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Extended Research Article

Optimising neonatal services for very preterm births between 27^{+0} and 31^{+6} weeks gestation in England: the OPTI-PREM mixed-methods study

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Dedicated to all babies born preterm, their families and their healthcare teams.

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Scientific summary

Optimising neonatal services for very preterm births between 27^{+0} and 31^{+6} weeks gestation in England: the OPTI-PREM mixed-methods study

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Scientific summary

Background

Recent global evidence indicates that place of birth matters for survival and morbidity advantages for extremely preterm babies born at ≤ 26 weeks gestation. This has shaped national policy. We do not know whether this benefit extends to the next most vulnerable group, born between 27^{+0} and 31^{+6} weeks gestation (hereafter referred to as born at 27–31 weeks). Globally these may be managed in different types of neonatal facilities. In England, they may be born into maternity units colocated with either neonatal intensive care units (NICU, also known as tertiary neonatal units) or local neonatal units (LNU, also known as non-tertiary neonatal units) and cared for in these. NICU can provide higher intensity of care than LNU, but both have facilities to support babies born at < 32 weeks gestation. Occasionally, they may be born outside these units, but, if viable, are quickly transferred for care in either. Current practice makes no distinction between care in either, as these babies, while vulnerable, do not all require the highest intensity of care. The decision about where an individual babies is born is based on maternal choice at booking, presentation to the nearest hospital and bed/staff capacity at the time of delivery. However, these two types of neonatal unit differ in facilities, staffing and staff skill-mix for care of very preterm babies.

Evidence on the most appropriate setting for post-delivery care has been lacking, and questions have been raised around whether, within this cohort of babies born at 27–31 weeks gestation, the optimal care setting could vary across the gestational age range. They account for ~12% of all preterm births and four times the throughput in neonatal units compared to babies born at ≤ 26 weeks gestation. They are a sizeably important group for whom the optimal care setting should be investigated if survival is to be maximised and morbidity minimised.

Aim

To investigate the best place of birth and early care for preterm babies born at 27–31 weeks gestation in England, so that this evidence can be used to inform and optimise neonatal healthcare delivery in England.

Study design

Mixed-methods study comprising five workstreams.

Setting

Neonatal units in England.

Workstream 1: A clinical outcomes study: the impact of place of birth and early care on mortality and morbidity in very preterm babies born at 27–31 weeks gestation in England

Objective

For very preterm babies born at 27–31 weeks gestation in England, and admitted to neonatal units, does birth in maternity units colocated with NICU or LNU offer a survival and/or morbidity advantage?

Design

National population-based cohort study using quality-assured electronic recorded patient data held within the National Neonatal Research Database (NNRD). For mortality the time horizon was 1 year, and for this, NNRD data were linked with mortality information from NHS Digital, Office for National Statistics. For morbidity, the time horizon was the hospital stay, prior to discharge from neonatal care.

Participants

Eighteen thousand eight hundred and forty-seven preterm babies born at between 27–31 weeks gestation in maternity units colocated with NICU compared with LNU in England, who were discharged from or died in neonatal care between 1 December 2014 and 31 December 2018. Neonatal care was assigned to unit designation at admission, and early care, to place of care in the first 72 hours of life.

Methods

We conducted overall and gestation-specific analyses, and adjusted for measured confounders of sex, birthweight z-score, multiplicity, mode of delivery, ethnicity, maternal age and indices of multiple deprivation. We used an instrumental variable approach to control for unmeasured differences between units. The instrument selected was maternal excess travel time between NICU and LNU. We performed sensitivity analyses excluding early postnatal transfers (at 24 hours and up to 72 hours after birth), and multiple births. We also analysed outcomes by volume of neonatal intensive care activity. We studied the outcomes of death in neonatal care, and the first year of life (infant mortality), necrotising enterocolitis (NEC), retinopathy of prematurity (ROP), severe/serious brain injury (SBI), bronchopulmonary dysplasia (BPD), and a care process, the receipt of any breast milk feeds at discharge from neonatal care (BMF). We calculated adjusted mean proportions in each unit with associated mean differences and 99% confidence interval (CI).

Results

Mortality: We included 18,847 babies (10,379 born into maternity units colocated with NICU and 8468 with LNU). Five hundred and seventy-four babies (3.0%) died while in NICU/LNU care, and a further 121 after discharge from neonatal care, within their first year of life (total infant mortality; 3.7%). There was no effect of place of birth on mortality in neonatal care (mean difference −0.001; $p = 0.842$) nor infant mortality (mean difference −0.002; $p = 0.579$). This lack of effect remained after sensitivity analyses.

Morbidity: 18,273 babies survived to discharge. The overall rate for NEC was 2.6%, ROP 1.7%, SBI 3.9% and BPD 10%. 55.9% received BMF. We observed an increase in SBI in babies born in maternity units colocated with LNU (mean difference −0.011; $p = 0.007$). The highest mean difference in gestation-specific SBI was in the group of babies born at 27 weeks gestation (−0.040); those who were transferred in the first 72 hours were more likely to have SBI. Statistical significance was lost after exclusion of early postnatal transfers ($n = 1545$; mean difference −0.002; $p = 0.554$) for the whole group, and then separately, on exclusion of all babies born at 27 weeks gestation (mean difference −0.008; $p = 0.037$). For babies born at 27 weeks gestation, birth in maternity services colocated with NICU reduced the risk of SBI from 11.9% to 7.7%, a reduction of 4.2%. This represented a number needed to treat (NNT) of 25 (99% CI 10 to 59) indicating that 25 babies would need to be delivered in NICU rather than LNU, to prevent one SBI at 27 weeks gestation. For babies born at 27 weeks gestation, birth in a high-volume unit (> 1614 intensive care days/year) reduced the risk of SBI from 0.242 to 0.028 [99% CI 0.035 to 0.542; $p = 0.003$; NNT = 4 (99% CI 2 to 29)].

There was no effect of place of birth on ROP, NEC or BMF. There was a higher likelihood of BPD in births in maternity units colocated with NICU (mean difference 0.018; $p = 0.006$). This remained after exclusion of early transfers (mean difference 0.029; $p \leq 0.001$) and was lost on exclusion of babies born at 27 weeks gestation (mean difference 0.011; $p = 0.065$).

Conclusions

The threshold above which birth and early care can safely be provided close to home, in either NICU or LNU, is 28 weeks gestation. We identified an increased likelihood of SBI in babies born in maternity units colocated with LNU. This appeared to be related to postnatal transfer too. As degree of illness at birth cannot always be predicted for babies born very preterm, our data indicate an urgent need to support antenatal transfers of mothers with expected preterm births at 27 weeks gestation to maternity units colocated with NICU. Where births at 27 weeks gestation inadvertently occur in LNU settings, clinicians should risk assess decisions for transfer.

Workstream 2: A clinical quality of care study addressing unit differences (independent of unit designation as neonatal intensive care unit or local neonatal unit) and impact on neonatal outcomes in very preterm babies born at 27–31 weeks gestation in England

Objective

To investigate the relationship between care provided (irrespective of unit designation) and outcomes for very preterm babies born at 27–31 weeks gestation.

Methods

We identified two areas to explore quality of neonatal care: (a) adherence to prespecified targets or benchmarks for clinical care measures, defined within the National Neonatal Audit Programme (NNAP), and data completion for these on the electronic patient records, and (b) benchmarking in the upper quartile for additional early preterm care evidence-based measures that could be extracted from our OPTI-PREM data set. We categorised units as high performing for quality of care based on their meeting of prespecified targets set by the NNAP for different measures, and for being above the upper quartile for benchmarking exercises. We developed a hierarchical list and compared those units above the top quartile (high-performing units) with those below the upper quartile (lower-performing units). We compared the demographic profiles and unit characteristics and conducted multivariate analyses (linear and logistic regression) exploring associations with length of stay and pre-discharge mortality.

Results

We identified a mean reduction in length of stay of 1 day for babies born at 27–31 weeks gestation in units within the top quartile, for high-performing units (95% CI 1.029 to 1.081; $p < 0.001$). We did not find a significant difference in pre-discharge mortality. Units in high areas of social deprivation and those with fewer staff were less likely to be higher-performing units.

Limitations

Our sample size was restricted to 1 year of the OPTI-PREM cohort, to limit the effect of unit change in care processes and structure on quality of care delivered.

Conclusions

If duration of hospital stay is influenced by the quality of care provided in units, our observations have patient-flow and cost-saving implications for neonatal units and the NHS.

Workstream 3: (a) Cost of neonatal care provided for very preterm babies born at 27–31 weeks gestation in neonatal intensive care unit and local neonatal unit in England within the National Health Service setting

Objective

To estimate neonatal costs to hospital discharge for very preterm babies born at 27–31 weeks gestation in NICU and LNU.

Design

Retrospective analysis of resource use data recorded within the NNRD.

Patients

Babies born at 27–31 weeks gestation in England and discharged from a neonatal unit between 1 April 2014 and 31 December 2018.

Main outcome measures

We costed days receiving different levels of neonatal care, along with other specialised clinical activities. We present mean resource use and costs per baby by gestational age at birth, along with total costs for the cohort.

Results

We used data for 28,154 very preterm babies born at 27–31 weeks gestation and estimated the annual total costs of neonatal care to be £262 million. 95% of costs were attributable to routine daily care provided by units. The mean (standard deviation) cost per baby of daily care varied by gestational age at birth; £75,594 (£34,874) at 27 weeks as compared with £27,401 (£14,947) at 31 weeks.

Conclusions

The findings presented here are a useful resource to stakeholders including NHS managers, clinicians, researchers and policy-makers.

Workstream 3: (b) A cost-effectiveness analysis: comparing the costs and effects of care for very preterm babies born at 27–31 weeks gestation in neonatal intensive care unit compared with local neonatal unit in England within the National Health Service setting

Objective

We quantified and compared the costs and effects of care provided to preterm babies born at 27–31 weeks gestation in NICU compared with LNU in England.

Methods

We analysed data from theNNRD for very preterm babies born at 27–31 weeks gestation, admitted to neonatal units in England and discharged between 1 January 2014 and 31 December 2018. We costed data on the daily levels of neonatal care provided to each baby and on key healthcare interventions, using unit costs from established sources. Survival status at neonatal unit discharge was our measure of health outcome. To facilitate an unbiased comparison of NICU and LNU, we adjusted for measured confounders and used an instrumental variable approach to account for unmeasured confounders.

Results

We did not observe a difference in mortality between babies admitted to NICU compared with LNU. The mean cost of babies managed in NICU (£45,860 SE = £313) was lower than the cost of babies managed in LNU (£48,393, SE = £386) [mean cost difference −£2534 (99% CI −£4096 to −£971)]. The costs of care for babies born at 27–29 weeks gestation were not significantly different between NICU and LNU. Costs were only significantly lower for babies born in NICU at later gestations (30 and 31 weeks) and were driven by differences in the durations of different levels of care provided.

Conclusions

Redirecting care of less sick very preterm babies to NICU to reduce costs may be challenging. Instead, research is needed to understand the reasons for the differences in the durations of intensive care between settings.

Workstream 4: A qualitative ethnographic study exploring place of care decision-making and the perspectives of parents and clinicians, for very preterm babies born at 27–31 weeks gestation in neonatal intensive care unit and local neonatal unit in England

Objective

To assess staff and parent perspectives on place of care for very preterm births at 27–31 weeks gestation in England.

Design

We undertook qualitative studies using an ethnographic approach that included observations of routine behaviours in their natural settings ('work-as-done' rather than 'work-as-imagined') and interviews with staff and parents.

Participants

Parents of babies born at 27–31 weeks gestation from across all geographic areas in England (retrospective and contemporaneous); staff working in four LNU and two NICU, in two neonatal operational delivery networks, and in neonatal transport teams.

Results

Staff were dealing with multiple priorities, making decisions in a rapidly evolving, time-consuming, unstandardised way. The complexities of decision-making and enacting place of care decisions, contextualising decisions and integrating managerial thinking into their decision-making processes was evident. For parents, being able to care for their baby

while on the neonatal unit was a priority. Transfer of a baby disrupted parental care and parenthood. It carried with it multiple stresses, including getting to know and to trust the new unit, and the impact of being far from home. Access to practical and emotional support was limited for parents. Optimising their baby's development and preparing for homecoming were important to parents.

Conclusions

Place of care discussions should include assessment of the burden placed on staff, and parents of various socioeconomic backgrounds, and the consequent ability to maintain continuity of care in the face of disruptions. Discussions and reviews of how resources are employed in neonatal units are required to optimise efficiency of staff working, and improve experiences of neonatal care for babies, parents and families.

Workstream 5: Stakeholder engagements on OPTI-PREM findings

Objective

To engage with stakeholders regarding investigation, findings and implications of findings from OPTI-PREM.

Design

We held multiple meetings with stakeholders from national bodies, regional networks and individual units. These were individuals involved in decision-making for delivery of NHS neonatal service provision of neonatal and obstetric clinical care, managers, operational delivery network leads, researchers, parents and members of the public. We presented at neonatal and obstetric meetings to discuss the project, results, and to obtain peer review in the form of comments and constructive criticism from these presentations.

Results

Scientific evidence was shared and considered timely, highly relevant and robust. Key stakeholders engaged, supported the OPTI-PREM project, and participated in discussions on potential implications of our findings. Ideas, critiques and suggestions have been considered and actioned where appropriate within this report. This engagement is ongoing.

Conclusions

OPTI-PREM findings provide timely, important scientific evidence for policy-makers and stakeholders to utilise, in optimising neonatal health care for very preterm babies born at 27–31 weeks gestation. Our findings align with the NHS 2023 3-year delivery plan for maternity and neonatal services in England.

Study registration

This study is registered as Current Controlled Trials NCT02994849 and ISRCTN74230187.

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