately optimize the outcomes of children. Pediatrics 2010;126:1182–1190

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The phrase “regionalization of health care” suggests the development of a structured system of care “to improve patient outcomes by directing patients to facilities with optimal capabilities for a given type of illness or injury.” The development of a regionalized system is typically driven by economic factors, such as the infeasibility of all hospitals to maintain the equipment and personnel to treat specific medical conditions, or by interhospital variations in patient outcomes within a geographic region.

The development of these regionalized systems is not the same as the development of regional centers of care. Competitive market forces that focus on improved outcomes create regional centers of excellence at which patients choose to receive care. Examples of such regional centers include adult cancer care and complex surgical procedures. However, a number of conditions, such as adult cardiac care and stroke management, are less amenable to these free-market principles, because their acute presentation does not allow patients to make informed choices on where they will receive care. For these conditions, regionalized systems ensure that patients receive the early care necessary to optimize their outcomes.

It is unfortunate that the evidence base for regionalized systems in pediatric medicine has lagged behind the development of such systems. The purpose of this article is to (1) present a conceptual framework for the development of regionalized health care systems, (2) describe types of evidence for regionalized systems, (3) describe the overall deficiencies in the current literature, and (4) outline a plan for future research. In this review we use neonatal intensive care and pediatric trauma care as examples for other pediatric conditions that, in the future, may be amenable to a more regionalized approach to care. In both areas, hospitals are already given a “level” of care based on their capabilities that differ between neonatal intensive care units (NICUs) and pediatric trauma centers (Table 1).

### CONCEPTUAL FRAMEWORK

Regionalization improves patient outcomes through 2 primary mechanisms (Table 2): improved outcomes at high-volume, high-specialty centers and improved coordination of care within a given geographic area. Regionalization may take several forms (Fig 1). Models such as the spoke-and-hub system and the web system are characterized by a specialized center that manages the most complex conditions in patients within a geographic area and is supported by less specialized hospitals. The degree of coordination between hospitals helps distinguish the 2 systems. The “mini-hub” model is a less coordinated, “deregionalized” system that may develop depending on financial incentives, hospital and geographic characteristics, patient preferences, and lack of coordination between centers (Fig 2).

### TABLE 1 Levels of Care for NICUs and Pediatric Trauma Centers

<table>
<thead>
<tr>
<th>Levels ofNICUs</th>
<th>Levels of pediatric trauma care</th>
</tr>
</thead>
<tbody>
<tr>
<td>I Basic neonatal care available</td>
<td>Regional resource trauma center</td>
</tr>
<tr>
<td>II Specialty neonatal care available, primarily for those ≥1500 g at birth</td>
<td>Trauma center, may not be able to provide comprehensive care for the most severely injured patients</td>
</tr>
<tr>
<td>III Subspecialty neonatal care available</td>
<td>Hospital provides assessment, resuscitation, emergency operations, and stabilization of patients before transfer to a facility that provides definitive trauma care</td>
</tr>
<tr>
<td>IIIA Hospital or state-mandated restriction on type and/or duration of mechanical ventilation</td>
<td>Facility provides advanced trauma life support before patient transfer</td>
</tr>
<tr>
<td>IIIB No restriction on mechanical ventilation; no major surgery</td>
<td></td>
</tr>
<tr>
<td>IIIC All surgeries except congenital heart disease repair and extracorporeal membrane oxygenation</td>
<td></td>
</tr>
<tr>
<td>III D All surgeries</td>
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### TYPES OF REGIONALIZATION STUDIES AND THEIR OUTCOMES

#### Studies of Individual Hospitals: Improved Outcomes at Specialty Hospitals

One recognized outcome of regionalization research is that the management of complex conditions at specialized hospitals may improve outcomes. For example, studies from California revealed that premature infants delivered at lower-level or lower-volume NICUs had a 19% to 272% increased odds of mortality. Older studies and other recent studies from Colorado, South Carolina, and Illinois had similar results.

In contrast, although evidence suggests that injured adult patients have improved outcomes at definitive trauma centers, state-specific or single-institution studies have not consistently resulted in improved outcomes for pediatric trauma victims treated at pediatric trauma centers or high-volume centers. One national study revealed that pediatric trauma victims have improved outcomes when cared for at freestanding children’s hospitals. However, this comparison disregards confounding from trauma level. The current classification of pe-
pediatric trauma centers lacks uniformity, which makes large-scale evaluations of outcomes according to trauma level extremely difficult. Although performing single-center or single-state studies standardizes this classification, these studies are poorly generalizable to the national trauma system. Thus, in 2007, the authors of a scientific review concluded that there was insufficient evidence to determine where pediatric trauma victims have the best outcomes.29

**Studies of Geographic Systems: Increased Geographic Coordination of Care and Knowledge Transfer**

Regionalization of care may also improve patient outcomes through increased coordination of care and knowledge transfer between central, specialized hospitals and non–specialty hospitals. Measured from a population perspective, implementation of a trauma system provides a 15% to 20% improvement in survival rate among seriously injured patients.30 Regionalized pediatric trauma care has been shown to result in similar improvement in mortality rates for patients who are injured and those who have been in a motor vehicle crash.31,32

Unlike pediatric trauma care, there have been few studies of the impact of neonatal intensive care systems on perinatal health and outcomes. Many studies occur outside the United States.33,34 Results of the 1 randomized study of neonatal intensive care regionalization performed in the late 1970s suggested that a regionalized system increases deliveries of very low birth weight infants at specialty hospitals without a significantly lower mortality rate.8 More recent studies have examined the impact of perinatal deregionalization within a single geographic area.18,35–39 There have been few attempts to measure the impact of these poorly organized deregionalization programs.
on outcomes within a geographic area. As with pediatric trauma studies, single-state studies have limited generalizability and statistical power to detect a difference in outcomes.

**Moderating Factors for the Development of Regionalized Systems**

There are a number of factors that help determine both the degree of regionalization and the type of system that develops in any given geographic area (Fig 2). Although there have been no studies of the relationship between geographic factors such as population density, the composition of the physician workforce, and the type of system that develops, studies of other modulating factors help explain the development of various regionalized systems of care.

**Financial Incentives**

Financial incentives play a role in the development of different types of regionalized systems. The regional model of neonatal intensive care began to weaken in many areas of the United States by the 1990s. For example, in California between 1990 and 1997, the percentage of very low birth weight births at regional perinatal centers declined from 36.5% to 27.2%, and the percentage of these births at community hospitals increased from 11.7% to 37.4%. The economic incentives in obstetric care help explain some of this expansion of specialty NICUs. Fees for the delivery of the infant are much higher than the fees, if any, for the provision of prenatal care. Thus, many hospitals are under economic pressure to open a specialty NICU to reduce the number of transfers of high-risk women to a central, specialty unit. These community specialty NICUs typically do not have the capability to manage all premature infants delivered at their hospital, which results in a "miniweb" model of health care, in which there are multiple large- and small-volume specialty centers that vary widely in their transport capability and coordination of care with non–specialty units and other specialty units (Fig 2). Although these community specialty hospitals may meet the evidence provided by studies that focused on the improved outcomes of patients treated at specialty hospitals, such systems undermine the original intent of regionalized care by limiting the number of infants transferred to central, high-volume hospitals. These factors result in maldistributed capacity. A comprehensive examination of the outcomes and costs of such systems is essential to optimize the outcomes of premature infants.

In pediatric trauma care, the financial incentives of care are quite different. Many hospitals do not profit from the provision of pediatric trauma care. Thus, an estimated 28.5% of the pediatric population lacks prompt access to high-level pediatric trauma care, whereas other regions have multiple hospitals with high-level pediatric trauma capabilities. As with neonatal intensive care, the expansion of pediatric trauma care has not historically matched the needs of the population. Remedies to this mismatch may require expansion of high-level pediatric trauma centers into new regions or the development of a coordinated-care approach.

**Coordination of Care Between Hospitals**

There has been interest recently in using alternatives to patient transport for the coordination of patient care. One feature that underlies the more interrelated “web” models of regionalized care is the amount of coordination between various specialty hospitals and between specialty and non–specialty hospitals. The most prominent alternative has been the use of technology such as telemedicine to deliver the doctor, albeit virtually, to the patient. For example, telemedicine may allow a patient to be kept at a local, less specialized center when access to a subspecialist is the primary reason to transfer a patient. This practice is amenable to subspecialists who rely on pattern recognition and cognitive decision-making, including radiologists interpreting radiographs, ophthalmologists examining the retina of a premature infant, dermatologists examining rashes, and vascular neurologists examining patients and reviewing imaging studies. Even for conditions that may require procedural interventions, such as critical care medicine, telemedical consultation has been used to assist in the management of patients before transfer. The effectiveness of such remote interactions, however, is uncertain, because of small sample sizes or technological barriers to accurate image quality.
An additional challenge to these telemedicine models is the continued need for a baseline level of specialist care or cognitive knowledge at the non-specialty unit. These services can extend beyond physicians, including the quality of nursing staff and specialized equipment that may be available only at the specialty hospital. Rigorous observational or experimental studies of the costs and benefits of these treatment modalities are still needed.

**DEFICIENCIES IN THE LITERATURE**

There are common deficiencies in many areas of regionalization research. These deficiencies include inadequate adjustments for case-mix differences between specialty and non-specialty hospitals, a limited number of assessed outcomes, and failure to account for the quality of individual hospitals in the analysis.

**Differences in Case Mix**

Because of the observational nature of most regionalization research, the research design must account for the fact that specialty hospitals typically care for sicker patients than non-specialty hospitals. These differences can be measured by using either basic markers of illness risk such as gestational age or mode of delivery in studies of premature infants or illness severity scores, such as the Score of Neonatal Acute Physiology (SNAP), in neonatology and the Injury Severity Score (ISS) and Trauma and Injury Severity Score (TRISS) in pediatric trauma. However, <30% of the studies of perinatal regionalization controlled for illness severity. Also, these scores may be inaccurate, may rely on data unavailable in large-scale population studies, or “control” away for poor-quality care that occurs when data are being collected. This latter point is potentially important for scores such as the SNAP, which uses information from the first 12 to 24 hours after delivery to calculate the score, which could adjust for poor-quality resuscitation. Even with methods to control for case mix, there still may be unmeasured differences in the patients receiving care at specialty hospitals. In pediatric trauma, a well-discriminating injury-scoring system cannot control for the unmeasured factors that lead an emergency medical service team to transport a pediatric trauma patient directly to a pediatric trauma center. These factors include weather, perceived severity of the injury, and the clinical stability of the patient. Unmeasured factors in neonatal studies include fetal heart tracing results and the severity of antepartum comorbidities such as hypertension. Authors of earlier studies of perinatal regionalization have noted that only those infants who “may survive” were transferred to a specialty hospital and were, consequently, less sick. Currently, though, physicians are more likely to transfer the sicker mother, although the number of transports have decreased. These issues demonstrate the need for other study designs to adjust for this bias in observational studies, such as propensity-score or instrumental-variables approaches. Propensity-score approaches improve the equality of various strata of case and control patients by using risk factors to predict the likelihood of receiving a treatment, whereas an instrumental-variables approach helps control for unmeasured differences in case mix by “pseudo-randomizing” patients to their delivery hospital by using factors that are associated with where a patient delivers but are not directly associated with outcomes. Both strategies help control for the selection bias inherent in all regionalization studies.

**Limited Assessed Outcomes**

Mortality is the most common outcome in studies of injury and neonatal intensive care. Mortality rates are useful, because mortality is clearly defined, mortality rates vary after adjusting for differences in case mix and there are associations between lower risk-adjusted mortality rates and some hospital-level processes of care. However, pediatric mortality is usually a rare event except in specific subpopulations such as very low birth weight infants.
Few studies have examined other outcomes. Only 2 studies of regionalized neonatal intensive care have examined neurodevelopmental outcome, but they revealed no differences between regionalized and nonregionalized areas, whereas 1 study revealed improved functional outcomes for severely injured children who were treated at pediatric trauma centers. Only 1 study examined a complication of either premature birth or injury. In general, differences in processes of care have also been poorly studied. One condition that has been examined is the management of splenic injury, for which centers with pediatric surgeons have lower operative rates than centers with adult-care surgeons. Differences in other processes of care between regionalized and deregionalized areas, either within pediatric trauma care or neonatal intensive care, have not been studied.

Assessing the Quality of Individual Hospitals Within Larger Groupings of Care Level

No pediatric regionalization study has accounted for differences in care delivered at individual hospitals. The authors of 1 study of very low birth weight infants estimated that measured hospital characteristics such as hospital volume predicted 9% of the variation in mortality rates between NICUs, whereas unmeasured characteristics—likely variations in quality—predicted 84% of these variations. A similar study of 47 level I adult trauma centers revealed wide variations in mortality rates, especially for the most severely injured patients. There has been no such analysis between high-level pediatric trauma centers. Proper methods should be used to distinguish variation related to the individual hospital and variation related to other characteristics of the hospital such as volume and level of care.

FUTURE AREAS OF RESEARCH

In this overview we have shown that the evidence base for regionalized care, although compelling, is incomplete. Recommendations for future areas of research should focus in 5 areas.

Improved Study Designs

1. Studies should include additional outcomes of interest in addition to mortality. These outcomes may include clinical outcomes, such as functional ability or neurodevelopmental outcome; complications of care; measures of patient safety, such as infection rates or medication errors; and costs of care using cost-effectiveness or cost-utility studies.
2. More research should develop and validate measures of illness severity, particularly by using data available from large-scale populations.
3. Regionalization studies should use methods to control for unmeasured differences in case mix between groups of hospitals, such as instrumental-variables approaches.
4. Studies should examine interhospital variations in outcomes, particularly within hospitals with similar consistently applied characteristics such as “high-level,” “high-volume,” and “teaching” hospitals.
5. Variables included in the risk-adjustment model and a measurement of the model’s discrimination, such as a c-statistic or area under a receiver operator curve, should be reported.
6. Researchers should examine the impact of the implementation of regionalization in countries or smaller geographic areas. Comparing the change in outcomes in these areas to the change in outcomes to similar areas that did not experience a change allows for valid assessments of the impact of these policy changes.

Financial Incentives

Additional research should assess the role of obstetric and neonatal financial incentives, both how payment is divided between providers of prenatal versus delivery care and how alternative forms of payment, such as pay-for-performance, affect the degree of regionalization and its outcome.

Development of New Systems of Regionalized Care: Hospitals and Competition

Researchers should examine new systems of regionalized care that account for both new technology and the economics of a given medical system. For example, to account for geographic areas with multiple central specialized hospitals, an “integrated web approach” may allow for a more collaborative approach to the management of both patients with routine conditions and those with complex conditions (Fig 1). Studies of these models should investigate the effect of reduced hospital competition on patient outcomes and methods to encourage collaboration between specialty centers.

Measures of Patient Preferences

Qualitative and quantitative research studies into parental preferences for treatment location during both the initial and chronic phases of treatment are needed. These preferences can be used as outcome measures for both standard studies of regionalized care and in cost-effectiveness or cost-utility studies.

Geographic Influences on Regionalization

There have been no studies of how geography, demography, and overall socioeconomic status influence the type of system that is implemented. These
CONCLUSIONS

To assess the optimal organization of pediatric health care, multiple outcomes from the perspectives of the individual, hospital, and population must be explored. Reliance on studies of individual, hospital, and population must come from the perspectives of the individual, hospital, and population.

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