

POLICY STATEMENT

Organizational Principles to Guide and Define the Child Health Care System and/or Improve the Health of All Children

Committee on Fetus and Newborn

Levels of Neonatal Care

**ABSTRACT.** The concept of designations for hospital facilities that care for newborn infants according to the level of complexity of care provided was first proposed in 1976. Subsequent diversity in the definitions and application of levels of care has complicated facility-based evaluation of clinical outcomes, resource allocation and utilization, and service delivery. We review data supporting the need for uniform nationally applicable definitions and the clinical basis for a proposed classification based on complexity of care. Facilities that provide hospital care for newborn infants should be classified on the basis of functional capabilities, and these facilities should be organized within a regionalized system of perinatal care. *Pediatrics* 2004;114:1341–1347; neonatal intensive care, high-risk infant, regionalization, health policy, very low birth weight infant, nurseries, hospital newborn care services.

ABBREVIATIONS. NICU, neonatal intensive care unit; TIOP, *Toward Improving the Outcome of Pregnancy*; TIOP II, *Toward Improving the Outcome of Pregnancy: The 90s and Beyond*; VLBW, very low birth weight; OR, odds ratio; ECMO, extracorporeal membrane oxygenation.

OBJECTIVES

The objectives of this statement are to review the current status of the designation of neonatal intensive care units (NICUs) in the United States and the association of the designated level of care of the site with neonatal outcomes and to make recommendations for uniform nationally applicable definitions of levels of neonatal intensive care that are based on the capability of facilities to provide increasing complexity of quality care.

BACKGROUND

The availability of neonatal intensive care has improved outcomes for high-risk infants including those born preterm or with serious medical or surgical conditions. The concept of regionalized perinatal care was articulated in the 1976 March of Dimes report *Toward Improving the Outcome of Pregnancy* (TIOP).<sup>1</sup> The report included criteria that stratified maternal and neonatal care into 3 levels of complexity and recommended referral of high-risk patients to centers with the personnel and resources needed for their degree of risk and severity of illness. At the time, resources for the most complex care were rel-

atively scarce and concentrated in academic medical centers.<sup>2</sup>

During the past 2 decades, the number of neonatologists in the United States has increased and NICUs have proliferated.<sup>2</sup> However, no consistent relationship seems to exist between neonatal mortality and the number of NICU beds within a service area.<sup>2</sup> The effect of the availability of highly specialized personnel and resources on other neonatal outcomes is not known. In addition, no standard definitions exist for the graded levels of complexity of care that NICUs provide, making it difficult to compare outcomes of care.

Development of uniform definitions of levels of care offers at least 4 advantages that may improve the assessment of outcomes for high-risk newborn infants and provide the basis for policy decisions that affect allocation of resources. First, standard definitions will permit comparisons for health outcomes, resource utilization, and costs among institutions. Second, standardized nomenclature will be informative to the public, especially high-risk maternity patients who may seek an active role in selecting a delivery service. Third, uniformity in definitions of levels of care published by a professional organization will minimize the perceived need for businesses that purchase health insurance for their employees to develop their own standards.<sup>3,4</sup> Finally, uniform definitions will facilitate the development and implementation of consistent standards of service provided for each level of care.

Regionalized Neonatal Care

In 1993, *Toward Improving the Outcome of Pregnancy: The 90s and Beyond*<sup>5</sup> (TIOP II) reaffirmed the importance of an integrated system of regionalized care. The designations were changed from levels I, II, and III to basic, specialty, and subspecialty, respectively, and the criteria were expanded. These definitions are included in the fifth edition of *Guidelines for Perinatal Care*.<sup>6</sup>

Within the regionalized system, personnel and technology at each level should be appropriate for patient needs to facilitate optimal outcomes. Level I, or basic neonatal care, is the minimum requirement for any facility that provides inpatient maternity care. The institution must have the personnel and equipment to perform neonatal resuscitation, evaluate healthy newborn infants and provide postnatal care, and stabilize ill newborn infants until transfer

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to a facility that provides intensive care. Level II, or specialty care nurseries, in addition to providing basic care, can provide care to infants who are moderately ill with problems that are expected to resolve rapidly<sup>6</sup> or who are recovering from serious illness treated in a level III (subspecialty) NICU. Level III, or subspecialty NICUs, can care for newborn infants with extreme prematurity or who are critically ill or require surgical intervention.

#### Variation in Definition and Enforcement

Although the TIOP designations provide a general framework for classification of NICUs, both interpretation and application vary widely within the United States, and no national definition exists.<sup>7,8</sup> In late 2003, 15 states and the District of Columbia had no formal definitions. An independent survey performed by the Section on Perinatal Pediatrics of the American Academy of Pediatrics that included corroboration by neonatologists within each state found that only 32 states had published definitions of levels of care. Great diversity exists among states (D. Bhatt, MD, Report to the Section on Perinatal Pediatrics Executive Committee, October 2002). In 11 states, 3 levels of care are defined based on TIOP I, TIOP II, or *Guidelines for Perinatal Care*, 3rd or 4th editions. In the remaining states, additional levels were added above or below the original highest level (level III or subspecialty). Nine states name a level above level III delegating regional responsibilities in addition to the level III designation for NICU services.

In states that have defined levels of care, the process for designating NICU levels and enforcing NICU-related regulations varies. NICU levels at specific hospitals may be designated by the state through the official process of licensing or granting a certificate of need or state-administered health care funding. In 9 states, formal definitions have been established through programs either supported by or affiliated with maternal child health programs of the state health department. More than 1 of these mechanisms is used in 12 states.

Policies regarding monitoring of compliance also vary (D. Bhatt, MD, Report to the Section on Perinatal Pediatrics Executive Committee, October 2002). Furthermore, only 14 states have minimum standards for utilization. These standards are based variously on NICU occupancy rates, annual births or NICU admissions, or capacity. Definitions include specific language regarding birth weight and/or gestational age as criteria for a given level of care in only 15 states.

A source of confusion has been that designations for levels of care are variably applied to units caring for newborn infants and to the hospitals themselves. Facilities are usually designated by the highest level of care they provide, although they may provide less complex care as well. One exception may be free-standing children's hospitals, which may provide specialty and subspecialty care but transfer newborn infants to other facilities (often the hospital of birth) for lower levels of care as their medical conditions improve. Some hospitals have single units that integrate specialty and subspecialty care, and others

have separate units for each level. Regional centers are hospitals that include the highest level of NICU care and serve regional needs through education, data collection, and transport services. Some perinatal centers with large delivery services have NICUs but depend on agreements with neighboring institutions for pediatric subspecialty services including advanced imaging and operating rooms. In some regions, perinatal centers may be great distances from pediatric subspecialty care. Furthermore, hospitals with specific designations may vary in the types of neonatal services that are provided. In a survey of California hospitals, for example, facilities that were designated by the state as regional, community, and intermediate newborn units varied considerably within these categories in the services available (L.J. Van Marter, MD, MPH, Report to the Section on Perinatal Pediatrics Executive Committee, October 2001).

#### Level of Care, Patient Volume, and Outcome

Most studies that link neonatal outcomes with levels of perinatal care indicate that morbidity and mortality for very low birth weight (VLBW) infants are improved when delivery occurs in a subspecialty facility rather than a basic or specialty facility even after adjustments for severity of illness.<sup>9</sup> Contributing factors include the increased experience available at tertiary centers and the potential negative effect of the transport process. One report examined outcomes of 3769 singleton infants born at less than 32 weeks' gestation admitted to 17 Canadian NICUs during 1996–1997.<sup>10</sup> Outborn infants (those born outside the centers and requiring transfer) had significantly greater risk of mortality (odds ratio [OR]: 1.7), severe intraventricular hemorrhage (OR: 2.2), respiratory distress syndrome (OR: 4.8), patent ductus arteriosus (OR: 1.6), and nosocomial infection (OR: 2.5), compared with infants born at tertiary care centers. In a separate report from the same database, the advantage of preterm birth at tertiary centers was inversely related to gestational age.<sup>11</sup> The risk-adjusted incidence was significantly greater for outborn than inborn infants for mortality (OR: 2.2) and grade 3 or 4 intraventricular hemorrhage (OR: 2.1) at 26 weeks' gestation or less and for chronic lung disease (OR: 1.7) at 27 to 29 weeks' gestation. Another study analyzed neonatal mortality rates of 2375 infants with VLBW in South Carolina in 1993–1995 by level of perinatal services at the hospital of birth.<sup>12</sup> Neonatal mortality rate, adjusted for birth weight and race, was significantly higher for infants born at level I and II hospitals and for level II hospitals with 24-hour neonatology coverage (267, 232, and 213 deaths per 1000 live births, respectively), compared with level III centers (146 deaths per 1000 live births). When a similar analysis of VLBW infants in South Carolina in 1991–1995 was restricted to Medicaid recipients (64% of VLBW births), the risk of death was also greater in level I and II hospitals (relative risk: 1.9; 95% confidence interval: 1.6–2.2), compared with level III hospitals, although not in level II hospitals with neonatology coverage.<sup>13</sup>

Even transfer between tertiary centers may in-

crease the risk of mortality. In a study in Australia, 25% of infants less than 30 weeks' gestational age born at a tertiary care center during an 18-month period required transfer to another tertiary care center because the initial NICU was fully occupied.<sup>14</sup> After exclusion of lethal malformations and adjustment for confounding variables, mortality in the transferred infants was significantly greater than in those who remained at the birth hospital. Thus, to the extent possible, delivery of a high-risk infant should be planned to occur in a facility capable of providing the anticipated appropriate level of NICU care. If delivery in a facility without the necessary capabilities cannot be avoided, the infant should be stabilized and transferred to a NICU with the appropriate capabilities to ensure optimal outcome.

In addition to level of care, patient volume in the NICU seems to influence outcome. However, it must be acknowledged that the relationship between volume and outcome tends to be true on the average, and considerable variability exists among individual hospitals and physicians.<sup>15,16</sup> In a study of hospitals in California in 1990, risk-adjusted neonatal mortality based on linked birth and death certificate data were significantly lower for births that occurred in hospitals with level III NICUs that had an average daily census of at least 15 patients, compared with lower-volume centers.<sup>17</sup> In another study using linked birth and death certificate data in California for 1992 and 1993, the effect on mortality of the level of care provided at the hospital of birth was examined for low birth weight infants.<sup>18</sup> Compared with birth in a hospital with a regional NICU, risk-adjusted mortality for infants with birth weight less than 2000 g was significantly higher at a hospital with no NICU, an intermediate NICU, or a community NICU with an average census less than 15 patients (OR: 2.38, 1.92, and 1.42, respectively). The ORs were larger when the analysis was restricted to infants with birth weight less than 1500 g or less than 1250 g. However, risk-adjusted mortality in a community hospital NICU with an average census of more than 15 was not significantly different from a hospital with a regional NICU.

No specific data are available on the influence on outcomes of the volume of complex procedures performed in newborn infants at hospitals or by physicians. However, these data are available for adults and older children.<sup>16</sup> Numerous studies have documented the inverse relationship between the volume of patients treated and mortality for surgical procedures<sup>19,20</sup> or medical conditions such as acute myocardial infarction in adults.<sup>21</sup> A similar relationship of patient volume to mortality has been demonstrated in children. Among 16 pediatric intensive care units with an annual volume ranging from 147 to 1378 patients, an increase in volume of 100 patients was associated with a significantly reduced risk-adjusted mortality and length of stay.<sup>22</sup> Other pediatric intensive care unit characteristics including number of beds, affiliation with a university or children's hospital, or fellowship training program did not affect mortality or duration of hospitalization. Similarly, a higher volume of pediatric cardiac sur-

gical procedures performed by a hospital and/or surgeon was associated with lower in-hospital mortality.<sup>23,24</sup> In 1 study, adjusted mortality rates of higher-volume hospitals (those that performed more than 100 procedures annually) were decreased (5.95% vs 8.26%), compared with lower volume hospitals.<sup>23</sup> Mortality rates were lower also for surgeons with annual volumes of 75 or more compared with lower volumes (5.9% vs 8.77%).

Some reports have not shown a consistent association of NICU volume and neonatal mortality, although the conclusions were likely influenced by the characteristics of the NICUs included in the study and aspects of the analysis. One study examined 28-day mortality of 7672 infants with birth weights of 501 to 1500 g in 62 NICUs participating in the Vermont Oxford Network in 1991–1992.<sup>25</sup> The median annual patient volume was 76 (interquartile range: 47–113). The standardized mortality ratio (ratio of observed to predicted deaths) varied among NICUs. However, differences in the mortality rate or standardized mortality ratio were not explained by differences in patient volume. This may be explained, in part, because most of the NICUs had annual admissions of 47 or more VLBW infants. In another study of 54 NICUs in the United Kingdom in 1998–1999, risk-adjusted mortality was not associated with patient volume, although mortality rate increased inversely with nurse-to-patient ratio, which reflected increasing nursing workload.<sup>26</sup> However, 8 of the 12 NICUs included in this study admitted 57 or fewer VLBW infants per year. In both the Vermont Oxford and United Kingdom studies, deaths were attributed to the NICU rather than the hospital of birth. Additional studies are needed to examine other characteristics of NICUs and specific care practices that affect the quality of care and rates of mortality and morbidity.<sup>15,27,28</sup> Comparisons among centers will be facilitated by more precise definitions of levels of care provided by NICUs.

### Risk of Complications

Appropriate matching of levels of complexity of neonatal care to patient needs requires recognition of risk factors. Mortality and morbidity are highest in infants of the lowest birth weights and gestational ages. For example, in centers of the National Institute of Child Health and Human Development Neonatal Research Network in 1995–1996, survival to discharge was 97% at birth weight of 1251 to 1500 g, 94% at birth weight of 1001 to 1250 g, 86% at birth weight of 751 to 1000 g, and 54% at birth weight of 501 to 750 g.<sup>29</sup> Similarly, the incidence in survivors of major morbidity, defined as chronic lung disease, severe intracranial hemorrhage, and/or proven necrotizing enterocolitis, was 10%, 23%, 42%, and 63% at birth weights of 1251 to 1500, 1001 to 1250, 751 to 1000, and 501 to 750 g, respectively.

However, any degree of prematurity confers some risk. Compared with those born at term, infants born at 34 to 37 weeks' gestation are at increased risk of complications because of their physiologic immaturity. Biological variability exists in the time of attainment of independent thermoregulation<sup>30</sup>; resolution

of apnea, bradycardia, and/or hypoxemic episodes<sup>31–33</sup>; and oral feedings.<sup>34</sup> Near-term infants (35–37 weeks' gestation) are at increased risk of hyperbilirubinemia and kernicterus.<sup>35</sup> Thus, proposed definitions for levels of care should take into account the increased risk along the continuum of decreasing gestational ages.

### Expanded Definitions of Levels of Care

Expansion of the definitions of levels of care should be based on the capability to provide increasing complexity of care. The need for mechanical ventilation is a reasonable indication of a minimum level of subspecialty intensive care. In the revised US Standard Certificate of Birth, the National Center for Health Statistics defined a NICU as a "hospital facility or unit staffed and equipped to provide continuous mechanical ventilatory support for a newborn infant."<sup>36</sup>

In 2001, the Section on Perinatal Pediatrics performed a survey of hospital-based newborn services in the United States. A NICU was identified as a unit providing care for newborn infants in which a neonatologist provided primary care, as indicated by the results of a previous survey that identified all US neonatologists and their site of practice.<sup>37</sup> The survey instrument was a modified version of the classification of NICU levels used by the Vermont Oxford Network.<sup>38</sup> The classification consisted of basic care (level I), specialty care (level II), and subspecialty intensive care (level III) (Table 1). Subspecialty care was divided further into 4 categories (IIIA–IIID) based on whether the use of mechanical ventilation

was restricted and the availability of major surgery, cardiovascular surgery, or extracorporeal membrane oxygenation (ECMO). A total of 880 NICUs were identified, of which 120 were level II and 760 were level III by survey definition.

### Proposed Definitions

The results of the survey have been used to refine the definitions of levels of care on the basis of a more comprehensive assessment of patient needs and distinction among low, moderate, and high levels of complexity and risk. These definitions reflect the capability to provide increasingly complex care, reflected in appropriate personnel, equipment, and organization. In the future, standards can be developed that delineate the specific components required for each capability (Table 2).

According to these definitions, level I units (well-newborn nurseries) provide a basic level of newborn care to infants at low risk. They have the capabilities to perform neonatal resuscitation at every delivery and to evaluate and provide routine postnatal care of healthy newborn infants. In addition, they can stabilize and care for near-term infants (35–37 weeks' gestation) who remain physiologically stable and can stabilize newborn infants who are less than 35 weeks' gestation or ill until they can be transferred to a facility at which specialty neonatal care is provided.

Level II (specialty) special care nurseries can provide care to infants who are moderately ill with problems that are expected to resolve rapidly.<sup>6</sup> These patients are at moderate risk of serious complications related to immaturity, illness, and/or their management. In general, care in this setting should be limited to newborn infants who are more than 32 weeks' gestational age and weigh more than 1500 g at birth or who are recovering from serious illness treated in a level III (subspecialty) NICU. Level II units are differentiated into 2 categories, IIA and IIB, on the basis of their ability to provide assisted ventilation.

Level IIA nurseries do not have the capabilities to provide assisted ventilation except on an interim basis until the infant can be transferred to a higher-level facility. Level IIB nurseries can provide mechanical ventilation for brief durations (less than 24 hours) or continuous positive airway pressure. They must have equipment (eg, portable chest radiograph, blood gas laboratory) and personnel (eg, physician, specialized nurses, respiratory therapists, radiology technicians, and laboratory technicians) continuously available to provide ongoing care as well as to address emergencies.<sup>6</sup>

Level III (subspecialty) NICUs are defined by having continuously available personnel (neonatologists, neonatal nurses, respiratory therapists) and equipment to provide life support for as long as needed. Level III NICUs are differentiated by their ability to provide care to newborn infants with differing degrees of complexity and risk. Newborn infants with birth weight of more than 1000 g and gestational age of more than 28 weeks can be cared for in level IIIA NICUs. These facilities have the

**TABLE 1.** Definitions of Hospital-Based Newborn Services Used for Survey Performed by Section on Perinatal Pediatrics

Basic neonatal care (level I)	
Well-newborn nursery	Evaluation and postnatal care of healthy newborns
	Neonatal resuscitation
	Stabilization of ill newborns until transfer to a facility at which specialty neonatal care is provided
Specialty neonatal care (level II)	
Special care nursery	Care of preterm infants with birth weight $\geq 1500$ g
	Resuscitation and stabilization of preterm and/or ill infants before transfer to a facility at which newborn intensive care is provided
Subspecialty neonatal intensive care (level III)	
Level IIIA	
	Hospital or state-mandated restriction on type and/or duration of mechanical ventilation
Level IIIB	
	No restrictions on type or duration of mechanical ventilation
	No major surgery
Level IIIC	
	Major surgery performed on site (eg, omphalocele repair, tracheoesophageal fistula or esophageal atresia repair, bowel resection, myelomeningocele repair, ventriculoperitoneal shunt)
	No surgical repair of serious congenital heart anomalies that require cardiopulmonary bypass and /or ECMO for medical conditions
Level IIID	
	Major surgery, surgical repair of serious congenital heart anomalies that require cardiopulmonary bypass, and/or ECMO for medical conditions

**TABLE 2.** Proposed Uniform Definitions for Capabilities Associated With the Highest Level of Neonatal Care Within an Institution (See Text for Details)

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Level I neonatal care (basic)

- Well-newborn nursery: has the capabilities to
  - Provide neonatal resuscitation at every delivery
  - Evaluate and provide postnatal care to healthy newborn infants
  - Stabilize and provide care for infants born at 35 to 37 weeks' gestation who remain physiologically stable
  - Stabilize newborn infants who are ill and those born at <35 weeks' gestation until transfer to a facility that can provide the appropriate level of neonatal care

Level II neonatal care (specialty)

Special care nursery: level II units are subdivided into 2 categories on the basis of their ability to provide assisted ventilation including continuous positive airway pressure

Level IIA: has the capabilities to

- Resuscitate and stabilize preterm and/or ill infants before transfer to a facility at which newborn intensive care is provided
- Provide care for infants born at >32 weeks' gestation and weighing  $\geq 1500$  g (1) who have physiologic immaturity such as apnea of prematurity, inability to maintain body temperature, or inability to take oral feedings or (2) who are moderately ill with problems that are anticipated to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis
- Provide care for infants who are convalescing after intensive care

Level IIB has the capabilities of a level IIA nursery and the additional capability to provide mechanical ventilation for brief durations (<24 hours) or continuous positive airway pressure

Level III (subspecialty) NICU: level III NICUs are subdivided into 3 categories

Level IIIA: has the capabilities to

- Provide comprehensive care for infants born at >28 weeks' gestation and weighing >1000 g
- Provide sustained life support limited to conventional mechanical ventilation
- Perform minor surgical procedures such as placement of central venous catheter or inguinal hernia repair

Level IIIB NICU: has the capabilities to provide

- Comprehensive care for extremely low birth weight infants ( $\leq 1000$  g and  $\leq 28$  weeks' gestation)
- Advanced respiratory support such as high-frequency ventilation and inhaled nitric oxide for as long as required
- Prompt and on-site access to a full range of pediatric medical subspecialists
- Advanced imaging, with interpretation on an urgent basis, including computed tomography, magnetic resonance imaging, and echocardiography
- Pediatric surgical specialists and pediatric anesthesiologists on site or at a closely related institution to perform major surgery such as ligation of patent ductus arteriosus and repair of abdominal wall defects, necrotizing enterocolitis with bowel perforation, tracheoesophageal fistula and/or esophageal atresia, and myelomeningocele

Level IIIC NICU: has the capabilities of a level IIIB NICU and also is located within an institution that has the capability to provide ECMO and surgical repair of complex congenital cardiac malformations that require cardiopulmonary bypass

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capability to provide conventional mechanical ventilation for as long as needed but do not use more advanced respiratory support such as high-frequency ventilation. Other capabilities that may be available are minor surgical procedures such as placement of a central venous catheter or inguinal hernia repair.

Newborn infants with extreme prematurity (28 weeks' gestation or less) or extremely low birth weight (1000 g or less) or who have severe and/or complex illness are in the highest risk group and have the most specialized needs. These infants require a more advanced level III unit (designated level IIIB) with a broad range of pediatric medical subspecialists and pediatric surgical specialists, highly skilled nursing and respiratory care staff, advanced respiratory support and physiologic monitoring equipment, laboratory and imaging facilities, nutrition and pharmacy support with pediatric expertise, social services, and pastoral care. Advanced respiratory care should include high-frequency ventilation and inhaled nitric oxide. For example, extremely low birth weight infants typically require sustained ventilator support, parenteral nutrition, and neuroimaging and may need surgical ligation of a patent ductus arteriosus, surgical treatment of necrotizing enterocolitis, or neurosurgical management of hydrocephalus. A level IIIB unit should have the capability to perform major surgery (including anesthesiologists with pediatric expertise) on site or at a closely related institution for patients with congenital malformations (such as abdominal wall defect, tracheoesophageal fistula and/or esophageal atresia, or meningocele) or acquired conditions (such as bowel perforation, retinopathy of prematurity, or hydrocephalus secondary to intraventricular hemorrhage). A closely related institution would ideally be in geographic proximity and share coordinated care such as physician staff. Outcomes of less complex surgical procedures in children, such as appendectomy or pyloromyotomy, are better when performed by pediatric surgical subspecialists compared with general surgeons.<sup>39-41</sup> Thus, it is recommended that pediatric surgical specialists perform more complex procedures in newborn infants.

The most advanced level III units, designated level IIIC, which may be located at children's hospitals, have additional capabilities within the institution, including ECMO and surgical repair of serious congenital cardiac malformations that require cardiopulmonary bypass.<sup>42-44</sup> It is logical to assume that substantial experience is needed for the best outcomes in patients who require the most advanced support.<sup>23,24,45</sup> However, data are not currently available to define this requirement. Concentrating the care of infants with conditions that occur infrequently and require the highest level of intensive care at designated level III centers allows these centers to develop the expertise needed to achieve optimal outcomes and avoids costly duplication of services in multiple institutions within close proximity.

Level IIIB and IIIC units care for the most complex and critically ill patients and should have immediate and on-site access to pediatric medical subspecialty consultants. These facilities should have the capability to perform advanced imaging with interpretation on an urgent basis, including computed tomography, magnetic resonance imaging, and echocardiography. Data are unavailable on the relationship between availability of these consultants or of imaging capability and neonatal outcomes.

Large regional differences exist in the numbers of neonatologists and NICU beds, and the availability of these resources is not consistently related to the number of high-risk newborn infants.<sup>2</sup> Regional differences also exist in the numbers of other pediatric subspecialists and in the distances patients must travel to receive care for serious illness.<sup>46</sup> Limitation of all complex neonatal care to high-volume centers distant from the homes of some patients must be weighed against developing other approaches to improve outcomes in institutions with lower volumes. In a theoretic analysis of regionalization of pediatric cardiac surgery in California, for example, referral of all cases to high-volume centers would reduce surgical mortality from 5.34% to 4.08% but would increase average travel distance from 45.4 to 58.1 miles.<sup>47</sup>

## RECOMMENDATIONS

1. Regionalized systems of perinatal care are recommended to ensure that each newborn infant is delivered and cared for in a facility appropriate for his or her health care needs and to facilitate the achievement of optimal outcomes.
2. The functional capabilities of facilities that provide inpatient care for newborn infants should be classified uniformly, as follows:
  - Level I (basic): a hospital nursery organized with the personnel and equipment to perform neonatal resuscitation, evaluate and provide postnatal care of healthy newborn infants, stabilize and provide care for infants born at 35 to 37 weeks' gestation who remain physiologically stable, and stabilize newborn infants born at less than 35 weeks' gestational age or ill until transfer to a facility that can provide the appropriate level of neonatal care.
  - Level II (specialty): a hospital special care nursery organized with the personnel and equipment to provide care to infants born at more than 32 weeks' gestation and weighing more than 1500 g who have physiologic immaturity such as apnea of prematurity, inability to maintain body temperature, or inability to take oral feedings; who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis; or who are convalescing from intensive care. Level II care is subdivided into 2 categories that are differentiated by those that do not (level IIA) or do (level IIB) have the capability to provide mechanical ventilation for brief durations (less than 24 hours) or continuous positive airway pressure.
  - Level III (subspecialty): a hospital NICU organized with personnel and equipment to provide continuous life support and comprehensive care for extremely high-risk newborn infants and those with complex and critical illness. Level III is subdivided into 3 levels differentiated by the capability to provide advanced medical and surgical care.
    - Level IIIA units can provide care for infants with birth weight of more than 1000 g and gestational

age of more than 28 weeks. Continuous life support can be provided but is limited to conventional mechanical ventilation.

Level IIIB units can provide comprehensive care for extremely low birth weight infants (1000 g birth weight or less and 28 or less weeks' gestation); advanced respiratory care such as high-frequency ventilation and inhaled nitric oxide; prompt and on-site access to a full range of pediatric medical subspecialists; and advanced imaging with interpretation on an urgent basis, including computed tomography, magnetic resonance imaging, and echocardiography and have pediatric surgical specialists and pediatric anesthesiologists on site or at a closely related institution to perform major surgery.

Level IIIC units have the capabilities of a level IIIB NICU and are located within institutions that can provide ECMO and surgical repair of serious congenital cardiac malformations that require cardiopulmonary bypass.

3. Uniform national standards such as requirements for equipment, personnel, facilities, ancillary services, and training, and the organization of services (including transport) should be developed for the capabilities of each level of care.
4. Population-based data on patient outcomes, including mortality, specific morbidities, and long-term outcomes, should be obtained to provide level-specific standards for volume of patients requiring various categories of specialized care, including surgery.

### COMMITTEE ON FETUS AND NEWBORN, 2003–2004

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