Anales de Pediatría 98 (2023) 301–307

analesdepediatría

www.analesdepediatria.org

SPECIAL ARTICLE

Care levels in neonatal units in Spain: an updated vision for a new reality

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Received 16 February 2023; accepted 18 February 2023
Available online 17 March 2023

KEYWORDS
Quality;
Care levels;
Newborn;
Neonatal units

Abstract The Spanish Society of Neonatology established the care levels of the Neonatal Units in Spain in 2013. Since then, the birth rate in our country, as well as the universalization of knowledge, techniques and patient treatment devices, has evolved significantly. This situation forces a redefinition of the current levels of care based on quality criteria that allow better comparability between the Units and represents a challenge to improve the care of our newborns.

DOI of original article: https://doi.org/10.1016/j.anpedi.2023.02.009
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PALABRAS CLAVE
Calidad;
Niveles asistenciales;
Recién nacido;
Unidades neonatales

Niveles asistenciales en las unidades neonatales en España: una visión actualizada para una nueva realidad

Resumen La Sociedad Española de Neonatología estableció en el año 2013 los niveles asistenciales de las Unidades Neonatales en España. Desde entonces, la natalidad en nuestro país, así como la universalización del conocimiento, de las técnicas y de los dispositivos de tratamiento de los pacientes ha evolucionado significativamente. Esta situación obliga a una redefinición de los actuales niveles asistenciales basándose en criterios de calidad que permitan una mejorar comparabilidad entre las Unidades y supongan un impulso para la mejora en la atención de nuestros recién nacidos.

Background

In 2004 and 2013, the Sociedad Española de Neonatología (SENeo, Spanish Society of Neonatology) established criteria to define the different levels of care of neonatal units in Spain.[1,2] These criteria are chiefly based on the definition of groups of neonates that may receive care in a given type of unit based on gestational age, weight, number of deliveries managed in the catchment area as an indirect indicator of the experience of health care staff, amount and type of available equipment or availability of techniques or procedures that could be applied based on disease severity and medical complexity, resulting in the establishment of 3 levels of care with different sublevels.

In brief, the current levels of care of neonatal units in Spain are defined according to the following criteria:

- Level I: management of low-risk pregnancies, healthy newborns and clinically stable newborns delivered between 35 and 37 weeks (wk) of gestation. Resuscitation in delivery room and operating room. Triage system established to identify patients that may require transfer to a higher level of care. Stabilization of patients in the event of unexpected neonatal problems, including the stabilization of newborns small for gestational age and severely ill preterm newborns before transport. Management, assessment and identification of neonatal disease in previously healthy newborns. Coordination with primary care to set up the followup of discharged newborns.
- Level II
  - IIA: management of select complicated pregnancies and newborns delivered after 32 weeks gestation and with birth weights greater than 1500 g. Care of newborns with minor disease and problems that can be resolved quickly without need of respiratory support or arterial vascular access (possibly with availability of nasal intermittent positive pressure ventilation [IPPV] for short-term conditions). Management of newborns transferred from the referral hospital that have overcome the severe phase of disease (back transfer). Programmes for the developmental followup of high-risk newborns.
  - IIB: management of at least 1500 deliveries a year in the catchment area. Care of newborns with moderately severe disease, including those who require conventional mechanical ventilation for brief periods (<24 h) or noninvasive ventilation.
- Level III: management of at least 2000 deliveries a year in the catchment area.
  - IIIA: management of selected complicated pregnancies and newborns delivered after 28 weeks gestation and with birth weight greater than 1000 g. Care of severely ill newborns, including those requiring conventional mechanical ventilation. Minor surgical procedures.
  - IIIB: management of any form of complicated pregnancy and newborns of any gestational age. Access to advanced respiratory support (high-frequency oscillatory ventilation [HFOV] and administration of inhaled nitric oxide [iNO]). Paediatric surgery resources immediately accessible for performance of major surgical interventions.
  - IIIC: newborns requiring the full spectrum of medical and surgical subspeciality services, including cardiac surgery with extracorporeal circulation, extracorporeal membrane oxygenation (ECMO) and paediatric transplantation.

Classification of levels of care in other countries

In the United States, the American Academy of Pediatrics published indicators that were mainly based on morbidity criteria rather than patient volume.[3]

- Level I: capabilities to provide neonatal resuscitation, evaluation and postnatal care for stable term newborn infants, stabilization and care for infants born at 35–37 weeks of gestation who remain physiologically stable, stabilization of newborn infants born at before 35 weeks gestation until transfer to a higher level of care.
- Level II: capabilities to provide care for infants born at or after 32 weeks gestation and weighing 1500 g or more with problems that are expected to resolve rapidly and are not anticipated to need subspecialty services on an

urgent basis; to provide care for infants convalescing after intensive care; invasive IPPV (for <24 h) or noninvasive ventilation or both; stabilization of infants born before 32 weeks gestation and weighing less than 1500 g until transfer.
- Level III (neonatal intensive care unit [NICU]): capabilities to provide life support, care for infants born before 32 weeks gestation and weighing less than 1500 g and infants born at all gestational ages and birth weights with critical illness, access to paediatric medical subspecialists, paediatric surgical specialists, paediatric anaesthesiologists, and paediatric ophthalmologists. Full range of respiratory support, including HFOV and iNO, and access to imaging (magnetic resonance [MR], computed tomography [CT], ultrasound).
- Level IV (regional NICU): capability to provide surgical repair of complex congenital or acquired conditions, full range of paediatric subspecialists. Paediatric surgical subspecialists. Capabilities for transport and outreach education. Includes cardiac repair surgery with or without ECMO.

Neighbouring countries have also established specific levels of care; for instance, in the United Kingdom, there are 3 levels of care corresponding to 3 types of neonatal units based on the care provided.[4,5]

- Level I: provision of care for babies who cannot be looked after at home. Includes breathing and heart rate monitoring, tube feeding, oxygen therapy and phototherapy for jaundice.
- Level II: provision of high-dependency care. Takes place in a specialised neonatal unit and provides continuous monitoring. Patients may include babies who weigh less than 1000 g (2 lbs 3 oz), or are receiving help with their breathing via continuous positive airway pressure (CPAP) or intravenous feeding, but who do not fulfil any of the requirements for intensive care.
- Level III: intensive care. Management of babies with the most complex problems who require constant supervision and monitoring and, usually, mechanical ventilation. A doctor must always be available in the premises.

Types of neonatal units in the United Kingdom:

- Special care unit: provide special care for their own local population. Depending on arrangements within their neonatal network, they may also provide some high dependency services. In addition, SCUs provide a stabilisation facility for babies who need to be transferred to a NICU for intensive or high dependency care.
- Local neonatal unit: provide neonatal care for their own catchment population, except for babies who require complex or longer-term intensive care. The majority of babies over 27 weeks of gestation will usually receive their full care, including short periods of intensive care, within their local neonatal unit. Some provide high dependency care and short periods of intensive care for their network population.
- Neonatal intensive care unit: provide the whole range of medical neonatal care for their local population. Many NICUs are co-located with neonatal surgery services and other specialised services.

The case for the redefinition of the levels of care of neonatal care units in Spain

At present, the definition of the levels of care of neonatal care units in Spain must be revised because recent advances in knowledge and their easy online dissemination have resulted in improved knowledge and skills in medical and nursing staff, techniques and equipment have become widely available (improvement in material resources in all units that allow multiple treatments) and there has been an important decline in birth rates throughout Spain. This calls for new criteria for the definition of care levels, not only based on volume, but also on the capabilities for providing different types of care and, perhaps more importantly, indicators of care quality.

Quality in health care is achieved when the needs of individuals and populations (in health education, prevention, promotion and maintenance) are accurately and fully identified, and the necessary resources (human or of a different kind) are allocated as promptly and effectively as current knowledge allows, as noted by the World Health Organization (WHO).[6]

Based on this definition of quality assurance, criteria need to be established to measure the quality of care[7]:

- Structure criteria: attributes that need to be in place for the proper operation of the unit. This includes elements such as staff training and qualification, nurse to patient ratios, the physical structure of the unit, the available technology or the presence of organizational structures (ethics committee, mortality review committee, perinatal mortality and morbidity review committee, safety committee, etc).
- Process criteria: these refer to what is done to the patient and how. This includes the existence of unit protocols and clinical practice guidelines, scientific output of the unit based on its publications, organization of courses and conferences or participation in public or privately funded clinical trials.
- Outcome criteria: patient outcomes at the end of the care episode. This includes indicators such as mortality, incidence of sepsis, retinopathy of prematurity, bronchopulmonary dysplasia or necrotising enterocolitis, satisfaction survey ratings, etc.

Making these criteria the expression of health care quality requires substantial effort by neonatal units in reformulating their work, so that they can be subject to external or internal auditing and achieve national or international quality and safety certifications. It is an objective of our society of neonatology that any neonatal unit or department, independently of size or patient volume, be able to achieve the highest quality standards in the day-to-day

Table 1 Quality levels (Q) in neonatal units in Spain.

	Quality level 1 (Q1)	Quality level 2 (Q2)	Quality level 3 (Q3)
Structure criteria	[1]Capabilities for neonatal resuscitation in the delivery room or a separate room. 2 Physician trained in neonatology and qualified to performed resuscitation. Physician does not need to be physically present in the unit. 3 Nurse to assist in deliveries with training in neonatology. Ratio of 1:8—10. 4 Access to pharmacy, imaging and laboratory 24 h a day. 5 Oxygen therapy equipment with flow regulation and capability to administer gas mixtures.	[1]Capabilities for neonatal resuscitation in the delivery room or a separate room. 2 Physician trained in neonatology and qualified to performed resuscitation. Physician must be physically present in the unit. 3 Neonatal nurse. Ratio of 1:3—5. 4 Access to pharmacy, imaging and laboratory 24 h a day. 5 Oxygen therapy equipment with flow regulation and capability to administer gas mixtures. 6 Nasal IPPV. 7 Dedicated space for neonatal hospitalization with basic monitoring (ECG, $SatO_2$, BP). It can be continuous with the paediatric ICU. 8 Continuing education of health care staff (at least one course a year by 60% of the staff in the unit). 9 Assessment of patient comfort. Use of pain scales.	[1]Capabilities for neonatal resuscitation in the delivery room or a separate room. 2 Adequate staffing of doctors with resuscitation skills in the unit. On-call shifts in the unit with doctor physically present. 3 Paediatric nurses on staff with specific training in neonatology and critical care. Ratio of 1:1—2, possibly as high as 2:1. 4 Access to pharmacy, imaging and laboratory 24 h a day. 5 Oxygen therapy equipment with flow regulation and capability to administer gas mixtures 6 Nasal IPPV. 7 Invasive IPPV and HFOV. 8 iNO. 9 Availability of therapeutic hypothermia. 10 Capabilities to provide haemofiltration/haemodialysis within the neonatal unit. 11 Availability of ECMO in the unit itself. 12 Architectural design of neonatal inpatient ward-neonatal ICU as separate space from other care settings with full monitoring. 13 Continuing education of health care staff (at least one course a year by 80% of the staff in the unit). 14 Family lounge area. 15 aEEG monitoring. 16 Cerebral and somatic oximetry monitoring. 17 Pain monitoring: fifth vital sign. 18 Unit-specific mortality review committee. 19 Specific perinatal review committee. 20 Specific safety committee. Culture of safety.

Table 1 (*Continued*)

	Quality level 1 (Q1)	Quality level 2 (Q2)	Quality level 3 (Q3)
Process measures	[1]Basic action protocols. 2 Unequivocal newborn identification.	[1]Basic action protocols. 2 Informed consent for admission and procedures (at least verbal). 3 Unequivocal newborn identification. 4 Scientific publications in journals included in the JCR (1–4 a year). 5 Participation in research projects funded by the private sector. 6 Daily information on the evolution of the newborn (at least in the inpatient setting). 7 Development and family centred care. 8 Noise control in the unit. 9 Specific neonatal followup clinic. 10 Paediatric surgery available in hospital.	[1]Protocols for specific diseases and procedures. Clinical practice guideline. 2 Written informed consent for admission and procedures. 3 Unequivocal newborn identification. 4 Availability of informational leaflets about procedures/diseases for families. 5 Scientific publications in journals included in the JCR (at least 5 per year). 6 Organization of continuous education courses (at least 1 per year). 7 Participation in research projects funded by the private sector. 8 Participation in research projects funded by competitive public grants (at least 1 a year). 9 Separate room to discuss the evolution of the newborn. 10 Individual isolation rooms. 11 Point-of-care ultrasound. 12 Availability of donor human milk (own milk bank or receiving hospital). 13 Individual inpatient rooms. 14 Family and developmental centred care. 15 Dimmed lights in unit. 16 Noise reduction in unit. 17 Participation in at least one humane care project. 18 Specific neonatal followup clinic. 19 Surgical interventions by paediatric surgeons in the hospital that houses the neonatal unit. 20 Postoperative care within the neonatal unit. 21 Interventional cardiology procedures in the hospital that houses the neonatal unit. Postoperative care in neonatal unit.
Outcome measures	[1]Correct identification of patients at risk or with severe disease and transfer to a higher level of care	[1]Correct identification of patients at risk or with severe disease and transfer to a higher level of care. 2 Internal audits. 3 Mortality outcome indicators. 4 Vertical and nosocomial sepsis outcome indicators. 5 Register of most prevalent morbidity indicators in very preterm infants.	[1]Internal audits. 2 External audits. 3 Annual report including mortality indicators. 4 Annual report including vertical and nosocomial sepsis indicators. 5 Annual report including indicators of frequency of retinopathy of prematurity. 6 Annual report including indicators of frequency of bronchopulmonary dysplasia. 7 Annual report including indicators of frequency of necrotising enterocolitis. 8 Satisfaction survey ratings.

aEEG: amplitude-integrated electroencephalogram; BP, blood pressure; ECG, electrocardiogram; ECMO: extracorporeal membrane oxygenation; HFOV, high-frequency oscillatory ventilation; ICU, intensive care unit; IPPV, intermittent positive pressure ventilation; iNO, inhaled nitric oxide; JCR, Journal Citation Report; $SatO_2$, oxygen saturation.
Note: ''health care staff'' refers to the doctors and nurses of the unit.

Table 2 Minimum number of criteria that must be met in each dimension to achieve a given quality level.

	Q1	Q2	Q3
Structure criteria	4	8	16
Process criteria	2	8	16
Outcome criteria	1	4	7

interaction between patients and providers.

The integration and definition of neonatal units based on level of care requires a series of core elements that they must all share. All must have staff trained and qualified to attend a complicated delivery and perform adequate cardiopulmonary resuscitation (CPR) according to the standards of the Group on CPR of the SENeo, the capabilities to stabilize severely ill neonates and transport them to the referral centre offering the necessary level of care, the capabilities to perform the newborn hearing and metabolic screens and promote breastfeeding and parent-child bonding.

Proposed levels of care

Neonatal care units or departments in Spain will come to be defined based on 2 criteria.

Based on the characteristics of the patients that they can manage, the following levels are established:

- Level I: neonatal units caring for neonates delivered after 35 weeks and/or weighing 2000 g when a complicated delivery or neonatal illness requiring evaluation or treatment are not expected. These are basic units that are part of every maternity ward with staff trained on CPR and qualified to stabilize critical newborns for subsequent transport.
- Level II: neonatal units caring for neonates weighing more than 1500 g and/or delivered after 32 weeks in whom significant complications are not expected. They also have the capabilities required to stabilize neonates with a lower weight or gestational age for transport to a higher level facility.
- Level III: neonatal unit with the necessary human, material and technical resources on site to manage any newborn independently of weight, gestational age or medical complexity.

Neonatal units are also classified into three levels based on quality (Q1, Q2 and Q3) (Table 1).

For a unit to be classified into a given quality level, it must meet at least 80% of the criteria in each dimension (structure, process, outcome). The minimum threshold must be achieved in all three to achieve the given level of quality. Table 2 specifies the minimum number of criteria that must be met in each dimension to achieve each level of quality.

Obtaining and maintaining certifications in a quality management systems standard recognised domestically or internationally (ISO [ISO 9001]/UNE [UNE 179003]/Joint Commission International [JCI], etc) is additional evidence of quality for the unit or department and is denoted by a plus (+) sign next to the Q level (Q1+, Q2+, Q3+). Achieving this type of certification requires the implantation and external evaluation of compliance with the standards of the certification system, which entails the ongoing analysis of health care outcomes and the implementation of corrective actions as needed.

Thus, any neonatal care unit in Spain could be classified as Level I to III based on the complexity of the patients it manages and as Q1 to Q3 based on the quality of the care it delivers. Level I units should have a Q1 or Q2 quality level; Level II units can have a level from Q1 to Q3, ideally Q2 or Q3, and Level III units should have a quality level of Q2 or Q3, ideally Q3, to guarantee access to care of the highest possible quality to very preterm infants. If the setting has an official certification, the + symbol is added to the classification of the unit or department.

Achieving a higher level of quality of neonatal units corresponds to improvement in patient care, especially the care of very preterm newborns,[8] so it is important for each unit to be aware of where it stands and what it needs to do to improve.

Funding

This research did not receive any external funding.

Conflicts of interest

The authors have no conflicts of interest to declare.

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