Project 27/28

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An enquiry into the quality of care and its effect on the survival of babies born at 27–28 weeks

The Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) devised Project 27/78 to identify the patterns of perinatal practice and service that may have affected the risk of a neonatal death between 27^{+0} and 28^{+6} weeks gestation. An executive summary is available on the CESDI website (www.cemach.org.uk). The report deals with perinatal care but this article concentrates on the key messages for neonatologists.

METHODOLOGY

All babies with a gestational age at birth of $26–29^{+6}$ weeks born in England, Wales, and Northern Ireland between 1 September 1998 and 31 August 2000 were entered into special logbooks and data were collected on a standard proforma. A four weeks range was chosen to allow for inaccuracies in the estimation of gestational age at birth. The information from all neonatal deaths was compared with that from an equivalent number of babies who were selected at random from those who survived to 28 days after delivery. A multidisciplinary panel then audited predetermined aspects of perinatal care against a set of standards.[1–4] Recommendations for future practice were derived using a Delphi consensus.

The Report has been appraised using the standards of the Royal College of Paediatrics and Child Health (RCPCH).[5] There is no description of the original process by which the standards were developed. Project 27/28 complies with two of the three attributes for a clinical guideline. The rigour of the report shows appropriate composition of the guideline development group and scoping of the guideline. However there is a lack of a description of the search strategy used to identify evidence, quantification of the merits of the recommendations, and a link between the recommendations and the evidence base for them.

Three of the 15 standards used are based on evidence from a randomised controlled trial. If these standards and the subsequent recommendations are categorised by the RCPCH standards,[5] then those relating to the administration of antenatal steroids and surfactant can be graded 1A. The remaining recommendations that are discussed in this paper are graded 4D. This grading does not address the clinical applicability or the importance of the evidence but does limit the validity of the derived recommendations.

The multidisciplinary panel involved in the Delphi process included representation from a number of professional and parent groups. To this end a recommendation reached might be considered to be acceptable and practical to a wide range of health care workers. However the methodology of the actual Delphi process has not been adequately described.

The number of rounds in the process, the mean and standard deviation scores (an indication of the degree of consensus reached) has not been documented. In addition, there is no description of the process or the level of consensus reached between rounds—both of which shed light onto the quality and reliability of the final panel consensus.[6] In this project a recommendation was rejected rather than being discussed further if the majority of a section group disagreed.[7] The drafted recommendations were then scored by relevance and validity and dropped from further discussion if the weighted score for percentage relevance and validity was $<50\%$.[7] The process of eliminating recommendations where there was little consensus might have omitted issues towards which primary research or further discussion could be directed. The RCPCH standards[5] suggest that a quality of practice committee should arbitrate in these circumstances.[5] This again limits the validity of the derived recommendations.

TRAINING

The balance between provision of a clinical service, training, and meeting the requirements of the European Working Time Directive is a difficult challenge. This is further emphasised by the plans for restructuring of the training for junior medical staff.[8] Structured training has been facilitated by the development of competency based objectives for training in neonatal medicine.[9] However, Project 27/28 has identified deficiencies in training that present an opportunity for the development of multidisciplinary professional training and team working. This training strategy is supported in the NHS workforce planning documents.[10] The widespread introduction of multiprofessional training in resuscitation (for example, APLS, NLS, and PALS) has confirmed the adage, long appreciated in the armed forces, that teams that train together work well together.

CLINICAL MANAGEMENT

Project 27/28 reports national data that were not previously available. To this end an overall survival of 88% is noteworthy in itself. The survival figures have not been adjusted for severity of illness at birth and this limits the generalisation possible from this figure. The formulation of survival curves from this data would be beneficial for planning service delivery and discussion with parents.

The standards used for assessing resuscitation are graded 4 by RCPCH criteria.[5] The Report has looked at aspects of resuscitation in isolation rather than assessing the progress through a defined algorithm. The standard for personnel to be present at resuscitation was met in 56% of cases with no significantly identifiable effect on survival. In 95% of cases a doctor (of an unspecified grade) or an advanced neonatal nurse practitioner (ANNP) was present. This suggests that the issue is the appropriate deployment of more than one member of staff for immediate resuscitation.

Some aspect of the resuscitation process was considered to have been poor in 38% of babies who died compared with 24% who survived. The degree of proficiency at resuscitation was high, however there was criticism of difficulties in intubation, drug and equipment errors, documentation staffing, and transfer. The newborn life support (NLS) training stresses the importance of effective airway management, focusing on bag and mask ventilation rather than endotracheal intubation as recommended in the Report.[11] Clinical management by junior staff might have been facilitated by the provision of clear guidelines for immediate management and anticipation of the need for an experienced clinician able to provide more individualised care.

The importance of thermal care of the small preterm newborn infant has long been recognised.[12–14] In the Epicure data multivariate analysis for factors associated with death before discharge showed that an admission temperature $\geqslant 35℃$ had an odds ratio of 0.58. The

standard in Project 27/28 was a temperature of >36°C on admission to the neonatal intensive care unit. This standard was not achieved in 61% of all babies and this took a median of approximately 2 hours (range 1.5–4 hours) to be corrected. After adjustment for gender, birth weight <5% centile, and poor condition at 5 minutes, a low admission temperature and a delay in its correction was significantly associated with death (adjusted odds ratio 1.71, 95% CI 1.21 to 2.43, p = 0.002).

The increased association between mortality and low admission temperature emphasises the importance of effective early thermal care. Lyon and Stenson have reported a novel approach to thermal care.[15] They show that the routine use of a polyethylene bag during the resuscitation of all newborn infants born at <29 weeks gestation was accompanied by a marked reduction in early hypothermia. The plastic bag did not interfere with resuscitation and was removed after the newborn infants had been placed into a warmed and humidified incubator. In the eight years since its introduction, this simple and cheap method abolished hypothermia in the authors' unit.

This strategy for the prevention of hypothermia confirms the previous findings of Vohra and Bjorklund.[16 17] What is not yet clear is whether the bag needs to be sterile and how one might prevent the deleterious effects of hyperthermia.[18 19]

The Report documented that in 79% of cases surfactant was administered by 2 hours of age. Soll and Morley have suggested that the administration of prophylactic surfactant to all newborn infants born between 27^{+0} and 28^{+6} weeks gestation might result in a 40% decrease in mortality.[3] For 38% of the babies who died and 40% of those who survived, surfactant was not given until after 1 hour of age. The level of evidence and grade of recommendation is 1A,[5] and measures to ensure the administration of prophylactic surfactant as soon as practical should be taken.

In Project 27/28 a low mean blood pressure was significantly associated with death at 27 or 28 weeks gestation. This would suggest that close monitoring and treatment of low blood pressure is important. The report recommends that no more than 20 ml/kg of volume expansion be used to maintain an appropriate blood pressure based on a series of 50 (evidence and recommendation graded 2C).[5] Controversy persists regarding the volume and nature of fluid boluses and the appropriate initial inotrope.

DOCUMENTATION

The organisation and quality of the contents of neonatal medical and nursing notes was poor in over 50% of cases. There is no universal solution to this challenge and there must be a balance between excessive repetitive paperwork and the need to provide a clinical service. However, effective training in clinical governance and risk management, and the future need to document performance against national standards makes this an important issue.

Documentation could be supported by an integrated and sustainable IT strategy. This would enable ready access to patient information and would facilitate the national harmonisation of data that currently hinders the development of an evidence based long term national strategy for neonatal care.[20] Issues of patient confidentiality, data integrity, IT infrastructure, reliability, and implementation and staff training need to be addressed to avoid these recognised pitfalls.[21 22]

ORGANISATION OF CARE

In Project 27/28 there were no significant differences in demographic characteristics, previous medical or obstetric history, gestation at booking, lifestyle, or place of delivery between mothers of babies who died and mothers of babies who survived. This poses a challenge for the identification of mothers at risk of premature delivery. However, the data were not adjusted for severity of illness at birth. Therefore if babies who were delivered in larger and busier units were sicker (as is likely), then one might have failed to detect a difference in outcome even if the neonatal care provided in those units was superior. In addition a comparison of the outcome of neonatal care between Trent and Denmark concluded that population characteristics rather than models of the organisation of neonatal services might have a greater effect on outcome.[23] The development of a national system of data collection with the characteristics described above would allow the establishment of a meaningful audit of the influence of changes in neonatal service provision on outcomes including mortality and morbidity.

Although 92% of the babies in this study were delivered in an appropriate unit, this was achieved by the transfer of 1 in 4 before delivery and 1 in 10 babies in the first week afterwards. This level of transfer is in excess of the recommendation of the Clinical Standards Advisory Group (CSAG)[24] and is likely to be associated with significant maternal and neonatal morbidity.[25] However, in a managed clinical network it is implicit that a certain level of transfer is necessary.

CONCLUSION

Project 27/28 has highlighted again deficiencies in the provision of a neonatal service that continue despite previous recommendations from CSAG in 1993 and 1996[24 26] and the findings from the 1999 national neonatal census.[27] There are difficulties with access to appropriate neonatal intensive care facilities, inadequate provision of neonatal intensive care cots, inadequate levels of medical and nursing staffing, and a lack of routine equipment checks.

There are limitations to the validity of this report's recommendations. However, they are broadly similar to the current standards proposed by the British Association of Perinatal Medicine and the Department of Health.[20 28] To respond to these recommendations and their limitations one might commission a panel for each, or each group of recommendations. This panel could then discuss the issue using the RCPCH guideline standards[5] and present a recommendation based on graded evidence or consensus if evidence is lacking. Such a process would prevent the further waste of resources involved in collating a report with recommendations that are not implemented and allow for appropriate policy changes in the strategic development of neonatal services within the United Kingdom.

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