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Designation of neonatal levels of care: a review of state regulatory and monitoring policies

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Abstract

Objective—Summarize policies on levels of neonatal care designation among 50 states and District of Columbia (DC).

Study design—Systematic review of publicly available, web-based information on levels of neonatal care designation policies for each state/DC. Information on designating authorities, designation oversight, licensure requirement, and ongoing monitoring for designated levels of care abstracted from 2019 published rules, statutes, and regulations.

Result—Thirty-one (61%) of 50 states/DC had designated authority policies for neonatal levels of care. Fourteen (27%) incorporated oversight of neonatal levels of care into the licensure process. Among jurisdictions with designated authority, 25 (81%) used a state agency and 15 (48%) had direct oversight. Twenty-two (71%) of 31 states with a designating authority required ongoing monitoring, 14 (64%) used both hospital reporting and site visits for monitoring with only ten requiring site visits.

Conclusions—Limited direct oversight influences regulation of regionalized systems, potentially impacting facility service monitoring and consequent management of vulnerable infants.

Introduction

The advent of neonatology as a subspecialty, and the availability of neonatal intensive care units (NICUs) during the late 1960s to 1970s, resulted in decreased infant mortality and improved outcomes for premature infants [1-5]. To further impact outcomes and enhance efficient care for all high-risk infants and mothers, the American Academy of Pediatrics (AAP) and American College of Obstetricians and Gynecologists (ACOG), in collaboration with March of Dimes, published recommendations for a regionalized system of NICUs in 1976 called *Toward Improving the Outcome of Pregnancy* (TIOP) [6]. These

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recommendations included the referral of high-risk mothers and infants to a hospital with a regional NICU [6].

In the following decade, most states widely implemented these regional systems of perinatal care coordination. Neonatal mortality rates decreased as the number of pregnant women who were at risk for a preterm delivery were antenatally transferred to hospital NICUs with the highest capabilities and staffing to provide risk-appropriate obstetrical and neonatal care [6-9]. In addition, hospitals with no or intermediate NICUs were expected to refer all infants weighing 2000 g or less to a regional NICU, [2] with referring facilities benefiting from the integrated health care, professional education, and transport services offered by the regional centers [10]. Regulation of the regionalized process was in part maintained by certificate of need (CON) laws [11]. State-developed CON laws, enacted in the 1960s and early 1970s, allowed state regulatory review of health-related capital expenditures [11]. By the 1970s, states adopted federally funded Section 1122 programs, an early form of state CON programs, which supported state agency approval of Medicare and Medicaid reimbursements [11]. The passage of the National Health Planning and Resources Development Act (NHPDA) of 1974 required all states to designate an agency to regulate the expansion or modernization of hospitals, and often, the provision of new hospital services [11-14]. Therefore, state CON programs were critical in this early phase, to establish and monitor perinatal costs, quality, and accessibility of services including NICUs, within a regionalized system [11].

However, during the late 1980s and 1990s a “deregionalization” of care occurred [15-18]. Managed care systems developed and began to direct care in many communities [16, 17], changing state reimbursement systems. At the same time, the number of trained and available neonatologists increased, and concurrently, hospital capabilities increased, stemming from changes in technology (e.g., use of surfactant, advanced isolettes, etc.), resulting in increased staffing and advanced capabilities for lower to midlevel NICUs [3, 17, 19]. This shift increased the rate of high-risk infants born in nontertiary hospitals [19, 20]. In addition, it produced competition between level II and level III centers, generating disincentives for patient referrals [3, 15, 21]. Several studies showed that deregionalization of perinatal care adversely affected outcomes, particularly for low birthweight deliveries [20-25]. For instance, Menard et al. (1998) found that very low birthweight (VLBW) infants were more likely to survive if born in level III hospitals than in level I or II facilities, with or without neonatologists [23]. Kastenbergh et al. (2015) demonstrated that the deregionalization continued in California from 2005 to 2011 and that risk-adjusted mortality was still higher for VLBW infants born in lower-level, lower-volume centers—an observation consistent with findings from previous decades [19].

Parallel to deregionalization, Congress repealed the NHPDA in 1986 giving states the option to continue or disband CON programs [14]. Although a substantial number of states currently maintain CON programs, they are often less restrictive compared with preceding programs [14, 26]. An independent survey, utilizing a web based search strategy similar to this study, performed by the Section on Perinatal Pediatrics of the AAP in 2002, found that not all 50 states had published definitions of levels of care, and among states with defined levels of care, the process for designating NICU levels and enforcing NICU-related

regulations varied [27]. Further, a study by Blackmon, Barfield, and Stark (2009) examined regulatory language in levels of care policies, and noted variability in mechanisms identified for enforcement, ranging from CON programs and hospital licensure to state health departments or other affiliated programs [28]. Building on earlier work with similar methodology, the objective of this study is to review the more recent process of designating levels of care among the 50 states and the District of Columbia (DC) by (1) identifying the current designating authority and the initial process for designating levels of neonatal care in each state, and (2) describing the ongoing monitoring process for these designations.

Materials and methods

Study design and data collection process

A systematic review of web-based, publicly available information on levels of neonatal care designation including CON laws was conducted in all 50 states and DC between January and June of 2019. All policies and legislation published by state agencies or state governments on levels of care were examined for inclusion. Available state-level CON requirements, policies, mandates, rules, codes, licensure regulations, health planning documents, and affiliated nongovernmental state perinatal health entities' publications were identified for data extraction using search engines such as Google and Bing. Both electronic copies of documents and/or the website link to the information source were catalogued. In addition, CON laws for each state were identified through the National Conference of State Legislatures website [26], and were included in analysis if specific to designation of neonatal levels of care, rather than general NICU requirements (e.g., number of beds). A standardized search strategy was applied based on multiple search terms to include a broad grouping of policies (Table 1). Search terms were amended as information was located for review, and expanded based on language identified in policies and/or legislation.

Study authors divided the United States into the ten Health Resources and Services Administration regions to facilitate an organized review and abstraction process. Information was captured by four abstractors using a standardized template developed by the authors. State policies in a region were searched separately by two abstractors. Each abstractor then independently cross-referenced the search findings of the other following double data entry. Study authors (DAG and CDK) further validated all abstracted information by reviewing and comparing it with source information. Discrepancies were reconciled during in-person meetings among researchers (EMO and CDK) and data abstractors to ensure consistency in search strategy and abstraction. Information abstracted included (1) state policies specifying designating authorities for hospital levels and/or hospital level capabilities; (2) documented processes for conducting designation oversight; (3) policies requiring hospital licensure in the designation process for providing neonatal services; and (4) mechanisms to perform ongoing monitoring for designated levels of care.

Data summary process and definitions

The primary abstractors (DAG and SML) reviewed and created an initial summary of all abstracted data. The secondary abstractors (EMO and CDK) validated abstracted data by reviewing summaries, verifying all summary information in the data, and classifying the

policy language. A designating authority or ‘designee’ was classified as a ‘state agency’ if the designee was part of the health department or a state agency. If the designee was a nonprofit in partnership with the state, then the grouping was noted as a ‘public/private partnership’. States with policies that did not clearly identify a designee were categorized as ‘not specified’ and no further categorizations (i.e., oversight or licensure) were reported. The oversight process by the designating authority was grouped as ‘direct’ or ‘indirect’. We defined direct oversight as a process, in which a state policy *required* a site visit as part of its designation process. Required site visits may confirm the designating authority’s designation or self-designation by hospitals. Conversely, an indirect oversight process was noted when a state policy permitted a hospital to self-designate neonatal levels of care with no required site visit from the designating authority for review. Among the subset of states with policy language specifying designating authorities, we classified ongoing monitoring in two ways. First, we grouped ongoing monitoring as ‘yes’ or ‘no’ depending on notation in policy language. Second, we grouped the mechanism, noted in the policies, for conducting ongoing monitoring as ‘hospital reporting’, ‘site visit’, or ‘not specified’. Among states with policies for site visits as part of the ongoing monitoring process, we further categorized visits into ‘required’ site visits or ‘permitted’ site visits to highlight differences in monitoring.

Statistical methods

Descriptive statistics were used to summarize the abstracted information. Counts of states with identified policies for initiating and monitoring graduated neonatal levels of care are reported and variations described. This study was determined to not need Institutional Review Board review at the Centers for Disease Control and Prevention because it did not include human subjects.

Results

Designating levels of care

Thirty-one (61%) of the 50 states and DC had a designating authority to oversee levels of care (Table 2). Maryland, Oklahoma, and Rhode Island had slight variations in oversight under the designating authority. While Maryland and Rhode Island had designating authority oversight only for Level III facilities or tertiary care NICU facilities, Oklahoma had oversight for emergency obstetric (OB) services only.

Among the group of jurisdictions with a designating authority, 25 (81%) used a state agency to determine designation, while the remaining 19% used a public/private partnership (Table 2). Fifteen (48%) of the states with a designating authority had direct oversight. Only 14 (27%) of the 50 states and DC incorporated oversight of neonatal levels of care into the licensure process. Of states with oversight incorporated into licensure, 10 (71%) required direct oversight by the designating authority.

Ongoing monitoring of levels of care

Among the 31 states with an authority identified for designating levels of care, 22 (71%) required ongoing monitoring (Table 3). Of these, six had specific language regarding what was covered by ongoing monitoring that included monitoring if participating in a public/

private partnership (Arizona), monitoring for specific levels of care (Maryland, Nevada, and Rhode Island), monitoring for regional care centers (Georgia), monitoring for OB facilities (Oklahoma), or as part of general licensure (Utah; Table 3). Nineteen (86%) of the 22 states with ongoing monitoring for levels of neonatal care used either hospital reporting or site visits to monitor designations, while 14 (64%) had both. Among the 17 states (77%) reporting site visits as part of their monitoring process, only 10 (59%) required a site visit.

Discussion

In the 40 years since TIOP was published encouraging regionalized care for the perinatal population, changes in technology, emergence of managed care, and changes in federal legislation, have affected state policies and the implementation of risk-appropriate neonatal care. In the last decade, federally funded initiatives, including the Collaborative Improvement and Innovation Networks and expert panels like the Secretary's Advisory Committee on Infant Mortality, have highlighted state-led improvements in infant health and renewed interest in perinatal regionalization [29, 30]. We provide the first comprehensive assessment, among 50 states and DC, of approaches to regulation of perinatal regionalization, or risk-appropriate levels of care. We found that almost two-thirds of states designate an entity for monitoring neonatal levels of care, and state health departments were the major designating authority used; however, more than half of the states with a designating authority allow facility designation or self-designation with no direct oversight. Direct oversight can serve as a mechanism to ensure that criteria are uniformly met or maintained and risk-appropriate services are improved [31]. Lack of direct oversight can influence regulation of regionalized systems that may impact neonatal survival, particularly for very low and extremely low birthweight infants, transport between facilities, and development of perinatal telemedicine programs for remote or rural facilities, though minimal research exists to examine the direct influence of these policies [32-35]. Although national standardized definitions have been developed for designating levels of neonatal care [36], lack of oversight, together with inconsistency in state-level policy language or level-specific measurement has impacted consistency in implementation.

Almost half of states with a designated authority included licensure as a part of the oversight process. State licensing and certification include authority to conduct compliance reviews of health care practitioners, health care entities, or providers for registration renewal, verification, or update of regulated professions [37]. The direct link from designation oversight to licensure allows states to query standards for health care entities or facilities, and take action to resolve noncompliance through reporting to federal entities including the National Practitioner Data Bank and consultation with nonfederal entities like the Joint Commission [37, 38]. Professional clinical membership organizations like the AAP have piloted 'NICU verification' programs consisting of surveys to further assess adherence to the standards for neonatal levels of care among neonatologists, neonatal nurses, and pediatric surgeons [39]. State policies may include such facility surveys or questionnaires filled by clinicians at facilities, for use by the designating authority to determine levels of care. Likewise, other federal agencies have partnered directly with state health departments to assess level of care designations, and determine comparability with the 2012 AAP guidelines [40] among those states where risk-appropriate care policies exist [41]. The

Levels of Care Assessment Tool, developed by the Centers for Disease Control and Prevention, is based on the most recent AAP and American College of Obstetricians and Gynecologists (ACOG)/Society for Maternal-Fetal Medicine (SMFM) guidelines, and is a web-based tool supporting state self-assessment of levels of care through collection of nonsurvey based information on facility capabilities, staffing, and infant outcomes [40]. While licensure and standard of care surveys or assessments provide one mechanism to inform regulation of levels of care, how states implement consistent monitoring varies.

Although the majority of states with a designated authority noted ongoing monitoring, the processes varied. Among states requiring site visits as the mechanism for monitoring, language on whether the visit is required or permitted also varied. Site visits provide designated authorities the opportunity to observe the actual structure and functioning of the NICU at the time of designation. Language requiring site visits and defining site visit frequency could provide the designated authority opportunity to collect independently verifiable data for continuous monitoring and oversight. Zimring offers a 'Guide to Conducting Healthcare Facility Visits' with a detailed toolkit for public use [42]. Other instruments exist to measure compliance and quality management of facilities [39, 43], and resources for assessing quality improvement are plentiful [44-46]; however, facility site assessment resources are limited, impacting enforcement of regulations and consequences for facility violations.

State variation in the monitoring process could reflect changes in CON laws and programs, with many states changing enforcement for a portion or all of oversight authority for hospital planning standards [41]. Existing CON programs, typically targeting outpatient or long-term care, may be used for state oversight and enactment of state CON laws [26]. However, evidence suggests CON laws and programs may negatively affect facility competition, reimbursement, and expenditures [14, 47]. Review of CON laws' impact on health care indicates that the laws may be less effective for cost control and more effective as a mechanism to redirect obligation and expenditure of funds [14]. For example, while a CON program may restrict the number of beds in a facility, it may not restrict the facility from purchasing electronic equipment. For neonatal risk-appropriate care, CON programs are associated with fewer functioning NICUs, including decreased bed supply in Level III NICUs, though no differences in infant mortality are reported [48]. By contrast, Rosko and Mutter (2014) concluded that in acute care settings, for example, CON programs could increase hospital efficiency and decrease costs [49], improving health outcomes. Differences in study findings may reflect the distinct capabilities or staffing required for emergency departments compared with labor and delivery departments, as the impact of CON programs on hospital quality of care and health outcomes is complex. Further research on the impact of CON programs, designation authority, and monitoring on neonatal outcomes is warranted [35].

Several limitations exist in interpreting our findings. First, we did not contact all states to verify policies related to monitoring and regulation of neonatal levels of care. Second, we included publicly available policies only, potentially missing any new, non-publically available or unpublished policies. Third, since the data collection time-frame, some state policies may have been reviewed or amended, potentially affecting our categorization of

state results. Regardless of these potential limitations, our analysis identifying the frequency of state-specific designated authorities with required site visits can inform states that aim to regulate and continuously monitor neonatal levels of care, potentially impacting the quality and availability of services to infants born in delivery facilities.

Designating an authority for monitoring and oversight can increase facility and hospital network accountability, efficiency, and ability to transfer neonatal patients to the most appropriate facility for care. Such oversight may result in the comprehensive access to risk-appropriate care necessary to increase survival of high-risk neonates. Inclusion of neonatal levels of care regulation language, whether through CON laws and programs or licensure and certification, enables systematic regulation of facility compliance and care quality that can improve equity in neonatal risk-appropriate care and outcomes.

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Table 1

Summary of search terms used for data collection and abstraction

Individual search terms (“State” was included in subsequent searches and variations of search phrases were subsequently searched)

[State] Perinatal regionalization
 [State] Level I policy (ies)
 [State] Level II policy (ies)
 [State] Level III policy (ies)
 [State] Perinatal program
 [State] Perinatal designation policy
 [State] Perinatal policy
 [State] Level I perinatal policy (ies)
 [State] Level II perinatal policy (ies)
 [State] Level III perinatal policy (ies)
 [State] Perinatal licensure
 [State] Neonatal levels of care
 [State] Neonatal program
 [State] Neonatal designation policy
 [State] Neonatal policy
 [State] Level I neonatal policy (ies)
 [State] Level II neonatal policy (ies)
 [State] Level III neonatal policy (ies)
 [State] Neonatal licensure
 [State] Designation neonatal intensive care unit (NICU)
 [State] NICU policy [ies]
 [State] Health plans
 [State] Certificate of need
 [State] Neonatal certificate of need
 [State] Perinatal certificate of need

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Table 2

Summary of levels of neonatal care policies specifying designating authority, oversight, and licensure by States and District of Columbia^a

| States/District of Columbia | Designee | Designating authority oversight process | Licensure included in designation |
|-----------------------------|----------------------------|---|-----------------------------------|
| Alabama | State agency | Indirect | No |
| Alaska | – | – | – |
| Arizona | Public/private partnership | Direct | No |
| Arkansas | Public/private partnership | Indirect | No |
| California | State agency | Direct | Yes |
| Colorado | Public/private partnership | Indirect | No |
| Connecticut | – | – | – |
| Delaware ^b | +++ | +++ | +++ |
| District of Columbia | – | – | – |
| Florida | – | – | – |
| Georgia | State agency | Direct | Yes |
| Hawaii | – | – | – |
| Idaho | – | – | – |
| Illinois | State agency | Direct | Yes |
| Indiana | State agency | Direct | No |
| Iowa | State agency | Direct | No |
| Kansas | – | – | – |
| Kentucky | State agency | Indirect | No |
| Louisiana | State agency | Indirect | Yes |
| Maine | – | – | – |
| Maryland ^c | State agency | Direct | No |
| Massachusetts | State agency | Indirect | Yes |
| Michigan | – | – | – |
| Minnesota | – | – | – |
| Mississippi | State agency | Indirect | No |
| Missouri | State agency | Indirect | No |
| Montana | – | – | – |
| Nebraska | – | – | – |
| Nevada | State agency | Direct | Yes |
| New Hampshire | – | – | – |
| New Jersey | State agency | Direct | Yes |
| New Mexico | – | – | – |
| New York | State agency | Indirect | No |

| States/District of Columbia | Designee | Designating authority oversight process | Licensure included in designation |
|-----------------------------|----------------------------|---|-----------------------------------|
| North Carolina | State agency | Indirect | No |
| North Dakota | – | – | – |
| Ohio | State agency | Direct | Yes |
| Oklahoma ^d | State Agency | Direct | Yes |
| Oregon | – | – | – |
| Pennsylvania | State agency | Direct | Yes |
| Rhode Island ^e | State agency | Indirect | Yes |
| South Carolina | State agency | Direct | Yes |
| South Dakota | – | – | – |
| Tennessee | Public/private partnership | Indirect | No |
| Texas | State agency | Direct | No |
| Utah | State agency | Indirect | Yes |
| Vermont | – | – | – |
| Virginia | State agency | Direct | Yes |
| Washington | State agency | Indirect | No |
| West Virginia | Public/private partnership | Indirect | No |
| Wisconsin | Public/private partnership | Indirect | No |
| Wyoming | – | – | – |

^aThe dashes in columns represent policies without an authority for designating levels of care, or where the authority is unclear, not specified, or not applicable

^bThe crosses in this row represent a state without levels of care

^cThe oversight occurs for Level III facilities only

^dThe oversight occurs for emergency obstetric level care facilities only

^eThe oversight occurs for tertiary care service neonatal intensive care units only

Table 3

Summary of ongoing monitoring for levels of neonatal care policies by states with an identified designating authority^a

| States | Ongoing monitoring | | | Process for monitoring | | |
|---------------------------|--------------------|------------|----------------------------|------------------------|------------|----------------------------|
| | Hospital report | Site visit | Requirement for site visit | Hospital report | Site visit | Requirement for site visit |
| Alabama | No | No | No | No | No | No |
| Arizona ^b | Yes | Yes | Permitted | Yes | Yes | Permitted |
| Arkansas | No | No | No | No | No | No |
| California | Yes | Yes | Permitted | Yes | Yes | Permitted |
| Colorado | – | – | – | – | – | – |
| Georgia ^c | Yes | – | – | – | – | – |
| Illinois | Yes | Yes | Required | Yes | Yes | Required |
| Indiana | No | No | No | No | No | No |
| Iowa | Yes | Yes | Required | Yes | Yes | Required |
| Kentucky | Yes | – | – | – | – | – |
| Louisiana | Yes | Yes | Permitted | Yes | Yes | Permitted |
| Maryland ^d | Yes | Yes | Required | No | Yes | Required |
| Massachusetts | Yes | Yes | Permitted | Yes | Yes | Permitted |
| Mississippi | Yes | – | – | – | – | – |
| Missouri | – | – | – | – | – | – |
| Nevada ^e | Yes | Yes | Required | Yes | Yes | Required |
| New Jersey | Yes | Yes | Required | Yes | Yes | Required |
| New York | Yes | Yes | Permitted | Yes | Yes | Permitted |
| North Carolina | No | No | No | No | No | No |
| Ohio | Yes | Yes | Required | Yes | Yes | Required |
| Oklahoma ^f | Yes | No | Required | No | Yes | Required |
| Pennsylvania | Yes | Yes | Required | Yes | Yes | Required |
| Rhode Island ^g | Yes | No | – | Yes | No | – |
| South Carolina | Yes | Yes | Required | Yes | Yes | Required |
| Tennessee | Yes | Yes | Permitted | Yes | Yes | Permitted |

| States | Ongoing monitoring | | Process for monitoring | |
|-------------------|--------------------|-----|------------------------|-----------|
| | Yes | No | Yes | No |
| Texas | Yes | No | Yes | No |
| Utah ^h | Yes | Yes | Yes | Permitted |
| Virginia | Yes | No | No | Required |
| Washington | No | No | No | No |
| West Virginia | No | No | No | No |
| Wisconsin | — | — | — | — |

^aThe dashes in the columns represent a monitoring policy that was unclear, not specified, or not applicable

^bThe monitoring occurs only for facilities participating in the public/private partnership

^cThe monitoring occurs only for regional perinatal centers

^dThe monitoring occurs only for Level III facilities

^eThe monitoring occurs only for Level II and Level III facilities

^fThe monitoring occurs for obstetric level care facilities

^gThe monitoring occurs for tertiary care service neonatal intensive care units only

^hThe monitoring occurs as part of general licensure not specific to levels of neonatal care