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

POLICY STATEMENT

Levels of Neonatal Care

COMMITTEE ON FETUS AND NEWBORN

KEY WORDS

neonatal intensive care, high-risk infant, regionalization, maternal and child health, health policy, very low birth weight infant, hospital newborn care services, nurseries

ABBREVIATIONS

AAP—American Academy of Pediatrics
aOR—adjusted odds ratio
CI—confidence interval
CON—certificate of need
ELBW—extremely low birth weight
TIOP—"Toward Improving the Outcome of Pregnancy"
VLBW—very low birth weight

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abstract

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Provision of risk-appropriate care for newborn infants and mothers was first proposed in 1976. This updated policy statement provides a review of data supporting evidence for a tiered provision of care and reaffirms the need for uniform, nationally applicable definitions and consistent standards of service for public health to improve neonatal outcomes. 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* 2012;130:587–597

OBJECTIVE

This revised policy statement reviews the current status of the designation of levels of newborn care definitions in the United States, which were delineated in a 2004 policy statement by the American Academy of Pediatrics (AAP).[1] Since publication of the 2004 policy statement, new data, both nationally and internationally, have reinforced the importance of well-defined regionalized systems of perinatal care, population-based assessment of outcomes, and appropriate epidemiologic methods to adjust for risk. This revised statement updates the designations to provide (1) a basis for comparison of health outcomes, resource use, and health care costs, (2) standardized nomenclature for public health, (3) uniform definitions for pediatricians and other health care professionals providing neonatal care, and (4) a foundation for consistent standards of service by institutions; state health departments; and state, regional, and national organizations focused on the improvement of perinatal care.

BACKGROUND

The availability of neonatal intensive care has improved the outcomes of high-risk infants born either preterm or with serious medical or surgical conditions.[2–4] Many of these improvements can be attributed to the concept and implementation of regionalized systems of perinatal care, broadly articulated in the 1976 March of Dimes report "Toward Improving the Outcome of Pregnancy" (TIOP I).[5] The TIOP I report included criteria that stratified maternal and neonatal care into 3 levels of complexity and recommended referral of high-risk patients to higher-level centers with the appropriate resources and personnel to address the required increased complexity of care. However, since the initial TIOP I report was published more than 3 decades ago, there have been signs of deregionalization, including (1)

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an increase in the number of NICUs and neonatologists, without a consistent relationship to the percentage of high-risk infants, (2) a proliferation of small NICUs in the same regions as large NICUs,[6–11] and (3) failure of states to reach the Healthy People 2010 goal that 90% of deliveries of very low birth weight (VLBW; <1500 g) infants occur at level III facilities.[12,13]

In the environment of deregionalization, preterm birth rates have increased 13% overall from 1990 to 2010 (10.6%–12.0%) as a result of a variety of factors, including increases in elective early cesarean deliveries, multiple births, advanced maternal age, and complications of pregnancy.[14–20] The majority of the increase in the preterm birth rate (>70%) is attributable to late preterm births.[21] Infants born late preterm can experience significant morbidity that may result in the need for specialized care and advanced neonatal services.[22,23] An increase in the supply of specialty staff[24,25] and availability of new neonatal therapies (eg, bubble continuous positive airway pressure), have expanded the scope of care in level II facilities.[26] Some have expressed concern that level II hospitals have expanded their scope of care without sufficient evidence of favorable outcome. Because most infant deaths in the United States occur among the most immature infants in the first few days after birth,[27,28] improvements in regionalized systems may reduce mortality among the most preterm newborn infants.

REVIEW OF THE LITERATURE ON NEONATAL LEVELS OF CARE SINCE THE 2004 AAP POLICY STATEMENT

In 2004, the AAP defined neonatal levels of care, including 3 distinct levels with subdivisions in 2 of the levels.[1] Level I centers provided basic care; level II centers provided specialty care, with further subdivisions of IIA and IIB centers; and level III centers provided subspecialty care for critically ill newborn infants with subdivisions of level IIIA, IIIB, and IIIC facilities. Data published since the 2004 statement have informed the development of the levels of care in this new policy statement.

A meta-analysis of the published literature from 1978 to 2010 clearly demonstrates improved outcomes for VLBW infants and infants <32 weeks' gestational age born in level III centers. Lasswell et al reviewed 41 English-language US and international studies, which included >113 000 VLBW infants and found that VLBW infants born at non–level III hospitals had a 62% increase in odds of neonatal or predischarge mortality compared with those born at level III hospitals (adjusted odds ratio [aOR], 1.62; 95% confidence interval [CI], 1.44–1.83). Subset comparisons of studies identifying infants <32 weeks' gestation and extremely low birth weight (ELBW) infants (<1000 g) demonstrated similar effects (aOR, 1.55; 95% CI, 1.21–1.98; aOR, 1.64; 95% CI, 1.14–2.36, respectively). When only higher-quality studies were included, the findings were consistent (VLBW aOR, 1.60; 95% CI, 1.33–1.92; <32 weeks' gestation aOR, 1.42; 95% CI, 1.06–1.88; ELBW aOR, 1.80; 95% CI, 1.31–2.36). The effect of level of care on VLBW mortality did not vary by decade of publication[29]; hence, the risk of death for VLBW infants born in level I or II facilities remained higher than those born within a level III facility. Figures 1, 2, and 3 summarize the findings of these studies.

As Lasswell and colleagues found, part of the difficulty in collecting evidence to provide accurate assessments of VLBW outcomes has been in obtaining appropriate standardized measures. Heterogeneity among studies on neonatal levels of care suggests the need for a quality standard for comparison which includes the following elements: (1) population-based studies within well-defined geographic regions, (2) clear definitions of the "intervention" or hospital level of care, and (3) appropriate adjustment for confounding factors to include maternal social and demographic risk factors, pregnancy and perinatal risks, and severity of illness at delivery.

Current Controversies in Levels of Care Designation

Although little debate exists on the need for advanced neonatal services for the most immature and surgically complex neonates, ongoing controversies exist regarding which facilities are qualified to provide these services and what is the most appropriate measure for such qualification. These issues are, in general, based on the need for comparison of facility experience (measured by patient volume or census), location (inborn/outborn deliveries, regional perinatal center, or children's hospital), or case mix (including stillbirths, delivery room deaths, and complex congenital anomalies).

Several studies have explored the topic of center experience as measured by volume or census of VLBW infants.[30–35] Phibbs et al conducted a population-based retrospective cohort study of 48 237 California VLBW infants to examine differences in neonatal mortality among NICUs with various levels of care and patient volumes. When compared with high-volume, high-level centers, the odds ratio of death was 1.19 (range, 1.04–1.37) for level IIIB, IIIC, or IIID centers with <100 annual admissions, 1.78 (range, 1.35–2.34) for level IIIA centers with 26 to 50 annual admissions, and 2.72 (range, 2.37–3.12) for level I centers with <10 annual admissions. The authors also found that the percentage of VLBW infants delivered in level IIIB, IIIC, or IIID centers decreased from 36% in 1991 to 22% in

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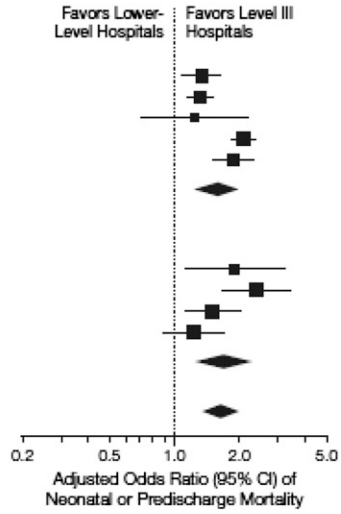
Source	Level Comparison	Deaths/Live Births, No. Lower Levels	Deaths/Live Births, No. Level III	Adjusted Odds Ratio (95% CI)	Z Value	P Value
Adjustment for Confounding: Case Mix						
Paneth et al,[30] 1982	II vs III	602/1083	423/869	1.32 (1.08-1.62)	2.68	.01
Gortmaker et al,[37] 1985[a]	I and II vs III	708/2717	508/2382	1.30 (1.14-1.48)	3.95	<.001
Sanderson et al,[18] 2000	II + vs III	15/88	292/2038	1.23 (0.70-2.17)	0.71	.48
Bode et al,[32] 2001[b]	II vs III	929/2266	2517/14 479	2.06 (1.82-2.33)	11.39	<.001
Kamath et al,[16] 2008	I and II vs III	757	1459	1.85 (2.31-1.22)	5.44	<.001
Combined estimate[c] Test for heterogeneity: $Q = 31.56$; $P < .001$		2254/6154	3740/19 768	1.56 (1.22-1.98)	3.61	<.001
Adjustment for Confounding: Extensive						
Verloove-Vanhorick et al,[22] 1988	II vs III	83/359	125/482	1.90 (1.11-3.24)	2.36	.02
Cifuentes et al,[13] 2002	II vs III	1414	2472	2.37 (1.65-3.40)	4.68	<.001
Bacak et al,[29] 2005	I and II vs III	232/545	570/1127	1.50 (1.11-2.02)	2.66	.01
Howell et al,[15] 2008	I and II vs III/IV	1626/11 781		1.23 (0.89-1.70)	1.25	.21
Combined estimate[c] Test for heterogeneity: $Q = 7.60$; $P = .06$		315/904	695/1609	1.66 (1.24-2.23)	3.42	<.001
Overall: all adequate- and high-quality VLBW studies[c] Test for heterogeneity: $Q = 39$; $P < .001$		2569/7058	4435/21 377	1.60 (1.33-1.92)	4.96	<.001



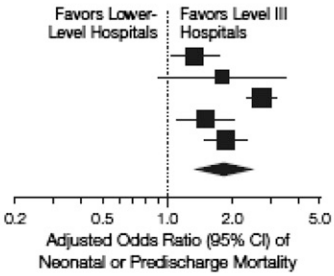
Case mix indicates adjustment for demographic and/or socioeconomic status variables; extensive indicates adjustment for case mix plus maternal/perinatal risk factors and infant illness severity. CI indicates confidence interval. Size of data markers indicates size of study population.
[a] Included data are for urban populations and combine reported black/white race strata and birth weight strata (750-1000 g and 1001-1500 g).
[b] Included data combine reported birth date interval strata (1980-1984, 1985-1989, and 1990-1994) and birth weight strata (500-1000 g and 1001-1500 g).
[c] Raw death counts are not reported in Cifuentes et al[13] and Kamath et al[16] and are not stratified by hospital level in Howell et al.[15] These studies are not included in combined death/birth counts.

FIGURE 1
Meta-analysis of adequate- and high-quality publications on VLBW infants, stratified by level of adjustment for confounding. (Reprinted with permission from Lasswell S, Barfield WD, Rochat R, Blackmon L. Perinatal regionalization for very low birth weight and very preterm infants: a meta-analysis. *JAMA.* 2010;304[9]:992–1000.[29])

2000 and estimated that shifting VLBW births in urban areas (92% of VLBW births) to level IIIC or IIID centers with >100 annual admissions would have prevented 21% of VLBW deaths in 2000.[30] In a secondary data analysis, Chung et al found that deregionalization of California perinatal services resulted in 20% of VLBW deliveries occurring in level I and level II hospitals, with lower-volume hospitals having the highest odds of mortality.[31]

A population-based study of 4379 VLBW infants who were born between 1991 and 1999 in Lower Saxony, Germany, evaluated neonatal mortality in relation to both the annual volume of births and NICU volume.[32] There was an increased odds of mortality in centers with annual NICU admissions of fewer than 36 VLBW infants; the largest

Source	Level Comparison	Deaths/Live Births, No. Lower Levels	Deaths/Live Births, No. Level III	Adjusted Odds Ratio (95% CI)	Z Value	P Value
Gortmaker et al,[37] 1985[a]	I and II vs III	245/442	249/515	1.33 (1.08-1.72)	2.19	.03
Sanderson et al,[18] 2000[b]	II + vs III	15/36	249/869	1.78 (0.90-3.51)	1.66	.10
Bode et al,[32] 2001[c]	II vs III	763/1100	1696/6243	2.71 (2.32-3.18)	12.44	<.001
Bacak et al,[29] 2005	I and II vs III	232/545	570/1127	1.50 (1.11-2.02)	2.66	.01
Kamath et al,[16] 2008	I and II vs III	757	1459	1.85 (1.43-2.31)	5.44	<.001
Overall Test for heterogeneity: $Q = 28.40$; $P < .001$[d]		1255/2123	2764/8754	1.80 (1.31-2.46)	3.66	<.001



CI indicates confidence interval. Size of data markers indicates size of study population.
[a] Included data are for urban populations and combine reported black/white race strata.
[b] Included data combine reported birth weight strata (500-749 g and 750-1000 g).
[c] Included data combine reported birth date interval strata (1980-1984, 1985-1989, and 1990-1994).
[d] The study by Kamath et al[16] does not report raw death count data and is not included in combined death/birth counts.

FIGURE 2
Meta-analysis of adequate- and high-quality publications on ELBW infants. (Reprinted with permission from Lasswell S, Barfield WD, Rochat R, Blackmon L. Perinatal regionalization for very low birth weight and very preterm infants: a meta-analysis. *JAMA.* 2010;304[9]:992–1000.[29])

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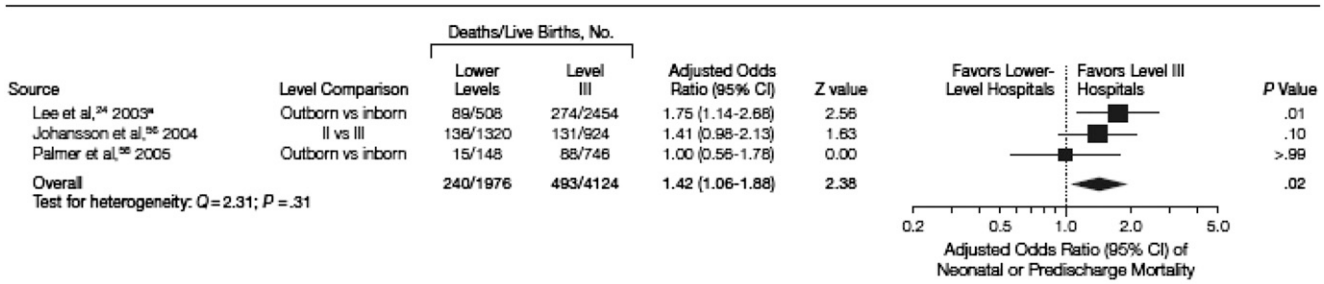

CI indicates confidence interval. Size of data markers indicates size of study population. Inborn infants are those born in a level III hospital; outborn infants are those born in a lower-level hospital then transferred to a level III hospital.
[a] Included data combine reported gestational age strata (<26 weeks, 27-29 weeks, and 30-31 weeks).

FIGURE 3
Meta-analysis of adequate- and high-quality publications on very preterm infants (<32 weeks' gestation). (Reprinted with permission from Lasswell S, Barfield WD, Rochat R, Blackmon L. Perinatal regionalization for very low birth weight and very preterm infants: a meta-analysis. *JAMA*. 2010;304[9]:992–1000.[29])

effect on mortality was for infants born at less than 29 weeks' gestation.

Other studies assessing NICU volume suggest caution in using this measure as an effective indicator of quality of care. Rogowski and colleagues assessed the potential usefulness of NICU volume as a quality indicator among 94 110 VLBW infants entered into the Vermont Oxford Network database between 1995 and 2000 and compared NICU volume with other indicators based on hospital characteristics and patient outcomes.[33] They found that although annual volume explained 9% of the variation in hospital mortality rates, other hospital characteristics explained another 7%. They suggested that direct measures based on patient outcomes are more useful quality indicators than volume for the purpose of selective referral.

Several studies assessed the effects of level of care, patient volume, and racial disparities on mortality of VLBW infants based on births in minority-serving hospitals. Morales[34] and Howell[35] evaluated mortality of VLBW infants born in minority-serving hospitals. In both studies, neonatal level of care and patient volume were each independently associated with mortality, suggesting that delivery of all VLBW infants at high-volume hospitals would reduce black-white disparities in VLBW mortality rates. Rogowski and colleagues further suggest that the quality of care in poor-outcome hospitals could be improved through collaborative quality improvement, and evidence-based selective referral.[36]

Several studies have compared the short-term outcome of VLBW infants born in centers with level III units (inborn) compared with those born at lower level centers and soon transferred to a higher level (level III or children's hospital; outborn). Many of these studies are retrospective and may be subject to selection bias because infants who were transferred most likely had the highest chance of survival and thus gave the impression of lower mortality.[24] In a secondary analysis of a randomized placebo-controlled study of preemptive morphine analgesia on neonatal outcomes, Palmer et al compared neonatal mortality as related to place of birth for 894 infants who were born at 23 to 32 weeks' gestation. Outborn babies were more likely to have severe intraventricular hemorrhage ($P = .0005$), and this increased risk persisted after controlling for severity of illness. However, when adjusted for antenatal steroids, the effect of birth center was no longer significant.[37]

Evaluating and controlling for confounding variables and "case-mix" presents another set of challenges because these factors vary by population. For example, race and insurance status may have more of an effect on birth outcomes in the United States[34–36,38] than in countries with a more homogenous population and universal national health care.[39] There are also potential confounding factors for which measurement is frequently lacking, such as parental wishes regarding aggressive resuscitation of an infant. Arad et al noted that parental wishes varied by religious affiliation in their 2-hospital study. Because religious affiliation was unequally distributed between the 2 hospitals, fewer attempts at resuscitation may have been made at the level III hospital, with a result of improved survival at the level II facility.[40] More comprehensive studies controlling for confounding factors are needed.

Measured outcomes other than VLBW mortality (notably, fetal mortality, postdischarge mortality, and long-term physical and neurodevelopmental outcomes) may offer important information in assessing the evidence for newborn levels of care and perinatal regionalization. Studies measuring the effect of hospital level of birth on fetal

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and neonatal outcomes stratified by gestational age, as well as by birth weight, are also helpful, because gestational age is a better gauge of fetal maturity.[41–44] Although some studies include stillbirths and intrapartum fetal deaths, measurement and surveillance of fetal death varies widely.[3] Congenital anomalies are often excluded from studies of perinatal regionalization but should be considered in the provision of risk appropriate care.[45]

Additional studies are also needed to assess the effectiveness and potential cost savings of centralizing expensive technologies and provider expertise for relatively rare conditions at a few locations and to assess the effectiveness, including costs, of antenatal transport.

IMPORTANCE OF NEONATAL LEVELS OF CARE

Provision of Standardized Nomenclature for Public Health

Since 2004, efforts have been made to improve the comparison of health outcomes by hospital facility through the use of standardized nomenclature on the US birth certificate. The National Center for Health Statistics at the Centers for Disease Control and Prevention has worked with states to use the newly revised US Standard Certificate of Birth.[46] This 2003 revised certificate defines a NICU as a "hospital facility or unit staffed and equipped to provide continuous mechanical ventilatory support for a newborn infant." It also includes information on the use of antenatal therapies and postpartum surfactant, which may be useful in monitoring population-based utilization of technologies at birth.[47] In an analysis of 16 states using the revised certificate of birth, Barfield et al found that overall, 77.3% of VLBW infants were admitted to NICUs; this estimate varied by state and ranged from 63.7% in California to 93.4% in North Dakota. Among VLBW infants of Hispanic mothers, 71.8% were admitted to NICUs, compared with 79.5% of VLBW infants of non-Hispanic black mothers and 80.5% of VLBW infants of non-Hispanic white mothers. In multivariable analysis, preterm delivery, multiple gestation, and cesarean delivery were associated with higher prevalence of NICU admission among VLBW infants.[13] State variations in the receipt of intensive care for VLBW infants may explain, in part, variation in VLBW outcomes across the country.

Use of Uniform Definitions of Levels of Care for Pediatricians and Other Health Care Professionals

Variation in definition, criteria, and state enforcement still occurs despite the TIOP I guidelines. Blackmon et al conducted an extensive review of all 50 states and the District of Columbia governmental Web sites to assess state definitions and levels terminology, functional and utilization criteria, regulatory compliance and funding measures, and citation of AAP documents on levels of neonatal care. The authors found that state definitions, criteria, compliance, and regulatory mechanisms for the specific type of care neonatal centers provide varied considerably, and they suggested a consistent national approach.[48] Lorch et al assessed all 50 states and the District of Columbia to identify state certificate of need (CON) legislation, a mechanism that regulates the expansion of NICU facilities and NICU beds. Thirty states regulated the construction of NICUs through CON programs, and non-CON program states were associated with more NICU facilities and more NICU beds (relative risk, 2.06; 95% CI, 1.74–2.45; and relative risk, 1.96; 95% CI, 1.89–2.03, respectively). In large metropolitan areas, non-CON states had higher infant mortality for all birth weight groups.[49]

The Maternal and Child Health Bureau of the Health Resources and Services Administration has worked with state Title V agencies to document the percentage of VLBW infants delivered in level III hospitals or subspecialty perinatal clinics. In 2009, only 5 states met the goal of at least 90% of VLBW infants delivered at high-risk facilities.[12] Yet, the interpretation and reporting of these facilities may be inconsistent as some states had unclear facility definitions or included level II facilities in their reporting. Recently, several states, in partnership with national organizations, have taken more definitive action in defining and regulating organization of perinatal care.[50]

Development of Consistent Standards of Service

Efforts by quality-improvement collaboratives, health services researchers, and public health officials will continue to improve the standards by which to measure quality of care.[51,52] Quality-improvement activities have begun to flourish at all levels to improve maternal and perinatal health and ideally prevent preterm births; this includes provider-level quality-improvement activities, hospital-level performance measures, and regional, state, and national performance measures.[53] Organizations such as the March of Dimes have promoted standard definitions of levels of care since the introduction of perinatal regionalization in the 1970s, reaffirmed its importance in 1993 (TIOP II),[54] and included the concept of quality care for the prevention of preterm birth with a new TIOP (TIOP III) in 2010.[53]

DEFINITIONS OF LEVELS OF NEONATAL CARE

The updated classification consists of basic care (level I), specialty care (level II), and subspecialty intensive care (level III, level IV; Table 1). These definitions reflect the overall evidence for risk-appropriate care through the availability of appropriate personnel, physical space, equipment, technology, and

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TABLE 1 Definitions, Capabilities, and Provider Types: Neonatal Levels of Care

Level of Care	Capabilities	Provider Types[a]
Level I Well newborn nursery	• Provide neonatal resuscitation at every delivery • Evaluate and provide postnatal care to stable term newborn infants • Stabilize and provide care for infants born 35–37 wk gestation who remain physiologically stable • Stabilize newborn infants who are ill and those born at <35 wk gestation until transfer to a higher level of care	Pediatricians, family physicians, nurse practitioners, and other advanced practice registered nurses
Level II Special care nursery	Level I capabilities plus: • Provide care for infants born ≥32 wk gestation and weighing ≥1500 g who have physiologic immaturity or who are moderately ill with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an urgent basis • Provide care for infants convalescing after intensive care • Provide mechanical ventilation for brief duration (<24 h) or continuous positive airway pressure or both • Stabilize infants born before 32 wk gestation and weighing less than 1500 g until transfer to a neonatal intensive care facility	Level I health care providers plus: Pediatric hospitalists, neonatologist, and neonatal nurse practitioners.
Level III NICU	Level II capabilities plus: • Provide sustained life support • Provide comprehensive care for infants born <32 wks gestation and weighing <1500 g and infants born at all gestational ages and birth weights with critical illness • Provide prompt and readily available access to a full range of pediatric medical subspecialists, pediatric surgical specialists, pediatric anesthesiologists, and pediatric opthalmologists • Provide a full range of respiratory support that may include conventional and/or high-frequency ventilation and inhaled nitric oxide • Perform advanced imaging, with interpretation on an urgent basis, including computed tomography, MRI, and echocardiography	Level II health care providers plus: Pediatric medical subspecialists[b], pediatric anesthesiologists[b], pediatric surgeons, and pediatric opthalmologists[b].
Level IV Regional NICU	Level III capabilities plus: • Located within an institution with the capability to provide surgical repair of complex congenital or acquired conditions • Maintain a full range of pediatric medical subspecialists, pediatric surgical subspecialists, and pediatric anesthesiologists at the site • Facilitate transport and provide outreach education	Level III health care providers plus: Pediatric surgical subspecialists

[a] Includes all providers with relevant experience, training, and demonstrated competence.
[b] At the site or at a closely related institution by prearranged consultative agreement.

organization.[55] Each level reflects the minimal capabilities, functional criteria, and provider type required. Currently, there are 148 specialty care units and 809 subspecialty care units self-identified in the 2009 AAP perinatal section directory.

Level I

Level I facilities (well newborn nurseries) provide a basic level of care to neonates who are low risk. They have the capability to perform neonatal resuscitation at every delivery and to evaluate and provide routine postnatal care for healthy newborn infants. In addition, they can care for preterm infants at 35 to 37 weeks' gestation who are physiologically stable and can stabilize newborn infants who are less than 35 weeks of gestation or who are ill until they can be transferred to a facility at which specialty neonatal care is provided. Because late preterm infants (34–36 weeks' gestation) are at risk for increased neonatal morbidity and mortality, more evidence is needed to determine their outcomes by level of care.

Level II

Care in a specialty-level facility (level II) should be reserved for stable or

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moderately ill newborn infants who are born at ≥32 weeks' gestation or who weigh ≥1500 g at birth with problems that are expected to resolve rapidly and who would not be anticipated to need subspecialty-level services on an urgent basis. These situations usually occur as a result of relatively uncomplicated preterm labor or preterm rupture of membranes. There is limited evidence to support the specific subdivision of level II care, in part because of the lack of studies with well-defined subdivisions. Level II facilities should take into consideration geographic constraints and population size when assessing the staffing resources needed to care appropriately for moderately ill newborn infants.

Level II nurseries may provide assisted ventilation on an interim basis until the infant's condition either soon improves or the infant can be transferred to a higher-level facility. Delivery of continuous positive airway pressure should be readily available by experienced personnel, and mechanical ventilation can be provided for a brief duration (less than 24 hours). Level II nurseries must have equipment (eg, portable x-ray machine, blood gas analyzer) and personnel (eg, physicians, specialized nurses, respiratory therapists, radiology technicians, laboratory technicians) continuously available to provide ongoing care as well as to address emergencies. Referral to a higher level of care should occur for all infants when needed for pediatric surgical or medical subspecialty intervention.

Level III

Evidence suggests that infants who are born at <32 weeks' gestation, weigh <1500 g at birth, or have medical or surgical conditions, regardless of gestational age, should be cared for at a level III facility. Designation of level III care should be based on clinical experience, as demonstrated by large patient volume, increasing complexity of care, and availability of pediatric medical subspecialists and pediatric surgical specialists. Subspecialty care services should include expertise in neonatology and also ideally maternal-fetal medicine, if mothers are referred for the management of potential preterm birth. Level III NICUs are defined by having continuously available personnel (neonatologists, neonatal nurses, respiratory therapists) and equipment to provide life support for as long as necessary. Facilities should have advanced respiratory support and physiologic monitoring equipment, laboratory and imaging facilities, nutrition and pharmacy support with pediatric expertise, social services, and pastoral care.

Level III facilities should be able to provide ongoing assisted ventilation for 24 hours or more, which may include conventional ventilation, high-frequency ventilation, and inhaled nitric oxide. Level III facility capabilities should also be based on a region's consideration of geographic constraints, population size, and personnel resources. If geographic constraints for land transportation exist, the level III facility should ensure availability of rotor and fixed-wing transport services to quickly and safely transfer infants requiring subspecialty intervention.[56] Potential transfer to higher-level facilities or children's hospitals, as well as back-transport of recovering infants to lower-level facilities, should be considered as clinically indicated.

A broad range of pediatric medical subspecialists and pediatric surgical specialists should be readily accessible on site or by prearranged consultative agreements. Prearranged consultative agreements can be performed by using telemedicine technology and/or telephone consultation, for example, from a distant location.[50] Pediatric ophthalmology services and an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity should be readily available in level III facilities.[57] Level III units should have the capability to perform major surgery on site or at a closely related institution, ideally in close geographic proximity. Because the outcomes of less complex surgical procedures in children, such as appendectomy or pyloromyotomy, are better when performed by pediatric surgeons compared with general surgeons, it is recommended that pediatric surgical specialists (including anesthesiologists with pediatric expertise) perform all procedures in newborn infants.[58]

Level III facilities should have the capability to perform advanced imaging with interpretation on an urgent basis, including CT, MRI, and echocardiography. Level III facilities should collect data to assess outcomes within their facility and to compare with other levels.

Level IV

Level IV units include the capabilities of level III with additional capabilities and considerable experience in the care of the most complex and critically ill newborn infants and should have pediatric medical and pediatric surgical specialty consultants continuously available 24 hours a day. Level IV facilities would also include the capability for surgical repair of complex conditions (eg, congenital cardiac malformations that require cardiopulmonary bypass with or without extracorporeal membrane oxygenation). More evidence is needed to assess the risk of morbidity and mortality by level of care for newborn infants with complex congenital cardiac malformations. A recent study by Burstein et al[59] was not able to note a difference in postoperative morbidity or mortality

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associated with dedicated pediatric cardiac ICUs versus NICUs and PICUs but did not separately assess the newborn and postneonatal periods. Although specific supporting data are not currently available, it is thought that concentrating the care of such infants at designated level IV centers will allow these centers to develop the expertise needed to achieve optimal outcomes.

Not all level IV hospitals need to act as regional centers; however, regional organization of perinatal health care services requires that there be coordination in the development of specialized services, professional continuing education to maintain competency, facilitation of opportunities for transport and back-transport,[60] and collection of data on long-term outcomes to evaluate both the effectiveness of delivery of perinatal health care services and the safety and efficacy of new therapies. These functions usually are best achieved when responsibility is concentrated in a single regional center with both perinatal and neonatal subspecialty services. In some cases, regional coordination may be provided adequately by the collaboration of a children's hospital with a subspecialty perinatal facility that is in close geographic proximity.[61]

STANDARDS OF SERVICE FOR HOSPITALS PROVIDING NEONATAL CARE

Current evidence indicates that family and cultural considerations are important for care of sick neonates.[62–65] These considerations include family- and patient-centered care, culturally effective care, family-based education, and opportunities for back-transport to level II facilities or transfer to the family's local community facility when medically and socially indicated.[64–67]

SUMMARY AND RECOMMENDATIONS

1. Regionalized systems of perinatal care are recommended to ensure that each newborn infant is delivered and cared for in a facility most appropriate for his or her health care needs, when possible, and to facilitate the achievement of optimal health outcomes.
   - Because VLBW and/or very preterm infants are at increased risk of predischarge mortality when born outside of a level III center, they should be delivered at a level III facility unless this is precluded by the mother's medical condition or geographic constraints.
2. The functional capabilities of facilities that provide inpatient care for newborn infants should be classified uniformly on the basis of geographic and population parameters in collaboration with state health departments, as follows:
   - Level I: a hospital nursery organized with the personnel and equipment to perform neonatal resuscitation, evaluate and provide postnatal care of healthy newborn infants, provide care for infants born at 35 to 37 weeks' gestation who remain physiologically stable, and stabilize ill newborn infants or infants born at less than 35 weeks' gestational age until transfer to a facility that can provide the appropriate level of neonatal care.
   - Level II: a hospital special care nursery organized with the personnel and equipment to provide care to infants born at 32 weeks' gestation or more and weighing 1500 g or more at birth 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 a higher level of intensive care. A level II center has the capability to provide continuous positive airway pressure and may provide mechanical ventilation for brief durations (less than 24 hours).
   - Level III: 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 critical illness. This includes infants born weighing <1500 g or at <32 weeks' gestation. Level III units have the capability to provide critical medical and surgical care. Level III units routinely provide ongoing assisted ventilation; have ready access to a full range of pediatric medical subspecialists; have advanced imaging with interpretation on an urgent basis, including CT, MRI, and echocardiography; have access to pediatric ophthalmologic services with an organized program for the monitoring, treatment, and follow-up of retinopathy of prematurity; and have pediatric surgical specialists and pediatric anesthesiologists on site or at a closely related institution to perform major surgery. Level III units can facilitate transfer to higher-level facilities or children's hospitals, as well as back-transport recovering infants to lower-level facilities, as clinically indicated.
   - Level IV units have the capabilities of a level III NICU and

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are located within institutions that can provide on-site surgical repair of serious congenital or acquired malformations. Level IV units can facilitate transport systems and provide outreach education within their catchment area.

3. The functional capabilities of facilities that provide inpatient care for newborn infants should be classified uniformly and with clear definitions that include requirements for equipment, personnel, facilities, ancillary services, training, and the organization of services (including transport) for the capabilities of each level of care.
4. Population-based data on patient outcomes, including mortality, morbidity, and long-term outcomes, should be obtained to provide level-specific standards for patients requiring various categories of specialized care, including surgery.

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